

The Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

These proposed 2024 quotas reflect the quantities that DEA believes are necessary to meet the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements; and the establishment and maintenance of reserve stocks. DEA remains committed to conducting continuous surveillance on the supply of schedule II controlled substances and list I chemicals necessary to treat patients with COVID-19, and, pursuant to her authority, the Administrator will move swiftly and decisively to increase any 2024 APQ that she determines is necessary to address an unforeseen increase in demand, should that occur.

In accordance with 21 CFR 1303.13 and 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2024 APQ and AAN as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will issue and publish in the **Federal Register** a final order establishing the 2024 APQ for controlled substances in schedules I and II and establishing an AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as directed by 21 CFR 1303.11(c) and 1315.11(f).

Signing Authority

This document of the Drug Enforcement Administration was signed on October 30, 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023-24282 Filed 11-1-23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23-17]

Isaac Sved, M.D.; Decision and Order

On December 8, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Isaac Sved, M.D. (Respondent) of Buford, Georgia. OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificate of Registration, Control No. BS4103610, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes "an imminent danger to the public health or safety." *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent has "committed such acts as would render [his] registration inconsistent with the public interest." *Id.* at 1, 4 (citing 21 U.S.C. 823(g)(1),¹ 824(a)(4)).

A hearing was held before DEA Administrative Law Judge Teresa A. Wallbaum (the ALJ) who, on June 20, 2023, issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), which recommended revocation of Respondent's registration. RD, at 27. Respondent did not file exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety of the ALJ's rulings, credibility findings,²

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 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.

² The Agency adopts the ALJ's summary of each of the witnesses' testimonies as well as the ALJ's assessment of each of the witnesses' credibility. *See* RD, at 3-17. The Agency agrees with the ALJ that the Diversion Investigator's testimony, which was focused on the uncontroversial introduction of documentary evidence and her contact with the case, was credible in that it was sufficiently detailed, plausible, and internally consistent. *Id.* at 4. Further, the Agency agrees with the ALJ that the testimony from the Government's expert witness, Dr. Steven Lobel, M.D., which was focused on the Georgia standard of care and Respondent's prescribing to the patients listed in the OSC/ISO, was credible in that it was consistent with Georgia statutes governing the prescribing of controlled substances, especially in the pain management context, and was clear, direct, substantial, and consistent with regards to the individual patients. *Id.* at 4-5. Finally, the Agency agrees with the ALJ that although Respondent's testimony was credible as to general facts, including Respondent

findings of fact, conclusions of law, sanctions analysis, and recommended sanction as found in the RD.

I. Findings of Fact

Georgia Standard of Care

DEA hired Dr. Lobel to testify as an expert in the standard of care for the practice of medicine and the prescribing of controlled substances in the state of Georgia, with a focus on pain management. RD, at 4; Tr. 105.³ Dr. Lobel defined "standard of care" as a "minimum level of competence or care so as not to harm the patient," and described how the Georgia standard of care requires a practitioner to, prior to prescribing controlled substances, obtain a patient's prior medical records; obtain a medical history, including family medical history and mental health history; conduct an appropriate physical examination; obtain a urine drug screen; check the PDMP; obtain informed consent from the patient; and document all information. RD, at 11; Tr. 120, 128-129, 134, 136. Further, the physical examination must be appropriate to the complaint, and for patients who have spinal pain, the practitioner should also conduct a complete neurologic exam. RD, at 11; Tr. 129-130. In addition, the Georgia standard of care requires that a practitioner determine and document the severity of pain. RD, at 11; Tr. 135-136.

Dr. Lobel testified that under the Georgia standard of care, opioids "are not first-line treatment for chronic pain," so a practitioner must "weigh the risks and benefits at every visit," as well as look out for adverse effects, side effects, and aberrant behavior. RD, at 11; Tr. 132-133, 136-137. According to Dr. Lobel, under the Georgia standard of care, a practitioner should consider taking a patient off of opioids when there is a "lack of functional benefit, toxic effects of the medicine where they're having end organ damage, . . . [or] someone [] showing any signs or symptoms of addiction," and patients

volunteering information regarding prior disciplinary actions, on the issue of whether his prescriptions were within the usual course of professional practice and for a legitimate medical purpose, Respondent's testimony was not fully credible in that his interpretations of the Georgia standard of care were inconsistent with the Georgia state statutes. *Id.* at 9-10.

³ During the hearing, both Government counsel and Dr. Lobel initially referenced a national standard of care established by the CDC Guidelines, *see* RD, at 10, but Dr. Lobel ultimately testified that the Georgia standard of care, upon which this decision is based, is grounded in the state medical board's publications and Georgia state statutes, with the CDC Guidelines incorporated to the extent that they deal with the prescriptions of opioids. RD, at 10; Tr. 114-115, 119, 125.

should be tapered off of opioids if they are not in pain or if they are abusing the opioid prescription. RD, at 11–12; Tr. 140, 146–147. Regarding the relevant red flags of abuse and diversion, Dr. Lobel testified that under the Georgia standard of care, there is never a legitimate medical purpose for prescribing the “Holy Trinity” because “[e]ach medicine synergistically affects the other to augment a high” and it produces “respiratory drive” as a side effect. RD, at 12; Tr. 148–149, 173. Moreover, Dr. Lobel testified that duplicative therapies, that is, prescriptions for the same drugs in different strengths at high quantities, are not legitimate medical practice and fall out of the standard of care, with Dr. Lobel differentiating between prescribing “two dose units of the same medication to get a higher dose unit at high quantities” and prescribing a separate daytime and nighttime pain medicine. RD, at 12; Tr. 109, 149–151.⁴

Respondent

In 2010, Respondent began a family medicine and pain management practice in Atlanta.⁵ RD, at 5; Tr. 335–336, 347, 363, 372. Respondent testified that most of his patients are “hard-working blue-collar workers” and “laborers” and that his patients prefer short-acting opioids because they do not make them as drowsy as long-acting opioids, therefore allowing the patients to control their pain but still be able to work. RD, at 6; Tr. 343–345, 376–377. Respondent testified that his patients also worry about “cost-effectiveness” because “they don’t have great insurance . . . [and] they can’t really afford to do physical therapy.” RD, at 7; Tr. 348.

Respondent testified that he has seen many of his pain patients since 2010 or 2012 and that he started these patients on lower doses of opioids that increased over time with changes in drugs and dosages. RD, at 7; Tr. 345. Respondent testified that he “do[es] the rational thoughts as to why [he] prescribe[s] these medications. [He] do[es not] willy-nilly prescribe 120 doses of anything without thinking it through.” RD, at 7; Tr. 345–346. According to Respondent,

⁴ Dr. Lobel testified that although Georgia law does not specifically prohibit prescribing the “Holy Trinity” or duplicative therapies, the standard of care described comes from the state medical board. RD, at 12 n.10; Tr. 173, 290.

⁵ Respondent testified that although he is not board-certified in pain management, he has completed many hours of training. RD, at 5; Tr. 372. Specifically, he “took specialized courses offered by . . . the American Academy of Pain Management.” RD, at 5; Tr. 347. Respondent is also a member of the American Academy of Pain Physicians, Integrative Pain Management, and performs immigration physicals. RD, at 6; Tr. 347, 363.

he is “kind of old school” and “spend[s] more time talking to [patients], examining them, and counseling them than writing notes.” RD, at 7; Tr. 346.

Regarding opioids, Respondent acknowledged that an opioid prescription must be medically necessary. RD, at 7; Tr. 378. Respondent testified that he does “everything [he is] supposed to do as far as the Georgia requirements for pain management,” but that he does not “always write them down because . . . most of [his] practice is to take care of the patients and not write paper.” RD, at 8; Tr. 350, *see also* Tr. 375, 376. Respondent also testified that although he sometimes “missed” information in his notes, all of the patient information is documented in patient files in an “abbreviated form.” RD, at 8; Tr. 375–376.

Regarding the prescription of the “Holy Trinity,” Respondent acknowledged that it is a dangerous combination, but testified that “if [patients] failed other muscle relaxants, I usually have to go to . . . the one that seems to work the best.” RD, at 8; Tr. 351, 353. Respondent asserted that he discusses the risk of combination prescriptions with patients. RD, at 8; 355–356. Respondent testified that he uses an application on his phone called Medscape to check for interactions between medications. RD, at 9; Tr. 354–355.⁶ Ultimately, Respondent testified that his job is “to make people feel healthy and good.” RD, at 9; Tr. 360.

Respondent testified that he is familiar with and adheres to the Georgia standard of care, as found in the laws published by the Georgia medical board website. RD, at 9; Tr. 338, 365–369. Regarding the patients listed in the OSC/ISO, Respondent testified that his patients were “fully informed as to the nature of [his] proposals” and that his prescriptions were within the standard of care, with his patients receiving “more medical benefit than risk.” RD, at 9; 365–366. Respondent also denied running a “pill mill” or having any arrangement with his patients regarding selling the controlled substance prescriptions and denied knowingly or directly profiting from any diversion, and according to Respondent, none of his patients have been arrested for diversion. RD, at 9; Tr. 342, 364–365.

⁶ Regarding the combination of oxycodone, Soma, and Xanax, the “Holy Trinity,” Respondent testified that the Medscape application reports three interactions of those drugs and says to “monitor closely” but does not say “severe adverse reaction.” RD, at 9; Tr. 355.

The Patients

Patient J.W.

On at least three occasions, Respondent issued prescriptions to Patient J.W. that in combination formed the “Holy Trinity.” Specifically, on May 15, 2022, June 12, 2022, and July 17, 2022, Respondent prescribed 30 mg oxycodone, 2 mg alprazolam, and 350 mg carisoprodol. RD, at 13; Tr. 109, 274, 277, 280; GX 2, at 14–15, 17–18, 20–21. On each date, Respondent also prescribed a second opioid, Percocet, a brand name for oxycodone/acetaminophen, a schedule II opioid. RD, at 13; Tr. 274, 277, 280; GX 2, at 14, 17, 20. Because there was no documentation justifying prescribing the “Holy Trinity,” Dr. Lobel concluded, and the Agency agrees, that the prescriptions were not issued within the Georgia standard of care. RD, at 13; Tr. 275, 277, 280–282; GX 2, at 16, 19, 22. Accordingly, the ALJ found, and the Agency agrees, that the prescriptions were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. RD, at 13.

Patient S.D.

On at least three occasions, Respondent issued prescriptions to Patient S.D. that in combination formed the “Holy Trinity.” Specifically, on April 27, 2022, May 25, 2022, and June 22, 2022, Respondent prescribed 30 mg oxycodone, 2 mg alprazolam, and 350 mg carisoprodol. RD, at 13–14; Tr. 265, 268–269, 270; GX 3, at 213, 217, 219. Moreover, on each date, Respondent also prescribed Percocet and Valium, a brand name for diazepam, a schedule IV benzodiazepine, forming a “double” “Holy Trinity” because there were two opioids and two benzodiazepines in combination with the carisoprodol. RD, at 14; Tr. 265, 268–270, 272; GX 3, at 213, 217, 219. Because there was no documentation justifying the prescriptions, Dr. Lobel concluded, and the Agency agrees, that the prescriptions were not issued within the Georgia standard of care. RD, at 14; Tr. 266, 267, 269, 271. Accordingly, the ALJ found, and the Agency agrees, that the prescriptions were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. RD, at 14.

Patient T.J.

On at least three occasions, Respondent issued prescriptions to Patient T.J. that in combination formed the “Holy Trinity.” Specifically, on May 9, 2022, June 6, 2022, and June 30, 2022, Respondent prescribed 30 mg

oxycodone, 2 mg alprazolam, and 350 mg carisoprodol. RD, at 14–15; Tr. 259, 261, 263; GX 4, at 190, 192, 195.

Because there was no documentation justifying prescribing the “Holy Trinity,” Dr. Lobel concluded, and the Agency agrees, that the prescriptions were not issued within the Georgia standard of care. RD, at 15; Tr. 260, 262, 264.⁷ Accordingly, the ALJ found, and the Agency agrees, that the prescriptions were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. RD, at 15.

Patient A.A.

On at least three occasions, Respondent issued prescriptions to Patient A.A. that were therapeutically duplicative. Specifically, on April 11, 2022, June 6, 2022, and July 6, 2022, Respondent prescribed 30 mg oxycodone and Percocet. RD, at 15; Tr. 245, 250–251, 255; GX 5, at 63, 64, 66. As Dr. Lobel testified, oxycodone and Percocet are both immediate release opioids and so prescribing them in combination is therapeutic duplication. RD, at 15; Tr. 245–246, 250–251, 257. Because there was no documentation justifying the therapeutic duplication, Dr. Lobel concluded, and the Agency agrees, that the prescriptions were not issued within the Georgia standard of care. RD, at 15; Tr. 246, 249, 251, 253, 256–258; GX 5, at 37, 38, 40. Accordingly, the ALJ found, and the Agency agrees, that the prescriptions were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. RD, at 15–16.

Patient L.B.

On at least three occasions, Respondent issued prescriptions to Patient L.B. that were therapeutically duplicative. Specifically, on May 15, 2022, June 12, 2022, and July 10, 2022, Respondent prescribed 30 mg oxycodone and Percocet. RD, at 16; Tr. 221, 235, 238–239, 241–242; GX 6, at 35, 37, 39. Because there was no documentation justifying the therapeutic duplication, Dr. Lobel concluded, and the Agency agrees, that the prescriptions were not issued within the Georgia standard of care. RD, at 16; Tr. 236, 239 241; GX 5, at 36, 38, 40. Accordingly, the ALJ found, and the Agency agrees, that the prescriptions were not issued for a legitimate medical

purpose by a practitioner acting in the usual course of professional practice. RD, at 16.

Patient A.T.

On at least three occasions, Respondent issued prescriptions to Patient A.T. that were therapeutically duplicative. Specifically, on April 6, 2022, May 4, 2022, and June 2, 2022, Respondent prescribed 30 mg oxycodone and Percocet. RD, at 16; Tr. 220–221, 225, 226, 228–229; GX 7, at 86, 87, 88. Because there was no documentation justifying the therapeutic duplication, Dr. Lobel concluded, and the Agency agrees, that the prescriptions were not issued within the Georgia standard of care. RD, at 16–17; Tr. 221–222, 226–227, 231; GX 7, at 31–33. Accordingly, the ALJ found, and the Agency agrees, that the prescriptions were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. RD, at 17.

I. 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 his 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).

DEA 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).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1), the Government’s evidence in support of its *prima facie* case for revocation of Respondent’s registration is confined to Factors B and D. RD, at 18; *see also* RD, at 18 n.20 (finding that Factors A, C, and E do not weigh for or against revocation).

Having reviewed the record and the RD, the Agency agrees with the ALJ, adopts the ALJ’s analysis, and finds that the Government’s evidence satisfies its *prima facie* burden of showing that Respondent’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 824(a)(4). RD, at 17–23.

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). DEA regulations require that for a prescription for a controlled substance to be effective, it must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a); *see also* 21 U.S.C. 829. Georgia state law too provides that a practitioner may only issue prescriptions while acting in the usual course of his professional practice and for a legitimate medical purpose. Ga. Code Ann. section 16–13–41(f)(2), (3).

In the current matter, the Agency agrees with the ALJ’s analysis that Respondent’s treatment of the six patients described above fell below the Georgia standard of care and thus violated Federal and State law because, as detailed above, Respondent continually prescribed the “Holy Trinity” and duplicative therapies while failing to establish a medical justification for the prescriptions; as such, Respondent’s prescribing was not within the usual course of professional practice and not for a legitimate medical purpose.⁸ RD, at 20–21. As

⁸ The Agency also agrees with the ALJ’s conclusion that none of Respondent’s arguments—including, among others, that the case was initially based on unfounded criminal allegations; that the patients suffered no injuries as a result of Respondent’s treatment; that the Government’s case was only an attack on Respondent’s recordkeeping; that both public and private insurance companies saw fit to cover Respondent’s treatments; and that

⁷ Dr. Lobel testified that the documentation for the June 30, 2022, prescriptions did not support prescribing the “Holy Trinity,” but the Government did not elicit any testimony regarding the adequacy of the documentation for the other two dates for Patient T.J. RD, at 15 n.15; Tr. 263.

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.