**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 1301.33(a), this is notice that on April 21, 2025, ANI Pharmaceuticals Inc., 70 Lake Drive, East Windsor, New Jersey 08520, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Levorphanol ..... | 9220 | II |

The company plans to bulk manufacture the listed controlled substance for development and eventual use in a commercial drug product. No other activity for this drug code is authorized for this registration.

**Matthew Strait,**

*Deputy Assistant Administrator.*

[FR Doc. 2025–10230 Filed 6–4–25; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Lee S. Altman, M.D.; Decision and Order

#### I. Introduction

On September 6, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Lee S. Altman, M.D., of Stoughton, Massachusetts (Respondent). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1. The OSC/ISO informed Respondent of the immediate suspension of his DEA Certificate of Registration, No. BA4429684, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes ''an imminent danger to the public health or safety.'' RFAAX, at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposes the revocation of Respondent's registration, No. BA4429684, pursuant to 21 U.S.C. 824(a)(1) and (a)(4), and 823(g)(1), alleging that Respondent materially falsified an application for renewal of his registration and his continued registration is inconsistent with the public interest. RFAAX 1, at 1.

The OSC/ISO notified Respondent of his right to file with DEA a written request for a hearing. RFAAX 1, at 11 (citing 21 CFR 1301.43). The OSC/ISO also notified Respondent that if he failed to file such a request or file an answer, he would be deemed to have waived his right to a hearing and be in default. *Id.* On September 10, 2024, Respondent timely requested a hearing in this matter. RFAAX 3.[1] The matter was placed on the docket of DEA Administrative Law Judge Teresa Wallbaum (ALJ).

Then on October 4, 2024, Respondent, through his attorney, submitted a letter stating that he was withdrawing his request for a hearing and that he would ''not contest the suspension of his DEA registration.'' [2] RFAAX 4, at 3–5. On October 7, 2024, Respondent filed a motion to terminate proceedings based on his voluntary withdrawal of the request for a hearing. RFAAX 4, at 1. On the same day, the ALJ granted the motion to terminate proceedings and canceled the hearing. RFAAX 5. After the ALJ terminated the proceedings, the Government requested final agency action based on Respondent's default pursuant to 21 CFR 1301.43(c), (f). RFAA, at 1–10.

Pursuant to 21 CFR 3101.43(e), ''[a] default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].'' Further, ''[i]n the event that a [registrant/applicant] . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.'' *Id.* 1301.43(f)(1). In this case, the Agency finds that Respondent's voluntary withdrawal of the request for a hearing constitutes a default.[3] *See Salman Akbar, M.D.,* 89 FR 82259 (2024) (finding that a voluntary withdrawal of a hearing request displayed a failure to defend one's case and therefore the respondent was deemed to be in default). Accordingly, in light of Respondent's default, the Agency finds that the factual allegations in the OSC/ISO are deemed admitted.

#### II. Applicable Law

The OSC/ISO alleges that Respondent violated multiple provisions of the Controlled Substances Act (CSA) and its implementing regulations. As the Supreme Court stated in *Gonzales* v. *Raich,* the ''main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels.'' 545 U.S. 1, at 12–13 (2005). The Supreme Court further explained that, to accomplish its objectives, ''Congress devised a closed regulatory system making it unlawful to . . . dispense[ ] or possess any controlled substance except in a manner authorized by the CSA.'' *Id.* at 13. Accordingly, the Supreme Court stated, the ''CSA and its implementing regulations set forth strict requirements regarding registration, . . . drug security, and recordkeeping.'' *Id.* at 14.

The OSC/ISO's allegations concern the CSA's ''statutory and regulatory provisions . . . mandating . . . compliance with . . . prescription requirements'' and, therefore, go to the heart of the CSA's ''closed regulatory system'' specifically designed ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances,'' and ''to prevent the diversion of drugs from legitimate to illicit channels.'' *Id.* at 12–14, 27.

##### *A. The Allegation That Respondent Materially Falsified His DEA Application*

The OSC/ISO alleges that Respondent materially falsified his May 6, 2022, application to renew his DEA registration. RFAAX 1, at 4. Pursuant to the CSA, the Attorney General is authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. 824(a)(1); *see* RFAAX 1, at 4.

##### *B. The Allegation That Respondent Issued Prescriptions Outside the Usual Course of Professional Practice*

The OSC/ISO also alleges that Respondent improperly issued controlled substance prescriptions to an undercover law enforcement officer and

[1] Based on the Government's submissions in its RFAA, the Agency finds that service of the OSC/ISO on Respondent was adequate. According to the Notice of Service of Order to Show Cause and Immediate Suspension Order, Respondent was personally served with the OSC/ISO on September 10, 2024. RFAAX 2, at 1.

[2] In the letter, Respondent asserted that on September 11, 2024, he submitted an Answer ''with a categorical denial of the factual allegations contained in the OSC/ISO'' and that he ''st[ood] by his earlier denial of the factual allegations.'' RFAAX 4, at 3–4. However, DEA's rules do not permit ''categorical denials.'' 21 CFR 1301.37(d)(3). Instead, ''[f]or each factual allegation in the order to show cause, the answer shall specifically admit, deny, or state that the party does not have and it unable to obtain sufficient information to admit or deny the allegation in the ISO/OSC.'' *Id.* Respondent admitted that he did not specifically address the allegations in the OSC/ISO, and therefore, Respondent's purported ''Answer'' was not an answer filed in compliance with the rules. *See* RFAAX 4, at 3–4; 21 CFR 1301.37 (d)(3).

[3] Respondent stated that he wished to ''waiv[e] his right to a hearing[] without any admission of guilt.'' RFAAX 4, at 4. While Respondent's waiver does not result in an admission that he is ''guilty'' of violating the Controlled Substances Act, it does result in ''an admission of the factual allegations of the order to show cause.'' 21 CFR 1301.43(e).

four other individuals. RFAAX 1, at 5–10. 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); *see Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006), *United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *rehearing den.,* 598 F.2d 620 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979); RFAAX 1, at 2.

Massachusetts state law similarly requires that ''[a] prescription for a controlled substance to be valid shall be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice,'' [4] and ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section one . . . .'' Mass. Gen. Laws ch. 94C, sec. 19(a); *see* RFAAX 1, at 2. A physician practicing in Massachusetts must ''maintain a medical record for each patient that is complete, timely, legible, and adequate to enable the licensee or any other health care provider to provide proper diagnosis and treatment . . . .'' 243 Mass. Code Regs. sec. 2.07(13)(a); *see* RFAAX 1, at 3.

Under Massachusetts law, effective December 2014, a physician ''must utilize the prescription monitoring program prior to prescribing, to a patient for the first time . . . a benzodiazepine,'' [5] and in addition, effective June 2019, a physician must access the prescription monitoring program ''each time the practitioner issues a prescription to a patient for any . . . benzodiazepine.'' 105 Mass. Code Regs. 700.012(G)(1)(b) [6]; *see* RFAAX 1, at 3. Moreover, effective August 9, 2019, a physician must ''obtain and record a patient's written informed consent before diagnostic, therapeutic, or invasive procedures, medical interventions or treatments.'' 243 Mass. Code Regs. 2.07(26).

## III. Findings of Fact

In light of Respondent's default, the Agency finds that the factual allegations in the OSC/ISO are deemed to be admitted. 21 CFR 1301.43(e).

### *A. Material Falsification*

The Agency finds clear, unequivocal, and convincing record evidence for each of the following facts, which are deemed admitted. Respondent admits that on August 8, 2019, the Massachusetts Medical Board (Medical Board) initiated a disciplinary proceeding against Respondent, and on March 25, 2021, the Medical Board amended its allegations. RFAAX 1, at 4. On May 6, 2022, while the state disciplinary proceeding was ongoing, Respondent applied to renew his DEA registration. *Id.* The renewal application asked whether ''the applicant [has] ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' (Liability Question 3). *Id.* (emphasis added). Respondent answered ''no'' to Liability Question 3 on his renewal application, representing that he was not undergoing a state action at that time. *Id.* On May 9, 2024, the Medical Board issued a final decision regarding Respondent's disciplinary proceeding and found that Respondent's misconduct warranted an indefinite suspension of his state medical license.[7] RFAAX 1, at 4–5.

### *B. Prescriptions Issued Outside the Usual Course of Professional Practice*

The Agency finds substantial record evidence for each of the following facts, which are deemed admitted. For about a decade, from 2013 through 2024, Respondent issued numerous controlled substance prescriptions to five individuals, including an undercover law enforcement officer (UC), outside the usual course of professional practice. RFAAX 1, at 5–10. For example, Respondent admits that he issued prescriptions without establishing diagnoses, preparing proper documentation, addressing red flags of abuse and diversion, and obtaining informed consent. RFAAX 1, at 5–10.

#### 1. Prescribing to UC

Respondent admits that on five occasions between March 2019 and July 2019 he issued controlled substances prescriptions to UC that lacked a legitimate medical purpose. RFAAX 1, at 5–6. Specifically, Respondent admits that on March 28, 2019, he issued to UC a prescription for dextroamphetamine-amphetamine [8] without a proper diagnosis and without properly documenting the encounter. RFAAX 1, at 5. Respondent further admits that he ignored evidence of diversion when UC stated that he/she was requesting the prescription after taking unprescribed dextroamphetamine-amphetamine obtained from one of Respondent's patients. RFAAX 1, at 5–6. Respondent admits that he prescribed UC dextroamphetamine-amphetamine on four additional occasions between April 29, 2019, and July 24, 2019, without addressing evidence of abuse and diversion and without properly documenting the encounter.

Respondent admits that on June 25, 2019, he issued to UC a prescription for alprazolam [9] without addressing evidence of abuse or diversion and without properly documenting the encounter. RFAAX 1, at 6. Respondent admits that he ignored evidence of diversion by prescribing despite UC stating that he had taken unprescribed Xanax that he received from one of Respondent's patients. RFAAX 1, at 6. Respondent also ignored evidence of abuse, which he acknowledged during the encounter by stating that he believed UC was '' 'gonna drink anyways,' '' and that '' 'I'm basically giving you Xanax to combine with alcohol.' '' RFAAX 1, at 6. Respondent admits that throughout his treatment of UC, he falsified medical records by describing events, statements and/or diagnoses that never occurred. RFAAX 1, at 6.

#### 2. Prescribing to J.G.

Respondent admits that from April 6, 2017, through February 1, 2024, he issued to J.G. monthly prescriptions for

[4] The Supreme Judicial Court of Massachusetts explained that the ''usual course of professional practice'' can be interpreted ''to mean the routines customarily expected in the context of the medical profession.'' *Commonwealth* v. *Stirlacci,* 137 NE3d 375, 384 (Mass. 2020) ('''usual course of professional practice' refers to 'generally recognized and accepted medical practices' '' (quoting *United States* v. *Smith,* 573 F.3d 639, 647–648 (8th Cir. 2009))).

[5] From December 5, 2014, until June 14, 2019, the state of Massachusetts required the physician to utilize the PMP prior to prescribing benzodiazepine to a patient for the first time. 105 Mass. Code Regs. 700.012(H)(1)(b) (2014). Effective June 14, 2019, the provision was amended and redesignated as 105 Mass. Code Regs. 700.012(G)(2), and the amended version required a physician to utilize the PMP every time a prescription for benzodiazepine was issued to a patient. *See infra* note 6.

[6] In 2023, the provision was redesignated from 105 Mass. Code Regs. 700.012(G)(2) to its current designation, 105 Mass. Code Regs. 700.012(G)(1)(b), but the substance of the provision remained the same.

[7] The OSC/ISO noted that the Medical Board stayed Respondent's suspension for 60 days to consider a '' 'standard, five-year Board Probation Agreement.' '' RFAAX 1, at 4. The OSC/ISO also noted the Medical Board's finding that Respondent demonstrated a lack of candor to state officials when he, among other things, failed to report his termination by a former employer, failed to report a prior disciplinary action, and failed to disclose a search warrant executed at his medical office. RFAAX 1, at 4–5.

[8] Respondent prescribed 30 tablets of Adderall 30 mg, which is a brand name for dextroamphetamine-amphetamine. RFAAX 1, at 5. Amphetamine, its salts, optical isomers, and salts of its optical isomers are Schedule II stimulants. 21 CFR 1308.12(d)(1).

[9] Respondent prescribed 10 tablets of Xanax 2 mg, which is a brand name for alprazolam, a Schedule IV depressant and benzodiazepine. RFAAX 1, at 6; *see* 21 CFR 1308.14(c)(2).

dextroamphetamine-amphetamine and alprazolam that lacked a legitimate medical purpose. Specifically, Respondent admits that he issued these controlled substance prescriptions without establishing a proper diagnosis and conducting periodic reassessments, without obtaining informed consent, and without properly reviewing J.G.'s record in the prescription monitoring program (PMP) before prescribing a benzodiazepine.[10] RFAAX 1, at 6–7. Respondent also admits that he did not consistently monitor J.G.'s drug consumption through urine drug screens and pill counts or resolve aberrant results; or address evidence of abuse and diversion, such as J.G.'s alcohol abuse and use of multiple pharmacies to fill prescriptions. RFAAX 1, at 6–7. Respondent further admits that he cut-and-pasted documentation in the medical records, he increased doses of controlled substances without recording a new assessment, and he issued duplicative prescriptions for dextroamphetamine. RFAAX 1, at 7.

3. Prescribing to D.B.

Respondent admits that from August 28, 2015, through February 2, 2024, he issued to D.B. monthly prescriptions for dextroamphetamine-amphetamine and alprazolam that lacked a legitimate medical purpose. RFAAX 1, at 7. Specifically, Respondent admits that he issued these controlled substance prescriptions without establishing a proper diagnosis and conducting periodic reassessments, without obtaining informed consent, and without properly reviewing D.B.'s record in the PMP prior to prescribing benzodiazepines.[11] RFAAX 1, at 7–8. Respondent also admits that he ignored evidence of potential abuse and diversion, including D.B.'s report that he had been incarcerated for drug trafficking and had a significant history of abusing alcohol, cocaine, and heroin. RFAAX 1, at 8. Respondent further admits that he cut-and-pasted documentation in the medical records, and he increased doses of controlled substances without recording a new assessment. RFAAX 1, at 8.

4. Prescribing to T.S.

Respondent admits that from October 10, 2013, through January 15, 2015, and again from August 3, 2018, through January 16, 2024, he issued to T.S. monthly prescriptions for dextroamphetamine-amphetamine, and on August 4, 2022, issued to T.S. one prescription for diazepam,[12] that lacked a legitimate medical purpose. RFAAX 1, at 8–9. Specifically, Respondent admits that he issued these controlled substance prescriptions without establishing a proper diagnosis, without obtaining informed consent, and without properly reviewing T.S.'s record in the PMP prior to prescribing a benzodiazepine. RFAAX 1, at 8–9. Respondent also admits that he ignored evidence of potential abuse and diversion, including that T.S. had a history of being arrested for selling and possessing drugs and driving under the influence of drugs and alcohol, and historically abused opiates and heroin. RFAAX 1, at 8. Respondent further admits that he cut-and-pasted documents in the medical record, and that he increased doses and changed medication at T.S.'s request and without recording a new assessment. RFAAX 1, at 8–9.

5. Prescribing to T.P.

Respondent admits that from March 21, 2013, through February 16, 2024, he issued to T.P. monthly prescriptions for dextroamphetamine-amphetamine and alprazolam. RFAAX 1, at 9. Respondent also admits that from May 6, 2015, through May 27, 2021, he issued to T.P. monthly prescriptions for modafinil,[13] and that from May 6, 2019, through February 16, 2024, he issued monthly prescriptions for clonazepam.[14] RFAAX 1, at 9. Respondent admits that all these prescriptions were issued without a legitimate medical purpose. RFAAX 1, at 9. More specifically, Respondent admits that he issued these controlled substance prescriptions without establishing a proper diagnosis, without obtaining informed consent, and without properly reviewing T.P.'s record in the PMP prior to prescribing benzodiazepines. RFAAX 1, at 9–10. Respondent also admits that he ignored signs of potential abuse and diversion, including an unexplained early refill for clonazepam; and that he increased doses and changed medication at T.P.'s request and without recording a new assessment. RFAAX 1, at 9–10. Finally, Respondent admits that he cut-and-pasted documentation in the medical records and that he issued controlled substance prescriptions on March 6, 2023, and on March 22, 2023, with no corresponding documentation in T.P.'s medical chart. RFAAX 1, at 9–10.

6. Expert Review

DEA consulted with an independent medical expert who reviewed Respondent's medical records and controlled substance prescriptions issued to each of the five individuals identified above. RFAAX 1, at 10. Respondent admits that DEA's medical expert concluded that each of ''the controlled substance prescriptions violated the minimal medical standards applicable to the practice of medicine in Massachusetts.'' RFAAX 1, at 10. Based on the expert's uncontroverted opinion and Respondent's admissions, the Agency finds substantial record evidence that each of the controlled substance prescriptions referenced above were issued without a legitimate medical purpose and/or outside the usual course of professional practice. RFAAX 1, at 10.

## III. Discussion

### *A. Material Falsification*

Pursuant to the CSA, the Administrator is authorized to suspend or revoke a registration ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. 824(a)(1); *see also Farmacia Yani,* 80 FR 29053, 29058 (2015) (''materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct''). Agency decisions have repeatedly held that false responses to the liability questions on an application for registration are material. *Kevin J. Dobi, APRN,* 87 FR 38184, 38184 (2022) (collecting cases).

Regarding proof of material falsification, the Government must prove an allegation of material falsification ''by evidence that is clear, unequivocal, and convincing.'' *Richard J. Settles, D.O.,* 81 FR 64940, 64946 (2016) (quoting *Kungys* v. *United States,* 485 U.S. 759, 772 (1998)). The Government need not show that an applicant *actually knew* that his response to a liability question was false. Rather, it is sufficient that the Government shows that an applicant *should have known* that his response to a liability question was false. *Narciso A. Reyes,* 83 FR 61678, 61680 (2018) (citing *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23852 (2007)). When the Government has made such a showing, *i.e.,* that an

[10] Respondent first documented his review of the PMP three years after J.G. became his patient. RFAAX 1, at 7.

[11] Respondent first documented his review of the PMP on March 4, 2020, which was more than four and a half years after D.B. became his patient. RFAAX 1, at 8.

[12] Respondent prescribed 30 tablets of diazepam 20 mg, which is a Schedule IV depressant and benzodiazepine. RFAAX 1, at 9.

[13] Provigil, which is a brand name for modafinil, is a Schedule IV stimulant. RFAAX 1, at 9; *see* 21 CFR 1308.14(f).

[14] Klonopin, which is a brand name for clonazepam, is a Schedule IV depressant and benzodiazepine. RFAAX 1, at 9; *see* 21 CFR 1308.14(c).

applicant should have known that his response to a liability question was false, an applicant's claim that he misunderstood a liability question, or otherwise inadvertently provided a false answer to a liability question, is not a defense. *Id.* (citing *Alvin Darby, M.D.,* 75 FR 26993, 26999 (2010)). Indeed, the applicant bears the responsibility to carefully read the liability questions and to answer them honestly; ''[a]llegedly misunderstanding or misinterpreting liability questions does not relieve the applicant of this responsibility.'' *Zelideh I. Cordova-Velazco, M.D.,* 83 FR 62902, 62906 (2018) (internal citations omitted).

As found above, Respondent submitted an application to renew his DEA registration on May 6, 2022. RFAAX 1, at 4. Respondent answered in the negative to the third Liability Question asking whether he had ''ever surrendered (for cause) or had a state professional license revoked, suspended, denied, restricted, or placed on probation, or whether any such action was pending.'' RFAAX 1, at 4; *see supra* section III.A. The Agency finds that there is clear, unequivocal, convincing and uncontroverted evidence that at the time Respondent answered in the negative, there was a disciplinary proceeding involving Respondent's professional license pending with the state Medical Board. RFAAX 1, at 4. In fact, the proceeding had been pending since August 9, 2019, and the Medical Board amended the allegations on March 25, 2021, just over a year from Respondent's renewal application. RFAAX 1, at 4. Accordingly, the Agency finds clear, unequivocal, convincing and uncontroverted evidence that Respondent knew or should have known that his answer to the third Liability Question was false. *See Robert L. Carter,* 90 FR 9631, 9633 (2025); *Frank Joseph Stirlacci, M.D.,* 85 FR at 45237–40 (collecting cases).

Regarding materiality, the Supreme Court explained decades ago that ''the ultimate finding of materiality turns on an interpretation of substantive law.'' *Kungys,* 485 U.S. at 772 (citing a Sixth Circuit case involving 18 U.S.C. 1001 and explaining that, even though the instant case concerned 8 U.S.C. 1451(a), ''we see no reason not to follow what has been done with the materiality requirement under other statutes dealing with misrepresentations to public officers''). The Supreme Court also clarified that a falsity is material if it is ''predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision.'' *Kungys,* 485 U.S. at 771.

Respondent's false answer is material under the Supreme Court's materiality analysis because it is ''capable of affecting . . . the [Agency's] official decision.'' *Id.* Indeed, Respondent's falsification relates to two of the five factors that the Agency must consider in determining whether an application is consistent with the public interest and should be granted or denied: Factors A and D. 21 U.S.C. 823(g); *see Frank Joseph Stirlacci, M.D.,* 85 FR at 45234–35. Therefore, Respondent's falsification directly implicates the Agency's CSA mandated analysis and final decision by depriving it of legally relevant facts needed to decide whether to grant Respondent's application. *Universal Health Servs., Inc.* v. *United States ex rel. Escobar,* 579 U.S. 176, 193 (2016) (''Under any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.' ''); *Maslenjak* v. *United States,* 582 U.S. 335, 348 (2017) (concluding that when ''there is an obvious causal link between the . . . lie and . . . [the] procurement of citizenship,'' the facts ''misrepresented are themselves disqualifying'' and the fact finder ''can make quick work of that inquiry''). In other words, there is no doubt that Respondent's false answer was ''predictably capable of affecting, *i.e.,* had a natural tendency to affect, the official decision'' the CSA instructs the Agency to make. *Kungys,* 485 U.S. at 771.

Consequently, based on the CSA and the analysis underlying multiple Supreme Court decisions involving materiality, the Agency finds that Respondent's false response on the registration renewal application in 2022 is material. Accordingly, the Agency finds that the Government has presented clear, unequivocal, and convincing record evidence establishing a *prima facie* case for revocation of Respondent's registration pursuant to 21 U.S.C. 824(a)(1).

*B. Public Interest Determination*

Pursuant to 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 . . . [21 U.S.C. 823] inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E).[15]

The five factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. 243, 292–93 (2006) (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive,'' citing *In re Arora,* 60 FR 4447, 4448 (1995)); *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. *Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007); *Morall,* 412 F.3d. at 185 n.2; *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

According to Agency decisions, the Agency ''may properly rely on any one or a combination of factors and give each factor the weight [it] deems appropriate'' in determining whether to revoke a registration. *David H. Gillis, M.D.,* 58 FR at 37508; *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 the Agency is required to consider each of the factors, it ''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.

[15] The five factors of 21 U.S.C. 823(g)(1)(A–E) are:

(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.

In this matter, while all the 21 U.S.C. 823(g)(1) factors have been considered, the Agency finds that the Government's evidence in support of its *prima facie* public interest revocation case regarding Respondent's violations of the CSA's implementing regulations is confined to Factors B and D. RFAAX 1, at 4. Moreover, the Government has the burden of proof in this proceeding. 5 U.S.C. 556(d); 21 CFR 1301.44.

Evidence is considered under Factors B and D when it reflects compliance or non-compliance with laws related to controlled substances and experience dispensing controlled substances. *See Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Registrant has violated federal and state law regulating controlled substances. RFAAX 1, at 1–2; *see supra* Section II.

1. Violation of Federal Law

Here, the Agency finds substantial record evidence that Respondent violated federal law, namely 21 CFR 1306.04(a), when he repeatedly issued prescriptions for controlled substances outside the usual course of professional practice and not for legitimate medical purposes. *See* RFAAX 1, at 5–10. Specifically, Respondent admits that he issued these prescriptions without establishing a proper diagnosis, documenting the encounters, and/or obtaining informed consent. RFAAX 1, at 5–10. Respondent also admits that he repeatedly ignored evidence of abuse and diversion, cut-and-pasted medical records, and increased dosages without proper assessments. RFAAX 1, at 5–10. An independent medical expert obtained by DEA concluded that Respondent's ''controlled substance prescriptions violated the minimal medical standards applicable to the practice of medicine in Massachusetts.'' RFAAX 1, at 10. Based on the Respondent's admissions, the Agency finds that from 2013 through 2024, Respondent issued prescriptions for controlled substances to five individuals, including one undercover law enforcement officer, that lacked legitimate medical purposes. RFAAX, 5–10; *see supra,* Section III.B.

2. Violation of State Law

For the same reasons that the Agency found that Respondent violated federal law, the Agency finds substantial record evidence that Respondent violated state law when he repeatedly issued prescriptions for controlled substances outside the usual course of professional practice and not for legitimate medical purposes. *See* RFAAX 1, at 5–10; Mass. Gen. Laws ch. 94C § 19(a); *see also* Section III.B.

Furthermore, the Agency finds substantial record evidence that Respondent violated 243 Massachusetts Code Regulations 2.07(13)(a), when Respondent failed to maintain complete and adequate treatment records. Specifically, Respondent admits that in prescribing to UC, he failed to document the encounters and falsified medical records by describing events, statements and/or diagnoses that never occurred. Additionally, Respondent admits that in prescribing to the other four individuals, he cut-and-pasted documentation, failed to document proper diagnoses and failed to record new assessments when increasing dosages. RFAAX 1, at 5–10.

The Agency finds substantial record evidence that Respondent violated state law when Respondent failed to utilize the PMP prior to issuing relevant prescriptions for benzodiazepine to four individuals, J.G., D.B., T.S., and T.P.[16] RFAAX 1, at 5–10; *see* 105 Mass. Code Regs. 700.12(G)(1)(b). The Agency also finds substantial record evidence that Respondent violated state law, 105 Mass Code Regs. 2.07(26), when Respondent issued controlled substances prescriptions to four individuals (J.G., D.B., T.S., and T.P.) without obtaining informed consent.[17] RFAAX 1, at 5–10.

Based on Respondent's admissions, the Agency finds substantial record evidence that Respondent violated federal and state laws involving controlled substances and issued prescriptions outside the usual course of professional practice. *See* RFAAX 1, at 1–11; *see also* 21 CFR 1306.04(a); Mass. Gen. Laws ch. 94C sec. 19(a); 243 Mass. Code Regs. 2.07(13)(a); 105 Mass. Code Regs. 2.07(26), 700.12(G)(1)(b). Accordingly, the Agency finds that Factors B and D weigh in favor of denying Respondent's registration and thus finds that Respondent's registration is 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 any evidence to rebut the Government's *prima facie* case.

## IV. Sanction

Here, the Government has met its *prima facie* burden of showing that Respondent's existing registration should be revoked because of his material falsification and because his continued registration is inconsistent with the public interest. The burden then shifts to Respondent to show why he can be entrusted with a registration. *Morall,* 412 F.3d. at 174; *Jones Total Health Care Pharmacy,* 881 F.3d at 830; *Garrett Howard Smith, M.D.,* 83 FR 18882, 18904 (2018).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Jones Total Health Care Pharmacy,* 881 F.3d at 833; *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995). A registrant's acceptance of responsibility must be unequivocal. *Jones Total Health Care Pharmacy,* 881 F.3d at 830–31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, the Agency has found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 & n.4. The Agency has also considered the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein, M.D.,* 84 FR at 46972–73.

Regarding these matters, there is no record evidence that Respondent takes responsibility, let alone unequivocal responsibility, for the founded violations meaning, among other things, that it is not reasonable to believe that Respondent's future controlled substance-related actions will comply with legal requirements. Accordingly, Respondent did not convince the Agency that he can be entrusted with a registration.

Further, the interests of specific and general deterrence weigh in favor of revocation. Given the foundational nature and vast number of Respondent's violations, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not a condition precedent to maintaining a registration.

[16] Only the benzodiazepine prescriptions issued after December 2014, the date the relevant state law went into effect, are relevant to the Agency's finding that Respondent's prescribing violated 105 Massachusetts Code Regulations 700.12(G)(1)(b). *See supra* notes 5–6.

[17] This applies only for the consent forms that Respondent failed to obtain after August 9, 2019, the date the relevant state law went into effect. *See* 243 Mass. Code Regs. 2.07(26).

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

**Order**

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. BA4429684 issued to Lee S. Altman, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby deny any pending application of Lee S. Altman, M.D., for registration in Massachusetts. This Order is effective July 7, 2025.

**Signing Authority**

This document of the Drug Enforcement Administration was signed on May 30, 2025, by Acting Administrator Robert J. Murphy. 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. 2025–10237 Filed 6–4–25; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

**[OMB Number 1125–0016]**

### Agency Information Collection Activities; Proposed Collection eComments Requested; Extension/ Revision of a Previously Approved Collection; Unfair Immigration-Related Employment Practices Complaint Form (Form EOIR–58)

**AGENCY:** Executive Office for Immigration Review, Department of Justice.

**ACTION:** 60-Day notice.

**SUMMARY:** The Executive Office for Immigration Review (EOIR), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

**DATES:** Comments are encouraged and will be accepted for 60 days until August 4, 2025.

**FOR FURTHER INFORMATION CONTACT:** If you have additional comments, especially on 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 Justine Fuga, Associate General Counsel, Office of the General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, VA 22041, telephone: (703) 305–0265, *Justine.Fuga@usdoj.gov, eoir.pra.comments@usdoj.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 the quality, utility, and clarity of the information to be collected; and/or

—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.

*Abstract:* Section 274B of the Immigration and Nationality Act (INA) prohibits employment discrimination on the basis of citizenship status or national origin; retaliation or intimidation by an employer against an individual seeking to exercise his or her right under this section; and ''document abuse'' or over-documentation by the employer, which occurs when the employer asks an applicant or employee for more or different documents than required for employment eligibility verification under INA section 274A, with the intent of discriminating against the employee in violation of section 274B. Individuals who believe that they have suffered discrimination in violation of section 274B may file a charge with the DOJ Immigrant and Employee Rights Section (IER). The IER then has 120 days to determine whether to file a complaint with the EOIR Office of the Chief Administrative Hearing Officer (OCAHO) on behalf of the individual charging party. If the IER chooses not to file a complaint, the individual may then file his or her own complaint directly with OCAHO. This information collection may be used by an individual to file his or her own complaint with OCAHO. The Form EOIR–58 elicits, in a uniform manner, all the required information for OCAHO to assign a section 274B complaint to an Administrative Law Judge for adjudication. Non-substantive revisions are being made throughout the form and instructions to improve formatting, clarity, and grammar. EOIR has also made changes updating the IER mailing address, revising the Privacy Act notice to include a citation to OCAHO's System of Record Notice (SORN), and revising the amount of time estimated to complete the form. Additionally, to account for anticipated expansion of electronic filing capabilities in the future, EOIR is also revising the instructions to clarify differences in filing procedures for those forms filed by mail versus forms filed electronically.

**Overview of This Information Collection**

1. *Type of Information Collection:* Extension and Revision of a previously approved collection.

2. *The Title of the Form/Collection:* Unfair Immigration-Related Employment Practices Complaint Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is EOIR–58, and the sponsoring DOJ component is EOIR.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public are individuals who wish to file a complaint alleging unfair immigration-related employment practices under INA section 274B. Individuals are obligated to respond to obtain/retain a benefit. However, using this form is voluntary and individuals may alternatively file a written submission alleging unfair immigration-related employment practices under INA section 274B, provided that the alternative submission format meets the requirements for OCAHO complaints as set forth in 28 CFR 68.7. The Form