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:** The proposed information collection was previously published in the **Federal Register**, on October 24, 2019, allowing for a 60-day comment period. Comments are encouraged and will be accepted for an additional 30 days until January 27, 2020.

**FOR FURTHER INFORMATION CONTACT:** If you have additional comments regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: Renee Reid, FO/ESB—Mailstop (7.E–401), either by mail at 99 New York Ave. NE, Washington DC, 20226, by email at *Renee.Reid@atf.gov,* or by telephone at 202–648–9255. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov.*

**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:* New Collection.

(2) *The Title of the Form/Collection:* Informant Agreement.

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

*Form number:* ATF Form 3252.2.

*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:* None.

*Abstract:* Any individual registering as a confidential informant (CI) for ATF, must provide their personally identifiable information (PII) on the Informant Agreement—(ATF Form 3252.2). ATF will utilize the information to verify the identity of the CI, who can provide useful and credible information to ATF regarding felonious criminal activities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 2,000 respondents will utilize the form annually, and it will take each respondent approximately 6 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 200 hours, which is equal to 2,000 (# of respondents) * .10 (6 minutes).

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: December 20, 2019.

**Melody Braswell,**

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

[FR Doc. 2019–27924 Filed 12–26–19; 8:45 am]

**BILLING CODE 4410–14–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–571]**

### Bulk Manufacturer of Controlled Substances Application: Johnson Matthey Pharmaceutical Materials Inc.

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before February 25, 2020.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:**

In accordance with 21 CFR 1301.33(a), this is notice that on October 31, 2019, Johnson Matthey Pharmaceutical Materials Inc., 25 Patton Road, Devens, Massachusetts 01434 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Amphetamine | 1100 | II |
| Methylphenidate | 1724 | II |
| Nabilone | 7379 | II |
| Hydrocodone | 9193 | II |
| Levorphanol | 9220 | II |
| Alfentanil | 9737 | II |
| Remifentanil | 9739 | II |
| Sufentanil | 9740 | II |

The company plans to utilize this facility to manufacture small quantities of the listed controlled substances in bulk for distribution to its customers as well as to conduct analytical testing in support of the company's primary manufacturing facility in West Deptford, New Jersey.

Dated: December 17, 2019.

**William T. McDermott,**

*Assistant Administrator.*

[FR Doc. 2019–27951 Filed 12–26–19; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 17–23]**

### Lisa Hamilton, N.P.; Decision and Order

On March 17, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause to Lisa Hamilton, N.P., (hereinafter, Respondent), of Taunton,[1]

[1] According to DEA records, Respondent filed to change her registered address during the proceedings to 113 Washington Street, Number 1, Foxboro, Massachusetts 02035, but the initial Order

Continued

Massachusetts. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposed the revocation of and denial of any pending application to modify or renew Respondent's Certificate of Registration No. MH0525153 ''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.*

Specifically, the OSC alleged that Respondent issued prescriptions for controlled substances to eight individuals for other than a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04(a), M.G.L. 94C § 19(a), and 244 CMR §§ 3.00, 4.00 *et. seq.,* and 9.03(5),(6),(39) and (44). *Id.* at 2–3. Additionally, the OSC alleged that from June 14, 2016, to February 3, 2017, Respondent's Massachusetts Controlled Substances Registration (hereinafter, MCSR) lapsed, yet Respondent continued to issue controlled substance prescriptions during that time period in violation of 21 CFR 1306.03(a), and M.G.L. 94C §§ 7(a) and 18(a). *Id.* at 4.

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). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 4–5 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated April 10, 2017, Respondent timely requested a hearing. ALJX 2 (Request for a Hearing), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, Chief ALJ). On April 13, 2017, the Chief ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1. The Government filed its Prehearing Statement on April 25, 2017, and its Supplemental Prehearing Statement on June 23, 2017. ALJX 4 and ALJX 10, respectively. On May 8, 2017, the Chief ALJ issued a Notice to Show Cause, which noted that Respondent had not timely filed an adequate prehearing statement and required her to show good cause as to the reasons for the deficiency and to correct it by filing a prehearing statement by May 15, 2017. ALJX 5. By letter dated May 13, 2017, Respondent replied that she had not understood the additional requirements and filed a Prehearing Statement in compliance with the Chief ALJ's Order. ALJX 6. On May 16, 2017, the Chief ALJ issued an Order Regarding Late Compliance accepting Respondent's Prehearing Statement. ALJX 7. On May 24, 2017, the Chief ALJ issued a Prehearing Ruling that, among other things, set out the nine Stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental prehearing statements. ALJX 8 (Prehearing Ruling), at 1–2. Respondent filed her Supplemental Prehearing Statement on June 23, 2017. ALJX 11.

The hearing in this matter spanned two days.[2] The Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereafter, R.D.) is dated September 18, 2017. Neither party filed exceptions to the R.D.; however, Respondent filed a motion to reconsider the R.D.,[3] which was denied by the Chief ALJ on October 24, 2017, because the motion ''raise[d] no newly discovered evidence and present[ed] no changed circumstances that would render the RD determination inappropriate.'' Transmittal Letter, at 1; ALJX 14 and 15 (citing *William H. Wyttenbach, M.D.,* 82 FR 18777 (2017)).

Having considered the record in its entirety, I agree with the R.D. that the record establishes, by substantial evidence, grounds for the revocation of Respondent's registration—that Respondent committed acts rendering her continued registration inconsistent with the public interest. R.D., at 56–59. I further agree with the R.D. that Respondent's acceptance of responsibility is insufficient, and that, even if it were sufficient, Respondent did not offer adequate remedial measures, and that overall the factors weigh in favor of sanction. *Id.*

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

## Findings of Fact

### Respondent's DEA Registration

Respondent is the holder of DEA Certificate of Registration No. MH0525153 at the registered address of 113 Washington Street, Number 1, Foxboro, Massachusetts 02035.[4] GX 1. Pursuant to this registration, Respondent is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.*

### The Government's Case

The Government's documentary evidence consists primarily of medical records for eight patients. The Government called two witnesses: a DEA Diversion Investigator (hereinafter, DI), and an expert, Marylou Gregory-Lee, MSN, ANP–BC (hereinafter, Nurse Practitioner Gregory-Lee).

DI testified about her investigation-related actions, including her roles in interviewing Respondent's former employer and collecting evidence on Respondent's prescribing activities and on her lapse in MCSR. Tr. 29–130; *see also* R.D., at 7–9. DI testified that Respondent came to her attention during an inspection of a practitioner at Signature Health, who, in response to standard questions related to whether he had ''information regarding any prescribers of concern, DEA registrants of concern, or . . . illegal activity involving controlled substances,'' stated that ''there was a person in the practice that got [sic] terminated'' and that ''some of the prescriptions in panel patients . . . were not indicated.'' Tr. 40, 41; *see also* R.D., at 7. Two subsequent subpoenas to Signature Health to obtain the identity of the practitioner produced the identification of Respondent and her prescribing activities and charts. Tr. 40–47; *see also* R.D., at 8. The DI also testified about her investigation into the seven-month lapse in Respondent's MCSR, during which Respondent issued approximately five hundred controlled substance prescriptions, of which DI obtained a ''representative sampling.'' Tr. 96–98; GX 18; *see also* R.D., at 8. Having read and analyzed all of the record evidence, I agree with the Chief ALJ that DI ''presented testimony that was plausible, detailed, consistent, and without any obvious motive to fabricate''; and, therefore, ''her testimony is afforded full credibility.'' R.D., at 9.

The Government's expert, Nurse Practitioner Gregory-Lee, is a Nurse

to Show Cause was issued to her registered address at the time, which was 1 Washington Street, Suite 900, Taunton, Massachusetts 02780.

[2] Hearings were held in Boston, Massachusetts on July 19 and 20, 2017.

[3] Respondent's motion for reconsideration states that she has ''in fact learned a lot from this case'' and indicates what she ''should'' and ''will'' do in the future. ALX 14, at 2. I agree with the Chief ALJ's denial of the motion. ALJX 15. This Agency's adjudicative process notably does not permit reconsideration in this manner and I do not believe that I can consider Respondent's promises, because doing so would, among other things, deprive the Government of an opportunity to address Respondent's representations and prevent a full credibility assessment.

[4] Since the issuance of the OSC, Respondent changed her address from 1 Washington St., Suite 900, Taunton, Massachusetts 02780. *See also* n.1, *supra.*

Practitioner in Florida. She was a registered nurse practitioner in Massachusetts but has been inactive in that state since February of 2016. GX 13, at 1 (Curriculum Vitae of Marylou Gregory-Lee, MSN, ANP–BC). She holds a Master of Science in Nursing from the University of Rhode Island. *Id.;* R.D., at 9. She testified that she has been a nurse for forty-nine and a half years and had practiced in Massachusetts from 1968 to approximately 2013, when she became a resident of Florida. Tr. 135–37. She was registered with the DEA to handle controlled substances, which expired in 2016. *Id.* The Chief ALJ accepted Nurse Practitioner Gregory-Lee as an ''expert in the field of controlled substance prescribing by advanced practice nurse practitioners in the State of Massachusetts and in the scope of their practice in the State of Massachusetts.'' *Id.* at 161–162. The matters about which Nurse Practitioner Gregory-Lee testified included her review and standard-of-care analysis of medical records belonging to eight of Respondent's patients, and she relied on her written reports analyzing the medical records for each patient. *e.g., id.* at 204–32, 233–62, 265–99, 300–14, 315–26, 370–82, 383–94, 394–402; *see also* R.D., at 13–28; GX 14 (Expert Summary Report).

**Patient E.B.**

The Government's records related to Patient E.B. show that the patient visited the Respondent on nine occasions and that controlled substances were prescribed on six. R.D., at 13; GX 5a and b; GX 14, at 3–5. Nurse Practitioner Gregory-Lee testified that the Massachusetts prescribing standard requires a pain assessment prior to prescribing controlled substances. Tr. 208. However, for Patient E.B, Respondent did not document a pain assessment during the initial physical exam, and instead noted remarks that the patient was ''pleasant,'' and had ''[n]o acute distress.'' *Id.;* GX 14, at 3; GX 5a, at 31. In a subsequent visit a month later, E.B. presented with a swollen wrist. GX 5a, at 24. Again, she testified that on April 3, 2013, Respondent documented that the patient ''is currently on a chronic pain medication'' and ''doesn't need any meds''; nevertheless, Respondent ordered oxycodone for the patient. Tr. 217; *see also* GX 5a, at 26; GX 5b, at 3 (demonstrating the prescription). Additionally, during this visit, Respondent did not document an assessment of pain related to the injury. Tr. 220. Nurse Practitioner Gregory-Lee also opined that it was generally inappropriate to issue prescriptions for post-hysterectomy abdominal pain from a 2006 operation, where the scarring tissue had been removed in 2007.[5] *Id.* at 224–25.

**Patient D.C.**

The file for Patient D.C. that was presented by the Government shows that the patient visited the Respondent on six occasions, at each of which the Respondent prescribed oxycodone. R.D., at 16; GX 6a and b; GX 14, at 6–7. Nurse Practitioner Gregory-Lee testified that it was unclear from the record what the patient's complaint was about—knee injury, lumbar disc, or coughing. Tr. 235–37; GX 6a, at 33–34. She determined that there was no physical evaluation and no pain assessment, and therefore, the oxycodone prescribed was not for a legitimate medical purpose. Tr. 238. On March 15, 2013, the record demonstrated that the purpose of Patient D.C.'s visit was an annual physical exam, but there was no physical exam documented. Tr. 243. Nurse Practitioner Gregory-Lee testified that a pain scale was mentioned but no results were recorded and oxycodone was prescribed. *Id; see also* GX 6a, at 30. On April 4, 2013, the physical exam stated, ''pleasant. No acute distress.'' GX 6a, at 28; Tr. 243. Nurse Practitioner Gregory-Lee testified that ''[t]here's a physical exam that's completely normal, and there's no pain assessment. Based on that information, why would you order oxycodone? So it's inappropriate.'' Tr. 245. Likewise, there were no pain assessments on further visits, but Respondent prescribed controlled substances. *Id.* at 247. After Respondent was terminated, a new nurse practitioner saw D.C. on June 24, 2013. *Id.* at 256; GX 6a, at 14–16. Unlike Respondent, she conducted a full physical examination, did not refill the oxycodone, referred D.C. for a toxicity screen, and had the patient follow up for a pain management visit.[6] *Id.*

**Patient T.D.**

The Government introduced records for Patient T.D. demonstrating ten visits to Respondent, which resulted in ten prescriptions for oxycodone and fentanyl. R.D., at 18; GX 7a and 7b; GX 14, at 8–10. Nurse Practitioner Gregory-Lee testified that the chart describes Patient T.D. as a binge drinker, and so the Respondent should have documented a conversation about the dangers of mixing alcohol and controlled substances and also should have done a urinalysis to check for alcohol. Tr. 266–69. She testified that, on February 14, 2013, the patient was documented as having ''tremors,'' but there was no physical evaluation, no pain assessment, and fentanyl and oxycodone were prescribed. GX 7b, at 8; Tr. 270. Further, she opined that on subsequent visits, there was no pain assessment, no documentation of pain or of the effectiveness of controlled substance medication, and no discussion with the patient, so the prescriptions for fentanyl and oxycodone were not issued for a legitimate medical purpose under Massachusetts standards. GX 7b, at 3, 8; Tr. 277–82. Additionally, she testified that on April 8, 2013, there was no office visit attached to Respondent's issuance of a controlled substance prescription and that the standard in Massachusetts requires an office visit for controlled substance prescriptions. Tr. 282–83; GX 7b, at 3. Finally, Nurse Practitioner Gregory-Lee testified that the records demonstrate that the patient requested that Respondent decrease his medication, but she prescribed him the full amount without further explanation in the charts. Tr. 287; GX 7b, at 4.

**Patient M.J.**

The Government's evidence related to Patient M.J. demonstrates four visits, each of which resulted in prescriptions for oxycodone, which Nurse Practitioner Gregory-Lee testified that, in her opinion, ''were not issued for a legitimate medical purpose because there was no pain assessment at any of the visits.'' R.D., at 22 (citing Tr. 301–14). Specifically, she testified that, on February 7, 2013, there was an initial visit with a physical exam, but there was no pain management or assessment. Tr. 299–300. On March 14, 2013, the records mentioned a ''Wong-Baker'' pain assessment, but the resulting number was not recorded. Nurse Practitioner Gregory-Lee stated, ''Exam was there. It was pleasant, no acute distress, gait was normal. Everything was—he did have some exam, and what he had was completely normal. There was no pain assessment, but she ordered oxycodone.'' *Id.* at 303; GX 8a, at 12; GX 8b, at 2. Again, regarding Patient M.J.'s visit on April 11, 2013, Nurse Practitioner Gregory-Lee testified that there was ''no pain assessment'' and ''[Respondent] did a physical exam that was completely normal.'' Tr. 306–7, GX

[5] On cross-examination, Respondent pointed out that EB's patient chart states, ''on chronic pain management went to Dr. Portnow for evaluation and he put her on oxycodone 15MG 3x daily as needed, she's doing well with this at this time.'' GX 5a, at 27; Tr. 425.

[6] It should be noted that another Physician did subsequently prescribe the patient with Oxycodone, but shortly thereafter, the patient was terminated from care by Signature Health for a violation of her Controlled Substances Agreement. GX 6a, at 3, 12.

8b,[7] at 3. GX 8a, at 8–10. Further, Nurse Practitioner Gregory-Lee noted that Signature Health terminated M.J.'s patient care on August 9, 2013, based on his violation of his controlled substances agreement. Tr. 311; GX 8a, at 3.

**Patient E.L.**

The Government's records on Patient E.L. encompass eight visits, during which Respondent prescribed him hydrocodone/acetaminophen and oxycodone/acetaminophen. R.D., at 23 (citing GX 9a and 9b and GX 14, at 13–15). Nurse Practitioner Gregory-Lee testified that Patient E.L. first visited Respondent on January 29, 2013, but there was no physical exam or pain assessment, and the patient was just documented as not feeling well. Tr. 315–17; GX 9a, at 22; GX 9b, at 1–2 (Percocet and Vicodin prescriptions). She testified further that on March 18, 2013, Respondent wrote a prescription with no corresponding patient visit, which does not meet the Massachusetts standard, because there was no pain assessment or physical evaluation. Tr. 322–23; GX 9b, at 6. On later visits, the patient presented with elbow pain, but there was no pain assessment and Nurse Practitioner Gregory-Lee opined that, in her expert opinion, the prescriptions were therefore not legitimate. Tr. 324–25; GX 9a, at 14. GX 9b, at 8–11. Nurse Practitioner Gregory Lee once again clarified that ''[a]ny time pain medication is ordered, you have to have a pain assessment.'' Tr. 366. Further, on May 10, 2013, Respondent increased the dosage without a pain assessment or physical exam, and Nurse Practitioner Gregory-Lee testified that an increase of dosage in particular requires a justification to comply with the standard in Massachusetts. Tr. 367–68; GX 9a, at 9.

**Patient K.M.**

The patient records presented by the Government regarding Patient K.M. reflect six visits to the Respondent, during four of which Respondent prescribed oxycodone, and none of which were prescribed for a legitimate medical purpose in the opinion of Nurse Practitioner Gregory-Lee, because there was no pain assessment. R.D., at 25 (citing GX 10a and b; and GX 14, at 16–17). Specifically, Nurse Practitioner Gregory-Lee testified that on March 4, 2013, Patient K.M. presented with a bruised elbow after a fall down the stairs, but Respondent did not order an x-ray, nor conduct a pain assessment. Tr. 374; GX 10a, at 17–19; GX 10b, at 1. On March 28, 2013, Patient K.M. returned claiming another fall down the stairs, but Respondent did not conduct a pain assessment and increased the dosage without documenting the reason. Tr. 376; GX 10b, at 1–2; GX 10a, at 14–16. Nurse Practitioner Gregory-Lee testified that further visits also resulted in the issuance of controlled substance prescriptions for other than a legitimate medical purpose under the applicable standard based on the lack of pain assessment—noting in one that ''[t]he pain was on physical exam, but there was no actual notation, assessment, of the severity, and no notation of the results of the x-rays, if they were even done, or reports, but the medication was ordered inappropriately as a result of that.'' Tr. 380; GX 10b, at 4a.

**Patient G.R.**

The Government's evidence for Patient G.R. demonstrates five visits to Respondent, at each of which the Respondent prescribed oxycodone. R.D., at 26; GX 11a and b; GX 14, at 18–19. Nurse Practitioner Gregory-Lee testified that Respondent did not conduct a pain assessment regarding the patient's shoulder pain on the first visit of this patient, and therefore, the prescription for oxycodone that Respondent issued was not legitimate. Tr. 386–88. On a subsequent visit, Respondent obtained an x-ray of the shoulder. Nurse Practitioner Gregory-Lee testified that there was a ''mention of a pain assessment, but there's no documentation of what it was. The findings on the x-ray that she now has show that there's no fracture, no dislocation, the joint is normal, there's no bone lesion, there's nothing wrong with that joint, but she orders oxycodone 10mg.'' Tr. 388–89; GX 11a, at 15; GX 11b, at 2.

**Patient S.V.**

The file for Patient S.V. demonstrates that the patient visited Respondent four times, three of which resulted in prescriptions for oxycodone. R.D., at 27; GX 12a and b; GX 14, at 20–21. In particular, Nurse Practitioner Gregory-Lee testified that Patient S.V. visited Respondent on April 18, 2013, and that, even though the chart mentions arthritis, it was unclear from the charts what the medication was prescribed to address. Tr. 395. She opined that the prescriptions for controlled substances were not legitimate under the standard ''for the first time you see a patient who comes in . . . to your practice and says, I have an ear infection, with a normal exam, and I have chronic pain, and I need oxycodone,'' and additionally, there was no documented pain assessment for this patient on any of the visits. Tr. 395–96. GX 12a, at 12–14.

Having read and analyzed all of the record evidence, I agree with the Chief ALJ that Nurse Practitioner Gregory-Lee is ''certainly a well-credentialed Advanced Practice Nurse Practitioner, and although she was not the most focused of witnesses, taken overall, her testimony was generally authoritative, consistent, objective and persuasive.'' R.D., at 29. I also agree that the Respondent's case did not adequately refute her representation of the Massachusetts standard of care; therefore, I agree and find that ''her opinions regarding the standard of care prevalent in Massachusetts . . . [should] be credited.'' *Id.*

**Respondent's Case**

Respondent's documentary evidence consists of emails related to the renewal of her Massachusetts controlled substance license and an advertisement for Signature Healthcare featuring herself. RX 2A–K and 1A. Respondent testified and called one witness, a pharmaceutical representative who knew Respondent for over ten years (hereinafter, D.W.). Tr. 471, 473.

Respondent initially demonstrated intent to have D.W. represent her at the hearing, but the Chief ALJ determined that D.W. was not eligible to represent her based on 21 CFR § 1316.50, which provides in relevant part that ''any person entitled to appear in a hearing may appear in person or by a representative in any proceeding or hearing . . . A representative must either be an employee of the person or an attorney at law who is a member of the bar, in good standing.'' *Id.;* R.D., at 4–6. The Chief ALJ found that, although D.W. had reportedly studied law and the Respondent ''pa[id] him hourly'' to give ''advice with law and licenses,'' he was not a barred attorney. Tr. 20; R.D., at 2. The Chief ALJ also found that he was not eligible to represent Respondent on the basis of an employee relationship, because he was not the Respondent's employee. *Id.* at 4. In making this determination, he relied on *Community for Creative Non-Violence* v. *Reid,* in which, in absence of a clear statutory definition of ''employee'' from Congress, the Supreme Court looked to the common law of agency and the Restatement of Agency for guidance. 490 U.S. 730, 751–52 (1989). Using the factors in the Restatement, the Chief ALJ analyzed the overall relationship between D.W. and the Respondent based on their testimony demonstrating that: payment was sporadic; D.W. was in a distinct occupation; the nature of

[7] Tr. 307 cites to GX8a, at 3, but the prescription issued on April 11, 2013, is in GX8b, at 3.

the work was not part of Respondent's regular business; and there was no demonstrated intent to form an employee relationship in the form of a contract or set wages. R.D., at 4–6 (citing to Restatement (Second) of Agency § 220).

The language in 21 CFR 1316.50 is not based on statutory mandate, other than the requirement that the Agency conduct its hearings in accordance with the procedures in subchapter II of chapter 5 of Title 5, which makes no mention of representation. 21 U.S.C. § 875(b). Further, the application of 21 CFR 1316.50 is necessarily fact-based. In this case, the ALJ repeatedly encouraged the Respondent to retain barred counsel. Tr. 24–25. Here, I find that the Chief ALJ's interpretation of the ambiguous term ''employee'' in the Agency's regulations is consistent with the purposes of the Controlled Substances Act (hereinafter, CSA) and is based on his ''fair and considered judgment,'' and I therefore, uphold the determination that D.W. was not an employee for purposes of representation under 21 CFR 1316.50. *Auer* v. *Robbins,* 519 U.S. 452, 462 (1997).

Called as a witness, D.W. testified to the Respondent's good reputation and that, in particular, she had a ''great representation'' with one of the physicians at Signature Health. Tr. 479; Tr. 476–79; R.D., at 37. He further testified that he knew about ''internal personnel records and decisions'' at Signature Health, and that he was present for ''a little bit heated of a discussion'' between Respondent and Human Resources, which he believed to be about vacation days. Tr. 480, 482–85; R.D., at 37. He also said that he spoke with one of the physicians, and he said Respondent's separation was about ''inappropriate something in the office, but it had to do with the argument.'' Tr. at 487; *see also* R.D., at 38.

I agree with the Chief ALJ that D.W.'s ''credibility was problematic.'' R.D., at 38. In particular, I find, as the Chief ALJ concluded, that ''his answers to whether and to what extent he has had a compensated business relationship with the Respondent were ambiguous, implausible, vague and confusing.'' *Id.* He testified that he was not providing the Respondent with legal advice,[8] but Respondent testified that he had provided legal advice. Tr. 505; Tr. 21, 23; *see also* R.D., at 38. Additionally, I find that his testimony related to his personal knowledge of the personnel decisions at Signature Health ''is likewise implausible.'' R.D., at 38.

Respondent testified regarding the allegations that her MCSR had lapsed. Tr. 523, 555–69; *see also* RX 2. She testified that she had been a nurse practitioner since 1999 and further described her education and experience. *Id.* at 528–47. She presented testimony about the circumstances of her termination from Signature Health. *Id.* at 548–51. She testified about the patients whose records the Government had presented. *Id.* at 570–74. Additionally, she testified about her standard practice in documenting patient visits. *Id.* at 583–622.

Regarding the allegations of the lapse in her MCSR, Respondent testified that renewal was due on June 14, 2016, and she provided paperwork to renew her license to the owner of Medi-Weightloss in Plainville, where she was employed on June 2, 2016, and he took the fee for the renewal out of her paycheck. *Id.* at 524–26; *see also* R.D., at 31. Respondent presented email evidence demonstrating that she had signed the form required to renew on June 2, 2016, prior to its expiration. Tr. 559–60; *see also* RX 2–H, Page 8 [9]; RX 2–I, Page 9 (back of form). She testified that, perhaps in August, she ''had called the office a couple of times to see if it had come in the mail, because it comes to the place where you work, but it's in your name.'' Tr. 527. When her current practice manager requested a copy of her license, she emailed her Medi-Weightloss employer to obtain it. *Id.* She provided email documentation between herself and her former employer requesting a copy of her renewal and demonstrating that she had thought it had been renewed. RX 2–A, Page 1. On October 12, 2016, she sent an email to her former employer that stated, ''[i]t has come to my attention that my MCSR renewal was not renewed by your facility. DPH [10] claims that they never received forms from your company for my renewal.'' *Id.* In approximately December or January, Respondent testified that she spoke to the Massachusetts Department of Health and Human Services and that they had no record of the check or her renewal, so she filed a new application ''right away.'' Tr. 568–69.

Regarding the circumstances of her termination at Signature Health, Respondent testified that she has never been fired from another job, but admitted that approximately two years ago, she left another job before she would be terminated for a personality conflict. *Id.* at 547–48. She testified that her termination from Signature Health was regarding a disagreement about vacation days that had not been paid and that the reason she was given was ''inappropriate conduct in a patient care setting.'' *Id.* at 549–51. She introduced an exhibit showing that Signature used her in an advertisement in May 2013, to demonstrate that there were no issues with her prescribing, because they were using her specifically to promote their business. RX 1; Tr. 586–88. She also testified that she was never approached for improper prescribing and that she had regular meetings with the collaborating physician, during which no one ever mentioned her prescribing practices. Tr. 586–87, 590; *see also* R.D., at 30.

Respondent testified that patients G.R., K.M., E.L., DC and E.B. had followed her through two practices to Signature Health. Tr. 570–71. She had treated G.R., K.M. and E.B. for approximately ten years and DC for approximately six years. *Id.* at 572. T.D., M.J. and S.V. had followed her from her previous employment, so she had been treating them for approximately a year previously, with the exception of M.J., whom she had been treating for ''[m]aybe less than a year.'' *Id.* at 573–74; *see also* R.D., at 33. She testified that she was merely continuing the care of these patients whom she knew well for chronic pain management. Tr. 580–81; *see also* R.D., at 35.

Respondent testified that several of the charts in the Government exhibits do not have her electronic signature on them. [11] Tr. 574–75; *see also* R.D., at 33. But when pressed, she said that the patients had still been prescribed the controlled substances. Tr. 576. She said that there may be notes on what she called ''scutsheets'' that she planned on entering in later, because she saw 18–28

[8] Respondent testified that D.W. had ''studied law,'' but was not an attorney. Tr. At 19.

[9] Respondent used both numbers and letters and page numbers on her exhibits. I am citing to both to avoid confusion.

[10] DPH is the acronym commonly used by the Massachusetts Department of Public Health. *See e.g., https://www.mass.gov/orgs/department-of-public-health.* Respondent uses this acronym in reference to the Massachusetts Department of Public Health in her testimony. Tr. 599 ([H]er practice manager ''said she had called DPH because we had put in for the addendum.'') If Respondent was referring to the Massachusetts DPH in this email, it would directly contradict her testimony that the first time she knew that DPH had not received the renewal was in December or January and she ''renewed it within less than a week'' of confirming that it had not been filed. Tr. 599–601.

[11] A review of the approximately fifty-two of patient records, where Respondent was the listed ''Document Author'' in the Government's exhibits demonstrates that seven of the records do not contain Respondent's electronic signature. GX5a, at 6, 9; GX6a, at 34; GX9a, at 6; GX9a, at 8; GX9a, at 10; GX12a, at 8. Due to the low percentage of records without signature, I find that Respondent's allegations do not hold weight.

patients a day and did not always have time to complete the charts. *Id.* at 577–80.

In response to Nurse Practitioner Gregory-Lee's testimony, Respondent stated that ''everybody does things different. It doesn't mean that it's a lower standard of care.'' *Id.* at 583. She additionally testified that she disagreed with Nurse Practitioner Gregory-Lee about the standard of care and that she does not ''believe that [she] unlawfully prescribed anything.'' *Id.* at. 584, 592, 605; *see also* R.D., at 35. On cross-examination, when pushed about whether her notes would be complete prior to seeing the patient again or prior to prescribing controlled substances, she said, ''I don't understand some of the notes. That's not my typical pattern.'' Tr. 612–16. She further alleged that the charts might have been tampered with, because they ''are not [her] typical charting.'' *Id.* at 627. When asked about writing a prescription without a patient visit, Respondent said, ''It wouldn't be what I usually do,'' but added that ''it's done all the time.'' *Id.* at 622. Respondent also raised concerns throughout her testimony that the DIs revised Nurse Practitioner Gregory-Lee's report and took such a long time to bring the charges against her. *Id.* at 593–94, 596; *see also* R.D., at 36. Additionally, Respondent specifically questioned the amount of time that it took for Nurse Practitioner Gregory-Lee to perform this audit, when she had testified that she had conducted ''over 100 chart audits.'' Tr. 409.

Having reviewed all the evidence, including and Respondent's testimony, I agree with the Chief ALJ that ''credibility for this witness is something of a mixed bag.'' R.D., at 36.

When called upon to explain the level of documentation supporting her controlled substance prescribing, the Respondent alternatively offered: (1) The documentation obtained from Signature omits handwritten ''scutnotes'' (described in no detail) that she obviously had not yet transferred to the EMR; (2) the documentation obtained from Signature is deficient because the Government did not (as she did not) subpoena medical records from other medical practices where she had treated the same Eight Patients; and, (3) some unknown person (possibly a medical assistant who had complained about the Respondent in the past) for unknown reasons has tampered with her [electronic medical record] entries pertaining to the Eight Patients to render them incomplete and unreliable . . . . Each theory arose independently at various times during the Respondent's testimony and struck more of convenience than an honest assessment of the lacking condition of the chart notes she prepared in support of her controlled substance prescribing. *Id.* at 36–37.

**Allegation That Respondent Prescribed Controlled Substances During the Lapse of Her MCSR**

I find that the Government proved that Respondent's MCSR expired on June 14, 2016, and was not renewed until February 3, 2017. GX15 (Original Controlled Substances Registration); GX 16 (New Controlled Substances Registration). I find that Respondent proved that she had provided the paperwork to her employer and that she had no reason to believe that her MSCR had not been renewed until approximately October of 2016. Tr. 559–60; *see also* RX2–H, Page 8, RX2–1, page 9. However, I find that ''Respondent's own documentary evidence makes it virtually uncontroverted that she suspected that her MCSR had lapsed as of October 12, 2016, and yet she continued to issue controlled substance prescriptions in the state.'' R.D., at 45. In fact, according to her own email evidence, I find that she may have known of the renewal failure from the Massachusetts Department of Public Health as early as October. *See* n.6, *supra.* Respondent admits, as the DI testified, that she had written controlled substance prescriptions during the lapse period. Tr. 96 (DI's testimony), 598 (Respondent's admission). Additionally, I find that the Government's evidence confirms that she wrote controlled substance prescriptions after October 12, 2016, when she knew or should have known that her MCSR had lapsed. *See, e.g.,* GX 18c, at 40 (prescription for oxycodone dated November 3, 2016). In sum, I find that Respondent prescribed controlled substances without state authority to do so.

**Allegation That Respondent's Controlled Substance Prescriptions Did Not Comply With DEA Regulations**

The Government's Prehearing Statement additionally alleged that the Respondent's controlled substance prescriptions during the period of the lapse of her MCSR did not comply with DEA regulations, because they did not include a full address of the patient on the face of the prescriptions in violation of 21 CFR 1306.05(a). ALJX 4 (Government's Prehearing Statement), at 5. *See, e.g.,* GX 18b, at 4, 5; GX 18c, at 2, 3, 5, 8, 10, 11, 14, 16, 18, 20, 22, 24–26, 28, 30. Respondent argued that the address was unnecessary because the patients lived in a long-term care facility, and therefore, the pharmacist knew where the patients lived; however, the DI confirmed that failure to include a patient's address on the face of the prescription is a regulatory violation, regardless of the patient's residence in a long-term care facility. Tr. 122–25, 128. I find that Respondent prescribed controlled substances in violation of 21 CFR § 1306.05(a).

**Allegation That Respondent Issued Prescriptions for Controlled Substances Below the Applicable Standard of Care**

Paragraph (2) of the OSC alleges that Respondent ''issued prescriptions for controlled substances to several individuals . . . for other than a legitimate medical purpose and outside the usual course of professional practice.'' [12] OSC, at 2. The Government's expert, Nurse Practitioner Gregory-Lee, credibly testified that the Massachusetts prescribing standard requires a pain assessment prior to prescribing controlled substances. Tr. 208. I agree with the Chief ALJ and find that Respondent's prescribing of: oxycodone on six occasions to Patient DC; oxycodone on four occasions to Patient M.J.; oxycodone on seven occasions and hydrocodone [13] on six occasions to Patient E.L.[14]; oxycodone on four occasions to Patient K.M; oxycodone on five occasions to Patient G.R.; and oxycodone on three occasions to Patient S.V. were below the applicable standard for prescribing because Respondent did not conduct a pain assessment prior to issuing those prescriptions. *Id.* at 48–51.

Further, I agree with the Chief ALJ and find that, as Nurse Practitioner Gregory-Lee opined, Respondent's prescribing of oxycodone on seven occasions and fentanyl on four occasions to Patient T.D. ''fell below the requisite standard based on documented evidence of alcohol abuse indications that contraindicate controlled medication use, as well as a general lack of documentation, including abnormal physical examination findings or pain assessments.'' *Id.* at 48–49.

[12] I agree with the Chief ALJ's recommendation that I not sustain a few of the Government's allegations based on its failure to adequately provide notice to the Respondent in the prehearing statements and OSC of the matters of fact and law asserted. For example, I agree that the OSC and prehearing statements did not adequately notice Respondent's alleged failure to document any pain assessment concerning Patient E.B., despite adequate testimony and evidence presented by the Government's expert and the OSC's focus on the lack of drug screens. R.D., at 47–48.

[13] There were additionally five refills (ten total prescriptions) of hydrocodone (Vicodin) during the alleged period. R.D., at n. 126.

[14] The Chief ALJ also sustained the allegation in the OSC and the Government's 1st Prehearing Statement that the charting for Patient E.L. did not document a physical examination and, as such, justified a finding of prescribing below the standard of care in Massachusetts. R.D., at 50. I agree and find a violation related to the lack of physical examination for Patient E.L.

In addition, I agree with, and appreciate the substantial work involved in, the Chief ALJ's careful analysis of the Government's allegations that Respondent's prescriptions were unlawful because they were issued before the previous prescriptions should have been exhausted, if the pills had been ingested as prescribed. *Id.* at 52; OSC, at 2–3. I agree with the Chief ALJ and find that Respondent credibly rebutted the Government expert's premise that the prescriptions were filled too early, based on the fact that they were ordered for a thirty day supply, because the Respondent asserted that the electronic system automatically ''pops out by computer'' thirty days for each prescription. Tr. 636; R.D., at 52. However, I concur with the Chief ALJ's detailed analysis and I sustain the specific allegations, where the prescriptions taken at the rate of their dosages could not have been exhausted prior to when Respondent issued the next prescription. R.D., at 53–55.

In particular, the Chief ALJ concluded, and I agree, that prescriptions to Patient DC, dated February 13, 2013, but instructed not to be filled before February 16th, could not, at the rate of sixty tablets taken one every six hours,[15] have been exhausted before Respondent issued the next prescription on February 27th. *Id.* at 53 (citing GX 6b, at 2–3). Similarly, I find that the prescription issued on February 27, 2013, could not be exhausted at a rate of 120 tablets taken one every four hours before Respondent issued the next prescription on March 15, 2013. R.D., at 53 (citing GX 6b, at 3–4). The Chief ALJ further recommended that I sustain, and I do sustain, the early prescribing allegations related to four of the oxycodone prescriptions and the fentanyl prescription to Patient T.D. R.D., at 54 (citing GX 7a, at 32; GX 7b, at 3–5, 8). Additionally, the Chief ALJ recommended that I sustain, and I do sustain, the early prescribing allegations for: Patient K.M. of oxycodone on two occasions (R.D., at 54 (citing GX 10b, at 1–3)); Patient G.R. for one prescription (R.D., at 55 (citing GX 11b, at 1–2)); and Patient S.V. for two prescriptions (R.D., at 55 (citing GX 12b, at 1–3)).

In sum, I find that Respondent issued multiple controlled substance prescriptions outside of the usual course of the professional practice for advanced practice nurse practitioners in Massachusetts. R.D., at 47, 55–56.

[15] For example, there being twenty four hours in a day and one tablet prescribed every six hours, the prescription would have permitted four tablets per day. Sixty tablets at a rate of four a day should have lasted fifteen days, which should not have been exhausted prior to the end of March 2nd, possibly March 3rd, depending on the time of the day that it was filled.

**Discussion**

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

Under Section 304 of the 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) and includes a nurse practitioner, 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 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, I agree with the Chief ALJ that the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four. R.D., at 42 (citing 21 U.S.C. 823(f)(2), (4)). I find that the Government's evidence with respect to Factors Two and Four satisfies its *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f). I further find that Respondent failed to produce sufficient evidence to rebut the Government's *prima facie* case.

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

Respondent has demonstrated substantial experience both as a nurse practitioner, since 1999, and as a DEA registrant, since approximately 2000. R.D., at 42 (citing Tr. 528, 537). Her treatment of the patients as alleged in the OSC demonstrates that her prescribing practices fell short of the applicable standard of care. Even though the Agency considers the evidence related to her prescribing as presented in the OSC, and assumes that other than those allegations that the Government has substantially evidenced, the registrant has prescribed legally, Respondent herself testified that these individuals had followed her from other practices. Tr. 570–72; *see Wesley Pope, M.D.,* 82 FR 14944, 14982–84 (2017). It is difficult to believe that she had not prescribed below the standard previously to these patients; however, it is also unnecessary to explore, because Respondent did not formulate an adequate defense that the prescriptions listed in the OSC are isolated and that her history of prescribing was otherwise flawless. She mentioned that her documentation was ''not [her] usual charting,'' but in defense she alleged that the records had been tampered

with, and she defended against the Government's evidence entirely by stating, ''[E]verybody does things different. It doesn't mean that it's a lower standard of care.'' Tr. 627; *id.* at 583.

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 prescribing of controlled substances.

**Allegation That Respondent Prescribed Controlled Substances During the Lapse of Her MCSR**

In Massachusetts, the state in which Respondent practices, a prescription for a controlled substance may be issued ''only by a practitioner who is: (1) authorized to prescribe controlled substances; and (2) registered pursuant to the provisions of this chapter.'' Mass. Gen. Laws Ann. ch. 94C, § 18(a) (West 2019); *see also id.* at § 7(a) (''[E]very person who manufactures, distributes or dispenses, or possesses with intent to manufacture, distribute or dispense any controlled substance within the commonwealth shall . . . register with the commissioner of public health.''); R.D., at 45. Additionally, as the Chief ALJ highlighted, the text of the Massachusetts Controlled Substances Act does not appear to include an excuse for compliance with the state registration requirement, regardless of intent. *Id.* Further, DEA's regulations provide that only an individual practitioner who is authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice his or her profession may issue a controlled substance prescription. 21 CFR 1306.03(a)(1). For all of these reasons, I find that Respondent violated federal and Massachusetts law by prescribing controlled substances without the authorization required in Massachusetts to do so.

**Allegation That Controlled Substance Prescriptions Respondent Issued Did Not Comply With DEA Regulations**

DEA regulations require that all prescriptions for controlled substance ''shall bear the full . . . address of the patient.'' 21 CFR 1306.05(a). As already discussed, I found that, during the time of the lapse in her MCSR, Respondent did not include the full address of the patients to whom they were issued. I find that this failure is a violation of 21 CFR 1306.05(a). *See also* R.D., at 46; ALJX 4, at 5.

**Allegation That Respondent Issued Prescriptions for Controlled Substances Below the Applicable Standard of Care**

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). Massachusetts state law also requires that controlled substance prescriptions ''shall be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice.'' Mass. Gen. Laws Ann. ch. 94C, § 19(a) (West 2019); *see also* R.D., at 45.

The Government also alleged several Massachusetts regulatory violations in the OSC. OSC, at 2. Section 3 covers the general responsibility of nurses licensed in Massachusetts and Section 4 covers the responsibilities and accountability of Advanced Practice Registered Nurses. 244 Mass. Code Regs. sec. nos. 3 and 4 (2019); *see, e.g., id.* at 4.06. Among the standards of conduct in Massachusetts, Section 9.03 sets forth that nurses licensed by the Board of Registration in Nursing shall: practice in accordance with the accepted standards of practice; comply with other federal and state laws and regulations; and administer controlled substances in accordance with, and make complete accurate, and legible entries in all records required by, ''all federal and state laws and regulations and in a manner consistent with accepted standards of nursing practice.'' *Id.* at 9.03(5), (6), (39) and (44) (2019).

As already discussed, I find credible the testimony of the Government's expert witness that Respondent issued multiple controlled substance prescriptions below the Massachusetts standard of care, and I find that those violations and the other federal and state law and regulatory violations establish violations of the Massachusetts state regulations as described above.

I agree with the Chief ALJ and find that the record in this case establishes by substantial evidence that Respondent issued multiple controlled substance prescriptions below the applicable standard of care and, therefore, violated 21 CFR 1306.04(a) and Massachusetts statutory and regulatory provisions.

In sum, I find that, although the Government did not notice all of the evidence and not all of the evidence supported all of the Government's allegations, there remains substantial evidence on the record that Respondent: prescribed controlled substances without a valid MCSR in violation of state law; prescribed controlled substances without fulfilling the DEA regulation's requirement to include the patient's full address; and recurrently prescribed controlled substances below the usual standard of the professional practice in Massachusetts; and repeatedly issued prescriptions for controlled substances prior to the exhaustion of the patient's supply.

**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 due to her violations of the state standard of care for controlled substance prescribing, as well as due to her non-compliance with state law, the burden shifts to the Respondent to show why she can be entrusted with a new registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases).

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,* 546 U.S. at 259. In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument Respondent submitted to determine whether or not she has presented ''sufficient mitigating evidence to assure the Administrator that [she] 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. *Drug Enf't Admin.,* 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 at 463 (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 credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Regarding all of these matters, I agree with the analyses and conclusions contained in the R.D.'s Recommendation. R.D., at 56–59.

Here, the Respondent has accepted absolutely no responsibility for her actions. Regarding the allegations of her lapsed MCSR, she testified and presented evidence that she had relied to her detriment on a previous employer to file on her behalf; however, she also demonstrated that she had knowledge, and, possibly even contrary to her testimony, that she knew directly from the state, that her MCSR had not been renewed in October; and yet, she still continued prescribing controlled substances without obtaining a new MCSR until February. Tr. 524–69; RX 2; *see also* R.D., at 56–57 (''[H]er testimony and her reliance on the email correspondence with [her employer] leave no doubt that she continues to adhere to her position that the former bears all the blame, and she bears none.'')

Additionally, Respondent took no responsibility for the allegations related to her prescribing practices. Instead, she provided vague theories about evidence tampering, unfinished charts and testified that the Government's exhibits were ''not [her] typical notes.'' Tr. 574–75, 610, 616; *see also* R.D., at 57. She offered no intention of instituting remedial measures. ''There was no indication from the Respondent that she planned to, or already had, improved her recordkeeping practices when issuing prescriptions for powerful controlled substance medications.'' R.D., at 57.

In sum, I find that the record supports the imposition of a sanction because the Respondent did not unequivocally accept responsibility.

In sanction determinations, the Agency has also historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants as a whole. *See Joseph Gaudio, M.D.,* 74 FR 10,083, 10,095 (2009); *Singh,* 81 FR at 8248. Here, the interests of specific and general deterrence ''militate in favor of revocation.'' R.D., at 58. Respondent has evidenced no understanding that her controlled substance prescribing fell short of legal requirements.

To the extent that her progress notes fail to establish an adequate basis for prescribing powerful controlled drugs, she chalks that up to the risks attendant upon the practice of a busy prescriber, and she fails to recognize any significance of prescriptions issued before the patient's previous medication supply would have been exhausted.

R.D., at 58–59. As such, it is not reasonable to believe that Respondent's future prescribing will comply with legal requirements. Further, given the number of Respondent's violations, a sanction less than revocation would send a message to the regulated community that ''so long as there is another person available to blame for failing to file required paperwork, and a busy . . . practice to blame for inadequate documentation,'' compliance with the law is not a condition precedent to maintaining a registration. *Id.* at 59.

In evaluating the egregiousness of Respondent's conduct, I agree with the Chief ALJ that although ''the record did not paint the picture of a pill mill operator, this Respondent failed to exercise the level of care in prescribing and documenting her prescribing decisions that would allow a meaningful evaluation by those charged with regulating controlled substances.'' *Id.* Throughout the hearing, she vehemently protested against any acceptance of responsibility, consistently pinning blame on everyone and anyone else, even when entirely implausible, and unsupported by the evidence, and she demonstrated a general disdain for the charges against her and the situation in which she had found herself. *Id.*

Accordingly, I find that the factors weigh in favor of sanction and I shall order the sanctions the Government requested, 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. 823(f) and 824(a), I hereby revoke DEA Certificate of Registration No. MH0525153 issued to Lisa Hamilton, N.P. I further hereby deny any pending application of Lisa Hamilton, N.P. to renew or modify this registration, as well as any other pending application of Lisa Hamilton, N.P. for registration in Massachusetts. This Order is effective January 27, 2020. ins

Dated: December 4, 2019.

**Uttam Dhillon,**

*Acting Administrator.*

[FR Doc. 2019–27945 Filed 12–26–19; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–572]**

### Importer of Controlled Substances Application: Siegfried USA, LLC

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 27, 2020. Such persons may also file a written request for a hearing on the application on or before January 27, 2020.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 1301.34(a), this is notice that on November 6, 2019, Siegfried USA, LLC, 33 Industrial Park Road, Pennsville, New Jersey 08070 applied to be registered as an importer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Opium, raw | 9600 | II |
| Poppy Straw Concentrate. | 9670 | II |