

Respondent's conduct displays clear violations of the Federal and State regulations described above, the Agency agrees with the ALJ and hereby finds that Respondent violated 21 U.S.C. 829; 21 CFR 1306.04(a); and Ga. Code Ann. section 16–13–41(f)(2), (3). *Id.*

Accordingly, the Agency agrees with the ALJ and finds that Factors B and D weigh in favor of revocation of Respondent's registration and thus finds Respondent's continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). *Id.* at 23.

III. Sanction

Where, as here, the Government has established sufficient grounds to revoke Respondent's registration, the burden shifts to the registrant to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, he must both accept responsibility and demonstrate that he has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior,⁹ the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33738, 33746 (2021).

Here, the Agency agrees with the ALJ that "Respondent's hearing testimony and post-hearing arguments constitute a blanket denial of any wrongdoing," RD, at 25. Notably, Respondent testified that he did "everything [he is] supposed to do as far as the Georgia requirements for pain management" and that "[t]his hobgoblin of a drug problem exists primarily in the mind of an easily excitable DEA." *Id.* at 24–25; Tr. 350; Respondent's Post-Hearing Brief, at 6. As stated by the ALJ, "Respondent's testimony and argument simply cannot

be reconciled with the record evidence." RD, at 25. As such, and because Respondent made no admittance of any wrongdoing on his part, the Agency agrees with the ALJ and finds that Respondent failed to unequivocally accept responsibility. *Id.*

When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency need not address the registrant's remedial measures. *Ajay S. Ahuja, M.D.*, 84 FR 5479, 5498 n.33 (2019) (citing *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.*, 81 FR 79188, 79202–03 (2016)); *Daniel A. Glick, D.D.S.*, 80 FR 74800, 74801, 74810 (2015). Even so, in the current matter, Respondent did not present any evidence of remedial measures, and the Agency thus agrees with the ALJ that "[Respondent's] failure to put forth any evidence of steps he has taken to avoid similar misconduct in the future shows that he cannot be entrusted with a [registration]." RD, at 26.

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.*, 80 FR at 74810. In this case, the Agency agrees with the ALJ that "failing to impose a significant sanction against Respondent would send the wrong message to registrants that the Agency does not take seriously a registrant who repeatedly prescribes dangerous drug cocktails and combinations." RD, at 26. Regarding Respondent in particular, "[g]iven Respondent's cavalier attitude regarding the standard of care, specific deterrence is necessary." *Id.* Moreover, the Agency agrees with the ALJ that Respondent's actions were egregious because Respondent not only ignored his obligations to issue prescriptions within the standard of care and instead prescribed combinations that he knew to be dangerous to his patients, but he also endangered the community at large given the risk of diversion when prescribing such combinations. *Id.*

In sum, Respondent has not offered any credible evidence on the record to rebut the Government's case for revocation of his registration and Respondent has not demonstrated that he can be entrusted with the responsibility of registration. RD, at 27. Accordingly, the Agency will order that Respondent's registration be revoked.

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. BS4103610 issued to Isaac Sved, M.D. Further, pursuant to 28

CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Isaac Sved, M.D., to renew or modify this registration, as well as any other pending application of Isaac Sved, M.D., for additional registration in Georgia. This Order is effective December 4, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 25, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–24153 Filed 11–1–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Blue Mint Pharmacy; Decision and Order

On July 26, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Blue Mint Pharmacy (Registrant) of Houston, Texas. Request for Final Agency Action (RFAA), Government Exhibit (RFAAX) 2, at 1. The OSC/ISO informed Registrant of the immediate suspension of its DEA Certificate of Registration (registration), Control No. FB4121327, pursuant to 21 U.S.C. 824(d), alleging that Registrant's continued registration constitutes "an imminent danger to the public health or safety." *Id.* The OSC/ISO also proposed the revocation of Registrant's registration, alleging that Registrant's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 824(a)(4), 823(g)(1))¹.

¹ Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA

none of Respondent's patients engaged in illicit activity—refute this analysis. RD, at 21–23.

⁹ The record shows that in 2006, Respondent entered into a Memorandum of Understanding (MOU) with DEA in which Respondent admitted to prescribing controlled substances arguably in violation of generally accepted standard practices and Federal regulations; prescribing a large number of narcotics, with over half of his 1,500 patients prescribed narcotics; and keeping samples of controlled substances at an unregistered location. RD, at 3; Tr. 24; GX 12.

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA dated April 17, 2023.²

I. Findings of Fact

Texas Standard of Care

DEA consulted Ms. Katherine Salinas, RPh, as an expert regarding the standard of care in the state of Texas for pharmacy practice.³ RFAAX 4, at 1. According to Ms. Salinas, the Texas standard of care requires that when dispensing a controlled substance, Texas pharmacists must ensure that the prescription for the controlled substance is valid, pursuant to a valid patient-practitioner relationship, and issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *Id.* at 1–2. Further, prior to dispensing a controlled substance, a pharmacist must resolve any questions regarding the prescription with the prescriber and maintain written documentation of any such discussions. *Id.* at 2. A pharmacist must also review the patient's medication record and "at a minimum identify clinically significant: . . . (III) reasonable dose and route of administration; . . . (IV) drug-drug interactions; . . . and (X) proper utilization, including overutilization or underutilization." *Id.*; see also 22 Tex. Admin. Code section 291.33(c)(2)(A)(i). According to Ms. Salinas, "[a]ll [s]tate of Texas pharmacists have access to these requirements[] and are required to pass a jurisprudence examination in order to become a licensed pharmacist." RFAAX 4, at 2. Further, "[a]ll [s]tate of Texas pharmacists know [that they are] required to exercise reasonable caution in practice to prevent diversion by following common sense and proper dispensing practices." *Id.* at 3.

redesignated 21 U.S.C. 823(f), cited in the OSC/ISO, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

²Based on the Declaration from a DEA Diversion Investigator, the Agency finds that the Government's service of the OSC/ISO on Registrant was adequate. RFAAX 3, at 5. Further, based on the Government's assertions in its RFAA, the Agency finds that more than thirty days have passed since Registrant was served with the OSC/ISO and Registrant has neither requested a hearing nor submitted a corrective action plan and, therefore, has waived any such rights. RFAA, at 2; see also 21 CFR 1301.43 and 21 U.S.C. 824(c)(2).

³For Ms. Salinas' qualifications, see RFAAX 4, Attachment P. Ms. Salinas is currently employed by the Texas State Board of Pharmacy as a Compliance Officer, and one of her duties is to inspect all classes of pharmacies for compliance with Texas pharmacy rules and regulations. RFAAX 4, at 1.

In particular, Ms. Salinas noted the Texas State Board of Pharmacy "Red Flag Checklist," which is available to all Texas pharmacists on the Texas State Board of Pharmacy's website and also provided during pharmacy compliance inspections. *Id.* The red flags listed on the checklist include pattern prescribing;⁴ prescriptions for controlled substances commonly known to be abused such as opioids or muscle relaxants; prescriptions for controlled substances at the highest strength and/or in large quantities;⁵ patients obtaining similar controlled substance prescriptions from multiple practitioners; multiple patients sharing the same address and obtaining similar controlled substance prescriptions from the same practitioner; and patients consistently paying for controlled substance prescriptions with cash rather than through insurance. *Id.* at 3–4. Ms. Salinas stated that Texas pharmacists must document how they address and resolve any red flags and must have prevention techniques in place to deter the dispensing of fraudulent controlled substance prescriptions, such as contacting doctors to verify prescriptions, searching the Texas Medical Board website, talking with patients, and checking patient identification cards. *Id.* at 4.

Ms. Salinas concluded her explanation of the Texas standard of care by stating that "a pharmacist must engage in a verification process of a prescription." *Id.* at 5. Further, Ms. Salinas stated: "If a pharmacist does not believe a prescription is for a legitimate medical purpose, the pharmacist should not fill it." *Id.* Ms. Salinas also noted that "[a]s a Compliance Officer, when [she identifies] a recurring pattern of certain combinations of controlled substances, with the same dosage and in large quantities to various patients, being paid for in cash instead of using insurance, [her] opinion is that the pharmacy is inappropriately dispensing controlled substance prescriptions and/or engaging in diversion activity." *Id.*

Expert Review of Registrant's Dispensing

Applying the Texas standard of care, Ms. Salinas reviewed Registrant's PMP data from approximately February 1, 2021, through March 31, 2022,

⁴Pattern prescribing is when "a pharmacy dispenses a reasonably discernible pattern of substantially identical prescriptions for the same controlled substances, potentially paired with other controlled substances, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner." *Id.*

⁵Such prescriptions can indicate a lack of individual drug therapy in prescriptions issued by the practitioner. *Id.*

Registrant's patient profiles for the fourteen patients at issue, and copies of certain controlled substance prescriptions issued to the fourteen patients. *Id.* Ultimately, Ms. Salinas concluded, and the Agency agrees, that between February 1, 2021, and March 31, 2022, Registrant repeatedly filled prescriptions for controlled substances for the fourteen patients at issue without addressing or resolving red flags of abuse or diversion in violation of the Texas standard of care and thus outside the usual course of professional practice. *Id.* at 5–6, 18.

Patients A.W., M.F., and D.H.

Registrant filled nearly identical prescriptions for patients A.W., M.F., and D.H., who all shared an address. Specifically, between January 31, 2022, and March 2, 2022, Registrant filled prescriptions for Patient A.W. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 85 tablets of 350 mg carisoprodol. RFAAX 4, at 6; see also RFAAX 3, Attachment B. Further, between December 31, 2021, and March 15, 2022, Registrant filled prescriptions for Patient M.F. for 120 tablets of 10/325 mg hydrocodone/acetaminophen and 85 tablets of 350 mg carisoprodol. RFAAX 4, at 11; see also RFAAX 3, Attachment H. Finally, between June 17, 2021, and August 26, 2021, Registrant filled prescriptions for Patient D.H. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 90 tablets of 350 mg carisoprodol. RFAAX 4, at 14; see also RFAAX 3, Attachment K.

In reviewing the prescriptions for these three individuals, Ms. Salinas found that all of the prescriptions were issued by the same practitioner, Dr. G.K., who prescribed the same controlled substances in identical or substantially similar quantities to multiple patients; both the hydrocodone/acetaminophen and the carisoprodol, controlled substances known to be abused, were prescribed in large quantities and at the highest dosage; the three patients shared the same address; and all three patients paid cash for all of the prescriptions. RFAAX 4, at 6, 11–12, 14–15; see also RFAAX 3, Attachments B, H, K. Ms. Salinas did not find any evidence that Registrant addressed these red flags of abuse or diversion and, as a result, opined that Registrant violated the minimum standard of care for a Texas pharmacy and operated outside of the usual course of professional practice. RFAAX 4, at 6–7, 12, 15; see also RFAAX 3, Attachments B, H, K.

Patient J.A., D.W., C.E., and S.F.

Registrant filled nearly identical prescriptions for patients J.A., D.W., C.E., and S.F., who all shared an address. Specifically, between January 26, 2022, and March 25, 2022, Registrant filled prescriptions for Patient J.A. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 85 tablets of 350 mg carisoprodol. RFAAX 4, at 7; *see also* RFAAX 3, Attachment C. Further, between January 18, 2022, and March 17, 2022, Registrant filled prescriptions for Patient D.W. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 85 tablets of 350 mg carisoprodol. RFAAX 4, at 8; *see also* RFAAX 3, Attachment D. Between January 4, 2022, and March 3, 2022, Registrant filled prescriptions for Patient C.E. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 85 tablets of 350 mg carisoprodol. RFAAX 4, at 10; *see also* RFAAX 3, Attachment G. Finally, between December 30, 2021, and March 24, 2022, Registrant filled prescriptions for Patient S.F. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 90 tablets of 350 mg carisoprodol. RFAAX 4, at 12; *see also* RFAAX 3, Attachment I.

In reviewing the above prescriptions issued to the four patients, Ms. Salinas found that all of the prescriptions were issued by the same practitioner, Dr. G.K., who prescribed the same controlled substances in identical or substantially similar quantities to multiple patients; both the hydrocodone/acetaminophen and the carisoprodol, controlled substances known to be abused, were prescribed in large quantities and at the highest dosage; the four patients shared the same address and three of the patients (J.A., D.W., and S.F.) shared the same phone number; and all four patients paid cash for all of the prescriptions. RFAAX 4, at 7–8, 10–11, 13; RFAAX 3, Attachments C, D, G, I. Ms. Salinas did not find any evidence that Registrant addressed these red flags of abuse or diversion and, as a result, opined that Registrant violated the minimum standard of care for a Texas pharmacy and operated outside of the usual course of professional practice. RFAAX 4, at 7–13; *see also* RFAAX 3, Attachments C, D, G, I.

Patients A.B. and C.B.

Between January 17, 2022, and March 18, 2022, Registrant filled prescriptions for both Patient A.B. and Patient C.B. for 120 tablets of 10/325 mg hydrocodone/acetaminophen and 90 tablets of 350 mg carisoprodol. RFAAX 4, at 9–10; *see also* RFAAX 3, Attachment E, F. In

reviewing the prescriptions, Ms. Salinas found that all of the prescriptions were issued by the same practitioner, Dr. G.K., who prescribed the same controlled substances in identical or substantially similar quantities to multiple patients; both the hydrocodone/acetaminophen and the carisoprodol, controlled substances known to be abused, were prescribed in large quantities and at the highest dosage; and Patients A.B. and C.B. paid cash for all of the prescriptions. *Id.* Ms. Salinas did not find any evidence that Registrant addressed these red flags of abuse or diversion and, as a result, opined that Registrant violated the minimum standard of care for a Texas pharmacy and operated outside of the usual course of professional practice. *Id.*

Patient T.P.

Between July 8, 2021, and September 10, 2021, Registrant filled prescriptions for Patient T.P. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 85 tablets of 350 mg carisoprodol. RFAAX 4, at 13–14; *see also* RFAAX 3, Attachment J. In reviewing the prescriptions, Ms. Salinas found that all of the prescriptions were issued by the same practitioner, Dr. G.K., who prescribed the same controlled substances in identical or substantially similar quantities to multiple patients; both the hydrocodone/acetaminophen and the carisoprodol, controlled substances known to be abused, were prescribed in large quantities and at the highest dosage; Patient T.P. shared the same phone number as Patient M.F.; and Patient T.P. paid cash for all of the prescriptions. RFAAX 4, at 14; *see also* RFAAX 3, Attachment J. Ms. Salinas did not find any evidence that Registrant addressed these red flags of abuse or diversion and, as a result, opined that Registrant violated the minimum standard of care for a Texas pharmacy and operated outside of the usual course of professional practice. RFAAX 4, at 14; *see also* RFAAX 3, Attachment J.

Patient G.A.

Between February 24, 2021, and February 9, 2022, Registrant filled prescriptions for Patient G.A. for 120 tablets of 10/325 mg hydrocodone/acetaminophen and 90 tablets of 350 mg carisoprodol. RFAAX 4, at 15; *see also* RFAAX 3, Attachment L. In reviewing the prescriptions, Ms. Salinas found that the prescriptions were issued by multiple, different practitioners. RFAAX 4, at 14–15; *see also* RFAAX 3, Attachment L. Ms. Salinas did not find any evidence that Registrant addressed this red flag of abuse or diversion and, as a result, opined that Registrant

violated the minimum standard of care for a Texas pharmacy and operated outside of the usual course of professional practice. RFAAX 4, at 16; *see also* RFAAX 3, Attachment L.

Patient K.G.

Between February 1, 2021, and March 15, 2022, Registrant filled prescriptions for Patient K.G. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 80 tablets of 350 mg carisoprodol. RFAAX 4, at 16; *see also* RFAAX 3, Attachment M. In reviewing the prescriptions, Ms. Salinas found that the prescriptions were issued by multiple, different practitioners. *Id.* Ms. Salinas did not find any evidence that Registrant addressed this red flag of abuse or diversion and, as a result, opined that Registrant violated the minimum standard of care for a Texas pharmacy and operated outside of the usual course of professional practice. *Id.*

Patient L.J.

Between March 12, 2021, and March 23, 2022, Registrant filled prescriptions for Patient L.J. for 112 tablets of 10/325 mg hydrocodone/acetaminophen and 80 tablets of 350 mg carisoprodol. RFAAX 4, at 17; *see also* RFAAX 3, Attachment N. In reviewing the prescriptions, Ms. Salinas found that the prescriptions were issued by multiple, different practitioners. *Id.* Ms. Salinas did not find any evidence that Registrant addressed this red flag of abuse or diversion and, as a result, opined that Registrant violated the minimum standard of care for a Texas pharmacy and operated outside of the usual course of professional practice. *Id.*

Patient T.T.

Between February 4, 2021, and March 8, 2022, Registrant filled prescriptions for Patient T.T. for 110 tablets of 10/325 mg hydrocodone/acetaminophen and 80 tablets of 350 mg carisoprodol. RFAAX 4, at 17; *see also* RFAAX 3, Attachment O. In reviewing the prescriptions, Ms. Salinas found that the prescriptions were issued by multiple, different practitioners. *Id.* Ms. Salinas did not find any evidence that Registrant addressed this red flag of abuse or diversion and, as a result, opined that Registrant violated the minimum standard of care for a Texas pharmacy and operated outside of the usual course of professional practice. RFAAX 4, at 17–18; *see also* RFAAX 3, Attachment O.

II. Discussion

A. The Five Public Interest Factors

Under the CSA, “[a] registration . . . to . . . dispense a controlled substance

. . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a). In making the public interest determination, the CSA requires consideration of the following factors:

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

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

(C) The [registrant]’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1)

The Agency considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993).

While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1),⁶ the Government’s evidence in support of its *prima facie* case for revocation of Registrant’s registration is confined to Factors B and D. See RFAA, at 23–29. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

⁶ As to Factor A, the record contains no evidence of a recommendation from any state licensing board or professional disciplinary authority. 21 U.S.C. 823(g)(1)(A). Nonetheless, an absence of such evidence “does not weigh for or against a determination as to whether continuation of the [Registrant’s] DEA certification is consistent with the public interest.” *Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011). As to Factor C, there is no evidence in the record that Registrant has been convicted of an offense under either federal or state law “relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(g)(1)(C). However, as Agency cases have noted, there are a number of reasons why one who has engaged in criminal misconduct may never have been convicted of an offense under this factor. *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010). Agency cases have therefore found that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Id.* Finally, as to Factor E, the Government’s evidence fits squarely within the parameters of Factors B and D and does not raise “other conduct which may threaten the public health and safety.” 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Registrant.

Here, the Agency finds that the Government’s evidence satisfies its *prima facie* burden of showing that Registrant’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 824(a)(4).

B. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. See *Sualeh Ashraf, M.D.*, 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Registrant violated numerous federal and state laws regulating controlled substances. RFAAX 2, at 2.⁷ Specifically, federal law requires that “[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice,” and that “[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a), 1306.06; see also 21 U.S.C. 829. Federal law also emphasizes that although “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.” 21 CFR 1306.04(a).

As for state law, Texas regulations require that “[a] pharmacist may not . . . dispense or deliver a controlled substance . . . except under a valid prescription and in the course of professional practice.” Tex. Health & Safety Code section 481.074(a)(1).⁸ The Texas Board of Pharmacy sets forth numerous “operational standards” for pharmacists filling prescriptions, requiring, firstly, that pharmacists “review the patient’s medication record. Such review shall at a minimum identify clinically significant . . . (III) reasonable dose and route of administration; . . . (VI) drug-drug interactions; . . . and (X) proper

⁷ The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. *Ruan v. United States*, 142 S. Ct. 2,370 (2022) (decided in the context of criminal proceedings).

⁸ Texas law notes that “[a] pharmacist may not . . . dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship.” *Id.* section 481.074(a)(2). Further, it is unlawful in Texas for any “registrant or dispenser” to knowingly deliver a controlled substance in violation of sections 481.070–481.075 of the Texas Health and Safety Code. *Id.* section 481.128.

utilization, including overutilization or underutilization.” 22 Tex. Admin. Code section 291.33(c)(2)(A)(i). Further, “[u]pon identifying any clinically significant conditions [or] situations[,] . . . the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.” *Id.* section 291.33(c)(2)(A)(ii). A pharmacist must also ensure that “[p]rior to dispensing, any questions regarding a prescription drug order [] be resolved with the prescriber and written documentation of these discussions [be] made and maintained.” *Id.* section 291.33(c)(2)(A)(iv). Finally, a pharmacist must consider the various “red flag factors” in preventing the non-therapeutic dispensing of controlled substances, including, among others: pattern prescribing; prescriptions for controlled substances commonly known to be abused; prescriptions for controlled substances at the highest strength and/or in large quantities; patients obtaining similar controlled substance prescriptions from multiple practitioners; multiple patients sharing the same address and obtaining similar controlled substance prescriptions from the same practitioner; and patients consistently paying for controlled substance prescriptions with cash rather than through insurance. *Id.* section 291.29(f).

Here, the record demonstrates that Registrant repeatedly filled prescriptions for controlled substances for multiple patients without adhering to Texas’ “operational standards” for pharmacists filling prescriptions and without addressing or resolving numerous and blatant red flags of abuse and/or diversion. Because Registrant’s conduct clearly violates the Texas standard of care—thus rendering its dispensing outside the usual course of professional practice—and clearly violates the various federal and state regulations described above, the Agency hereby sustains the Government’s allegations that Registrant repeatedly violated federal and state law relating to controlled substances.

Accordingly, the Agency finds that Factors B and D weigh in favor of revocation of Registrant’s registration and thus finds Registrant’s continued registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Registrant failed to provide sufficient evidence to rebut the Government’s *prima facie* case.

III. Sanction

Where, as here, the Government has established grounds to revoke

Registrant's registration, the burden shifts to the registrant to show why it can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.*, 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, it must both accept responsibility and demonstrate that it has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195*, 77 FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.*, 86 FR 33738, 33746 (2021).

Here, Registrant did not request a hearing, submit a corrective action plan, respond to the OSC/ISO, or otherwise avail itself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to its future compliance with the CSA nor made any demonstration that it can be entrusted with registration. Moreover, the evidence presented by the Government clearly shows that Registrant violated the CSA, further indicating that Registrant cannot be entrusted. Accordingly, the Agency will order the revocation of Registrant's registration.

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. FB4121327 issued to Blue Mint Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Blue Mint Pharmacy, to renew or modify this registration, as well as any other pending application of Blue Mint Pharmacy, for additional registration in Texas. This Order is effective December 4, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 25, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been

authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed First Modification To Consent Decree Under the Clean Water Act

On October 25, 2023, the Department of Justice lodged a proposed first modification to the consent decree ("First Modification") with the United States District Court for the District of Massachusetts in the lawsuit entitled *United States and Commonwealth of Massachusetts v. City of Revere, Massachusetts*, Civil Action No. 1:10–cv–11460, D.J. Ref. No. 90–5–1–1–09299. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

The United States filed this lawsuit in 2010 under the Clean Water Act ("Act"). The complaint sought injunctive relief and civil penalties for violations of the Act in connection with the City of Revere's operation of its sewage collection system and municipal separate storm sewer system ("MS4"). The allegations in the Complaint were resolved in a consent decree entered on November 17, 2010 ("Consent Decree") in which the City of Revere agreed, among other things, to develop and implement a Comprehensive Wastewater Management Plan and Comprehensive Stormwater Management Plan ("CWMP/CSMP") to ensure identification and implementation of capital projects necessary to eliminate sanitary sewer overflows ("SSOs") and bring its MS4 into compliance with National Pollutant Elimination System ("NPDES") permit requirements.

The proposed First Modification replaces the Consent Decree CWMP/CSMP provisions with new provisions that require the City of Revere to update portions of its CWMP/CSMP by December 31, 2026. This update must include a summary of work completed pursuant to the Consent Decree, assessment of the City of Revere sewer system current service level and associated review of capacity-related SSOs, development and assessment of alternatives to achieve the goal of the Consent Decree to prevent collection system surcharges or capacity-related

SSOs events, and a recommended plan and implementation schedule identifying projects to attain the target level of sewer system service of a ten-year design storm. The new provisions also extend the deadline for completion of all work proposed under Revere's CWMP/CSMP to December 31, 2038.

The publication of this notice opens a period for public comment on the First Modification. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and Commonwealth of Massachusetts v. City of Revere, Massachusetts*, Civil Action No. 1:10–cv–11460, D.J. Ref. No. 90–5–1–1–09299. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

<i>To submit comments:</i>	<i>Send them to:</i>
By email	<i>pubcomment-ees.enrd@usdoj.gov.</i>
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the First Modification may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>. We will provide a paper copy of the First Modification upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for \$4.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Notice of Availability; Service Contract Inventory

AGENCY: Justice Management Division, Department of Justice.

ACTION: Notice of availability.

SUMMARY: The Justice Management Division (JMD), Department of Justice (DOJ) is publishing this notice to advise