



BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 24-32]

Svetlana Burtman, N.P.; Decision and Order

I. INTRODUCTION

On December 28, 2023, the then-Administrator issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Svetlana Burtman, N.P., of Tucson, Arizona (Respondent). OSC/ISO, at 1. The OSC/ISO informs Respondent of the immediate suspension of her Drug Enforcement Administration (DEA or Government) Certificate of Registration, No. MB2645767, 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 proposes the revocation of Respondent’s registration, No. MB2645767, as well as the denial of Respondent’s application for a new registration for her Green Valley clinic (GVC), No. W23106194M, alleging that Respondent’s registration is inconsistent with the public interest. *Id.* at 1-2.

More specifically, the OSC/ISO alleges that Respondent (1) dispensed controlled substances from an unregistered location, in violation of 21 CFR 1301.12(a) (a separate registration is required for each principal place of business or professional practice where controlled substances are dispensed), (2) failed to maintain, readily retrievable from her

ordinary business records, a complete and accurate record of each controlled substance received, in violation of 21 U.S.C. 827(a)(3) and 827(b) and 21 CFR 1304.04(a) and 1304.21(a), and (3) failed to maintain the requisite dispensing logs, in violation of 21 CFR 1304.22(c).¹ OSC/ISO, at 2-4.

Respondent requested a hearing.² The hearing was held before Chief Administrative Law Judge John J. Mulrooney, II, (Chief ALJ) who, on June 20, 2024, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (RD). The RD recommends that Respondent's Tucson registration be revoked and that her application for a GVC registration be denied. RD, at 35-36. On July 10, 2024, Respondent timely filed "Exceptions to ALJ Recommendations" (Exceptions). Eleven exceptions challenge the RD's Conclusions of Fact, and four challenge the RD's Conclusions of Law.³

¹ The OSC/ISO also alleges violations of Arizona law, none of which the Agency is adjudicating due to the seriousness of the alleged federal violations. Each of the alleged federal violations alone, if proven, is a sufficient basis to revoke Respondent's registration and deny her registration application.

² The Agency agrees with the final rulings contained in the Order Regarding the Government's Motions *In Limine* and for Partial Summary Disposition (May 9, 2024).

³ The Agency carefully considered each of Respondent's Exceptions. *Infra*.

Respondent's first factual Exception concerns "Conclusions Regarding the 2021 Investigation" and states, in essence, that the Chief ALJ wrongly denied Respondent the opportunity to present one of the several attorneys who represented her during the "2021 Investigation" as a rebuttal witness. Exceptions, at 4. That rebuttal witness, according to the first factual Exception, would testify that the United States Attorney's Office "never informed [him] of any purported regulatory violations arising from the 2021 visit." *Id.* at 5. Accordingly, the first factual Exception continues, Respondent "had a reasonable belief that her storage and record-keeping practices were compliant following the 2021 visit." *Id.*

The Agency rejects Respondent's first factual Exception. The violations alleged in the OSC/ISO do not date back to 2021, and matters dating back to 2021 are not factually relevant to the Agency's adjudication of the allegations. Further, the Agency rejects Respondent's theory that, if a registrant's "storage and record-keeping practices" are compliant in one year, the registrant may maintain a "reasonable belief" that she will remain compliant going forward regardless of changes in the registrant's practices or without the registrant continuously monitoring for required changes.

The content of Respondent's first factual Exception, however, indicates a pattern of Respondent's failure to follow up with DEA staff about their encounters. *Infra*. section V.

Respondent's fourth factual Exception states that the Government's case wrongly claims that Respondent had "6 mg Testosterone pellets at the GVC," because "no such formulation exists in the record." *Id.* at 8-9. As the Agency's Decision and Order does not mention, let alone rely on, the Exception's alleged factual inaccuracy, the Agency rejects Respondent's fourth factual Exception.

Having carefully reviewed the entire record, the Agency agrees with the RD's recommended sanction of (1) revocation of Respondent's registration and (2) denial of Respondent's GVC registration application.

II. THE ALLEGED VIOLATIONS

As already discussed, the OSC/ISO alleges that Respondent violated multiple provisions of the Controlled Substances Act (CSA) and its implementing regulations.⁴ 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

Respondent's second, fifth, sixth, seventh, and eleventh factual Exceptions concern the credibility of record evidence. The second factual Exception challenges the credibility of a DEA Investigator's testimony about whether Respondent said that she "did not plan on conducting regulated activities" at GVC. *Id.* at 6. The fifth factual Exception attacks the credibility of "aspects" of the DEA Investigator's testimony that the Exception admits have "limited significance to the Chief ALJ's recommendations." *Id.* at 9-10. The sixth factual Exception concerns the Chief ALJ's "characterization" of Respondent's testimony about the "storage of controlled substances at GVC" as "inconsistent and fatal to her credibility." *Id.* at 10-12. The seventh factual Exception concerns the Chief ALJ's "[r]eference to [a] [n]on-[e]xistent August 9, 2023 [v]isit [f]rom the D[EA] Audit Team." *Id.* at 12-13. And the eleventh factual Exception, like the sixth factual Exception, concerns the Chief ALJ's recommendation that, when there is a conflict, the DEA Investigator's testimony should be credited, not Respondent's testimony. *Id.* at 16-17.

The Agency carefully evaluated each of these five factual Exceptions. As discussed in this Decision and Order, the Agency's found facts are based on Respondent's own testimony, on Respondent's own evidence, and/or on evidence that Respondent does not contest. Accordingly, Respondent's second, fifth, sixth, seventh, and eleventh factual Exceptions play no role in the Agency's adjudication of the OSC/ISO's allegations and, therefore, the Agency rejects them.

⁴ The OSC/ISO also mentions 21 U.S.C. 1301.71 and 1301.75. OSC/ISO, at 3. The Government's Proposed Findings of Fact, Conclusions of Law, and Argument (Closing Brief), however, does not mention either of these provisions, apparently abandoning them. Accordingly, the Agency is not adjudicating them and they are not sustained.

The OSC/ISO also mentions 21 U.S.C. 1301.72(b)(8)(ii) ("Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated."). OSC/ISO at 3. The Government's Closing Brief addresses this provision. It does so, however, in only one sentence, followed by a cite to four lines of the transcript about Respondent's registered Tucson location. The Agency finds that the Government did not submit substantial evidence that Respondent violated 21 U.S.C. 1301.72(b)(8)(ii) and, therefore, the Agency does not sustain the 21 U.S.C. 1301.72(b)(8)(ii) allegation.

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; *see also Gonzales v. Oregon*, 546 U.S. 243, 266 (2006) (“Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General.”).

The OSC/ISO’s allegations concern the CSA’s “strict requirements regarding registration . . . and recordkeeping” 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.” 545 U.S. at 12-14.

A. Dispensing Controlled Substances from an Unregistered Location (21 CFR 1301.12(a))

First, the OSC/ISO alleges that Respondent dispensed controlled substances from GVC, an unregistered location. OSC/ISO, at 2-4. According to the applicable CSA regulation, “[a] separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are . . . dispensed by a person.” 21 CFR 1301.12(a).⁵ Further, “dispense” means “to deliver a controlled substance to an ultimate user . . . including the prescribing and administering of a controlled substance.” 21 U.S.C. 802(10).

⁵ *See also* 21 U.S.C. 822(e)(1). The OSC/ISO does not allege a violation of the statutory provision, so the statutory provision plays no role in the Agency’s adjudication.

The Agency finds no merit to Respondent’s argument that the separate registration requirement is confusing, and that its application to her practice is “unclear.” Her argument relies on guidance documents and other materials applicable to registrants who travel to patients’ locations to provide medical treatment (such as patients’ homes and, for animals, stables). Those materials do not apply to registrants, such as herself, who transport controlled substances from a practice location that is registered to another practice location that is not registered. For a practitioner such as Respondent, whose business model is to practice at brick and mortar locations to which patients come for medical treatment, the meaning and application of these provisions are clear.⁶ *Jeffery J. Becker, D.D.S. v. Drug Enf’t Admin.*, 541 F. App’x 587, 590 (6th Cir. 2013) (“We have no occasion to disturb . . . [the Deputy Administrator’s] determination that Becker’s

⁶ It is Respondent’s first Exception to the ALJ’s Conclusions of Law that argues that there is confusion about the “separate registration” requirement. Exceptions, at 18-20. To support her claim of confusion, she cites a Diversion Control Division “Guidance Document” titled “Practice of Medicine” whose “Question” asks “Can a physician transport controlled substances and administer at the patient’s home residence (the so-called ‘black bag exception’)?” EO-DEA212, DEA-DC-047, October 8, 2020. Respondent does not explain how this Guidance Document clearly addressing the administering of controlled substances “at the patient’s home” pertains to and, therefore, confuses her about her transporting to, and administering of controlled substances at, her GVC location, which is not a residence, let alone a “patient’s home.” The Agency finds unpersuasive Respondent’s confusion defense based on this Guidance Document and rejects this aspect of her first legal Exception.

Respondent’s first legal Exception, to support her argument that the separate registration requirement is unclear, also cites a proposed rulemaking titled “Principal Place of Business or Professional Practice,” RIN: 1117-AB52, DEA Docket number 474, Fall 2023.” Exceptions, at 18-19. To date, this proposed rulemaking remains in the most incipient stages and explicitly states, similar to the purpose of the so-called “Black Bag” exception, that it concerns “allow[ing] a broader range of practice for practitioners traveling to administer controlled substances.” *Id.* As Respondent, herself, testified, however, she intends the GVC to be a brick and mortar clinic like her Tucson clinic. Tr. 303 (Respondent testifying that she “wanted to have[] pellets that designated to Green Valley office so when . . . [she] get[s her] license, . . . [she] would be able to order specifically to Green Valley location and keep the logs at Green Valley office pertaining to that office only, and separate . . . [her] inventory. And in terms of business, . . . [she] wanted to see what location does what and how it is going.”). In other words, Respondent plans for her patients to travel to GVC for treatment; she does not plan to travel to patients’ homes. Tr. 282-84 (Respondent testifying that she first decided to open a clinic in Green Valley in 2021, and that “[t]here is nothing similar or like it in Green Valley, and there is a high demand for that type of medicine. . . . People would drive to Tucson from Green Valley, asking to bring something like that into Green Valley.”). Accordingly, the Agency disagrees with Respondent’s argument in her first legal Exception that a DEA proposed rulemaking supports her claim that the separate registration requirement, as applied to her medical practice, is unclear. The Agency rejects Respondent’s first legal Exception in its entirety.

claim of reasonable confusion or mistake was not credible.”); *United States v. Clinical Leasing Service, Inc.*, 925 F.2d 120, 121-23 (5th Cir. 1991) (concluding that “each principal place of business” is not unconstitutionally vague).⁷

B. Failing to Maintain, Readily Retrievable from Her Ordinary Business Records, at Respondent’s Tucson Clinic a Complete and Accurate Record of Each Controlled Substance Received (21 U.S.C. 827(a)(3) and 827(b) and 21 CFR 1304.04(a) and 1304.21(a))

Second, the OSC/ISO alleges that Respondent failed to maintain, readily retrievable from her ordinary business records, a complete and accurate record of each controlled substance she received. OSC/ISO, at 3; *see* 21 U.S.C. 827(a)(3) and 827(b) and 21 CFR 1304.04(a) and 1304.21(a). According to the CSA and its implementing regulations, “every” registrant who dispenses a controlled substance “shall maintain, on a current basis, a complete and accurate record of each such substance . . . received . . . or otherwise disposed of by him . . . except that this paragraph shall not require the maintenance of a perpetual inventory.” 21 U.S.C. 827(a)(3); *see also* 21 CFR 1304.21(a) (“Every registrant required to keep records pursuant to § 1304.03 shall maintain, on a current basis, a complete and accurate record of each substance . . . received . . . or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and

⁷ *Jeffery J. Becker, D.D.S. and Jeffery J. Becker, D.D.S. Affordable Care*, 77 FR 72,387, 72,387-88 (2012) (“[T]he statute provides clear notice that it is the activity of dispensing, which includes the administration of controlled substances, itself, which triggers the requirement, in the case of a practitioner, of obtaining a separate registration for a principal place of professional practice. . . . To the extent Respondent suggests that the Expert’s testimony establishes that there is widespread confusion among practitioners as to the scope of the registration requirements, the argument is unavailing. The clarity of the Act and the Agency’s regulations is not determined by whether there are even a substantial number of members of the dental profession in Ohio who are confused as to the scope of the registration requirements. Rather, it is determined by assessing whether the text of the Act and regulations provide fair notice such that a person of ordinary intelligence can understand when a separate registration is required. *See FCC v. Fox Television Stations, Inc.*, . . . [267 U.S. 239] (2012) (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)). The Act and regulations pass this test with flying colors. . . . While the record establishes that the Government’s Expert travels to numerous offices of other dentists to provide anesthesia services for their patients, he does so on an apparently as-needed and random basis, and there is no evidence that he maintains a place of professional practice, let alone a principal one, at any of these locations.”).

returned mail-back package, except that no registrant shall be required to maintain a perpetual inventory.”).

C. Failing to Maintain the Required Dispensing Logs for Respondent’s Tucson Clinic (21 CFR 1304.22(c))

Third, the OSC/ISO alleges that Respondent failed to maintain the required controlled substance dispensing logs for her Tucson location. OSC/ISO, at 3. According to the CSA’s implementing regulations, a dispenser is to maintain records of, among other things, the “number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.”⁸ 21 CFR 1304.22(c).

III. FINDINGS OF FACT

A. Dispensing Controlled Substances from an Unregistered Location (21 CFR 1301.12(a))

The Agency finds substantial, uncontroverted record evidence that Respondent’s GVC is not, and never has been, a registered location. GX 9 (Respondent’s Form 224 GVC registration application showing the submission date as July 19, 2023); Tr. 300 (Respondent testifying that she thought DEA would approve her GVC registration application “quickly,” but “[i]t didn’t happen at all”). The Agency finds substantial record evidence that Respondent admitted that she transported controlled substances to GVC, an unregistered location, and that she dispensed controlled substances there by administering them directly to individuals. *E.g.*, Stipulation Order, at 3 (Stipulation No.

⁸ A dispenser is also required to “maintain records with the same information required of manufacturers” pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section.” 21 U.S.C. 1304.22(c).

18: “The logs and patient records indicated that Respondent dispensed testosterone pellets/injections between July 1, 2021, and September 18, 2023, to at least eight patients at the unregistered Green Valley Clinic location.”); Tr. 285 (Respondent testifying that she transported controlled substances from her Tucson location to GVC), Tr. 292, 297 (Respondent testifying that she administered controlled substances to individuals at GVC); *see also* GX 13 and GX 14 (GVC dispensing logs).⁹

The Agency also finds substantial record evidence that Respondent admitted that she told DEA Investigators that she did not “dispense” controlled substances from GVC. *E.g.*, Tr. 291 (Respondent testifying that the DEA Investigators asked her if she “dispensed” controlled substances from GVC and that her answer was “no”).¹⁰ The

⁹ Respondent’s ninth factual Exception concerns the “ALJ’s conclusion that . . . [Respondent] administered controlled substances at the GVC after the . . . [DEA Investigators] left on July 19, 2023.” Exceptions, at 14. This factual Exception further states that the “ALJ rejected . . . [Respondent’s] correction to the hearing transcript, which refutes the conclusion on page 13 [of the RD] that she “administered controlled substances [at GVC] shortly after the . . . [DEA Investigators] departed.” *Id.*

The Agency carefully considered Respondent’s ninth factual Exception. The Agency rejects it because the precise timing of Respondent’s July 19, 2023 GVC dispensing of controlled substances plays no role in this adjudication.

¹⁰ *But see* Stipulation Order, at 3 (Stipulation No. 23: “On November 6, 2023, under oath, the Respondent was asked the following question and provided the following answer (Tr. 51:8-18):

Q: So when I asked you specifically why you had controlled substances at a non-registered location you stated to me that you were prepping the office. Does that sound accurate to you?

A: I have patients that travel from Tucson to Green Valley location and from Green Valley location to Tucson based on where I’m working, which kind of defeats the purpose of having my two clinics. So, say a patient that comes to Green Valley is from Tucson that was allowed to be dispensed, so this was my train of thought that I was carrying the controlled substances with me.”);

Stipulation Order, at 4 (Stipulation No. 24: “On November 6, 2023, under oath, the Respondent was asked the following question and provided the following answer (Tr. 53:9-15):

Q: Okay. So upon reviewing your controlled substance dispensing logs for the Green Valley location when we did the administrative inspection warrant on September 20, 2023, you had, you were administering controlled substances at an unregistered location since prior to DEA’s visit on July 19th; is that true?

A: Yes.”); and

Stipulation Order, at 4 (Stipulation No. 25: “On November 6, 2023, under oath, the Respondent was asked the following question and provided the following answer (Tr. 54:14-19):

Q: Okay. So my question to you: Were you just administering controlled substances at the Green Valley location that was not a DEA registered location?

A: I was, but they were also patients in Tucson. They would come to Tucson just like they come to Green Valley.”).

Agency finds substantial record evidence that Respondent’s denial that she “dispensed” controlled substances from GVC was premised on her use of an incorrect meaning of the word “dispense.”¹¹ Tr. 292 (Respondent testifying that “dispense,” “in . . . [her] mind,” is “something that occurs with shipping to you and . . . you account for the drug at that location. That only was happening at Tucson.”), *see also* Tr. 342-43 (Respondent testifying that she understands “dispensing” to mean “receiving and dispensing drugs out of that location” and that giving testosterone to a patient to take home “could be one of the instances”); *cf. supra* section II.A. (CSA definition of “dispense”); *see* GX 13 and GX 14 (GVC liquid testosterone and testosterone pellet, respectively, “dispensing” logs from July 2021 through September 18, 2023).

Further, the Agency finds substantial, uncontroverted record evidence that DEA Investigators told Respondent and Respondent knew that she needs a registration to dispense or administer controlled substances at GVC. Stipulation Order, at 2 (Stipulation No. 11: “On or about July 19, 2023, DEA investigators informed the Respondent that in order to handle, dispense, and/or administer controlled substances at the Green Valley Clinic location she would have to apply for a separate DEA C[ertificate] O[f] R[egistration] for that address.”); Tr. 294-95 (Respondent testifying that, on July 19,

¹¹ Respondent’s eighth factual Exception states that Respondent’s “testimony regarding the distinction she held in her mind between administering and dispensing was not offered as a defense to the allegations here, but rather as an explanation for her state of mind at the time of the July 19, 2023 conversation with investigators She felt that she was not dispensing.” Exceptions, at 13-14. The exception also states that Respondent’s response was “deemed by the . . . [DEA Investigators] and ALJ to have been a lie.” *Id.* at 14.

The Agency carefully considered Respondent’s eighth factual Exception and notes the reference to Respondent’s “state of mind” on July 19, 2023. This Decision and Order does not conclude that Respondent’s “distinction between administering and dispensing” was, or was not, a lie. Instead, Respondent’s clear failure to understand and adopt the statutory definitions of “dispense” and “administer” is relevant to whether the Agency can re-entrust Respondent with her Tucson registration and issue her a registration for GVC. 21 U.S.C. 802(2) and 802(10); *infra* section V.

2023, the DEA Investigators told her that she needed a registration to administer controlled substances at GVC); Stipulation Order, at 2 (Stipulation No. 14); GX 9 (Respondent's GVC registration application showing the submission date of July 31, 2023).

Despite her admission that, on July 19, 2023, she knew that she needed a registration to dispense or administer controlled substances from GVC, Respondent took about 12 days, or almost two weeks, to submit an electronic application for a GVC registration. *Supra*. Further, although she knew that it was unlawful to “handle, dispense, and/or administer” controlled substances from an unregistered location, the Agency finds uncontroverted, substantial record evidence that Respondent continued to do so into September of 2023. *Supra* Stipulation Order, at 2 (Stipulation No. 11); GX 13 and GX 14. Indeed, according to her own records, Respondent dispensed controlled substances from GVC at least seventy-one times on and after July 19, 2023.¹² GX 13, at 7-9 (showing 43 liquid testosterone dispensings at GVC from July 19, 2023 to September 18, 2023), GX 14, at 9-10 (showing 28 testosterone pellet dispensings at GVC from July 19, 2023 to September 19, 2023). Further, Respondent testified that she continued to handle controlled substances at GVC, in essence, for her convenience. Tr. 309 (Respondent testifying that she “learned that it’s absolutely not okay” to “draw up” “halfway empty, at least most empty,” controlled substance vials at GVC because she had “more time [on September 20, 2023] at Green Valley than at Tucson to do that”).

¹² During the approximately nine weeks between July 19 and about September 19, Respondent worked at GVC “at least once a week,” although “[o]ccasionally, it was not even once a week, it was once every two weeks.” Tr. 284. This means that, based on her own testimony, Respondent administered controlled substances at GVC to an average minimum of about eight people per day for each of those nine weeks.

Accordingly, the Agency finds substantial record evidence that Respondent dispensed controlled substances from GVC, an unregistered location, for over two years. Tr. 306 (Respondent testifying and admitting that GVC never had, and still does not have, a registration).

Thus, having read and analyzed all of the record evidence, the Agency finds substantial record evidence, in the forms of stipulations and Respondent's hearing testimony and documentary admissions, of each element of the allegation that Respondent dispensed controlled substances from her GVC unregistered location. *Supra.*

B. Failing to Maintain, Readily Retrievable from her Ordinary Business Records at Respondent's Tucson Clinic, a Complete and Accurate Record of Each Controlled Substance Received (21 U.S.C. 827(a)(3) and 827(b) and 21 CFR 1304.04(a) and 1304.21(a))

The Agency finds substantial record evidence that, on July 19, 2023, Respondent signed a Notice of Inspection of Controlled Premises consenting to the inspection of her Tucson facility on that same day. GX 5; Stipulation Order, at 2 (Stipulation No. 12"); Tr. 295. The Agency finds substantial record evidence that Respondent suggested that the DEA Investigators "work with her [Tucson] office lead," CO. Tr. 43-44 (DEA Investigator testifying). The Agency finds substantial record evidence that CO represented to be "willing and able to provide . . . [the DEA Investigators] whatever records . . . [they] requested." *Id.* at 45 (DEA Investigator testifying).

The Agency finds substantial record evidence that the DEA Investigators asked CO for, but did not receive, a complete and accurate record of each controlled substance that Respondent received at her Tucson clinic. Tr. 47, 61-62 (DEA Investigator testifying).¹³ The Agency finds substantial record evidence that CO told DEA

¹³ CO did, however, provide dispensing logs. *Infra.*

Investigators that she was “unable to retrieve the records on the spot” because Respondent changed her “computer systems twice in . . . [the] past year.”¹⁴ *Id.* at 61 (DEA Investigator testifying). Accordingly, the Agency finds substantial record evidence that the DEA Inspection Team never received Respondent’s Tucson purchase invoice records.¹⁵ *Id.* at 234-35. Further, the Agency finds no record evidence that Respondent contests that the DEA Inspection Team never received her Tucson purchase invoice records.¹⁶ Finally, the Agency finds no record evidence that Respondent proffered at the hearing any of the Tucson controlled substance-received records that the DEA Inspection Team requested, but did not receive. *E.g., Int’l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW) v. Nat’l Labor Relations Bd.*, 459 F.2d 1329, 1336 (D.C. Cir. 1972) (“Simply stated, the rule provides that when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an

¹⁴ CO stated, though, that she could obtain “purchase invoice records” for the DEA Inspection Team “from the supplier” even though she did not have “any on hand to provide” to the investigators. *Id.* at 62 (DEA Investigator testifying). The Agency finds no record evidence, however, that CO obtained the Tucson clinic purchase invoice records from the supplier and gave them to the DEA Inspection Team. *See also* Tr. 227-28 (DEA Investigator testifying and explaining that suppliers’ records about registrants’ controlled substance purchases are insufficient to show that the registrant actually received the controlled substances).

¹⁵ The Agency finds substantial record evidence that the DEA Investigator explained to CO that “in order to do a complete audit we required all the documents that we were requesting, and because we were unable to get the full scope of documents, we weren’t able to complete a full audit.” Tr. 62-63.

¹⁶ Respondent’s third factual Exception challenges the credibility of the DEA Investigator’s testimony that Respondent was given the opportunity to supplement missing records following the inspection of the Tucson clinic. The Agency carefully considered this exception. It rejects the exception because this adjudication does not require a finding of whether the DEA Inspection Team asked Respondent for the missing records. Instead, the germane finding, which Respondent does not contest, is that Respondent’s Tucson clinic’s controlled substance purchase invoice records were not readily available to the DEA Inspection Team. Indeed, the DEA Inspection Team never received those records.

Further, and of relevance to this adjudication, Respondent’s testimony does not evidence an interest in, or concern about, the inspection of her Tucson clinic. For example, immediately after testifying that CO was present for the Tucson inspection, Respondent declined to provide a substantive answer to the question her counsel asked: “And what did you learn of what happened at the inspection at the Tucson clinic on July 19?” Tr. 297. Instead of answering, Respondent stated: “Ask me another question. So much happened.” *Id.* In other words, while the substantial record evidence is that Respondent voluntarily, on the day of the inspection, provided her in-person agreement to the DEA inspection of her Tucson facility, the Agency finds no record evidence that Respondent took the initiative to contact any member of the DEA Inspection Team or her own staff, whose identities she knew, to take any follow-up steps after DEA’s inspection of her Tucson clinic. *See id.*

inference that the evidence is unfavorable to him.”); *see also Huthnance v. District of Columbia*, 722 F.3d 371, 378 (D.C. Cir. 2013) (same).

Having read and analyzed all of the record evidence, the Agency finds substantial record evidence, uncontested by Respondent, of each element of the allegation that Respondent failed to maintain, readily retrievable from her ordinary business records at her Tucson clinic, a complete and accurate record of each controlled substance received. *Supra*.

C. Failing to Maintain the Required Dispensing Logs for the Tucson Clinic (21 CFR 1304.22(c))

The Agency finds substantial record evidence that Respondent maintained insufficient records of controlled substances that she dispensed at her Tucson clinic.¹⁷ GX 6, for example, shows Respondent’s dispensing of testosterone at her Tucson clinic from June 28, 2023 to July 19, 2023. *Id.* GX 6, however, only shows the “dispense date,” the “patient name,” the “DOB,” the “dose,” and the “MA Initial’s” [sic]. It does not show the size or number of milligrams in the containers “opened” and dispensed, the form of the controlled substance, the patient address, or more than a month of dispensing. Tr. 338 (Respondent testifying), *id.* at 67 (DEA Investigator testifying that GX 6 is “missing the drug strength, form, patient address, and it only encompasses less than a month of dispensing”); *see also* GX 7 (same for the record of Phentermine dispensed at Respondent’s Tucson clinic); RX D (records of testosterone dispensed at Respondent’s Tucson clinic with the more recent pages improved to show the patient’s address).

¹⁷ The data that must be included in a controlled substance dispensing log are discussed in section II.C., *supra*.

The Agency further finds substantial record evidence that parts of Respondent's hearing testimony admit that both liquid testosterone and testosterone pellets come in various strengths. Thus, Respondent knows that there are different strengths of those controlled substances, but did not include that information in her records of Tucson controlled substance dispensings.¹⁸

The Agency acknowledges that Respondent added at least the patient addresses to her dispensing logs starting on November 10, 2023, "after . . . [her] deposition in November."¹⁹ RX D, at 23; Tr. 320. While the inclusion of the required patient address is an improvement, Respondent's dispensing logs still do not contain all of the required elements, such as the strength of the dispensed controlled substance. *Supra*. For the above reasons, the Agency finds substantial record evidence that Respondent's "updated" dispensing logs continue not to comply with the regulations.

According to Respondent's tenth factual Exception, the RD incorrectly characterizes Respondent's testimony as a concession that her dispensing logs continue not to comply with the regulations. Exceptions, at 15. She further argues that "[t]o conclude that . . . [Respondent's] updated logs are inadequate places form well over substance," and that any failure on her part is "inconsequential." *Id.* at 16. As already

¹⁸ For example, Respondent's testimony admits that testosterone pellets come in dosages ranging from 25 mg to 200 mg. Tr. 309, 312. Her testimony also admits that liquid testosterone "absolutely" comes in different "dosage bottles." *Id.* at 336. In addition, some of Respondent's testimony admits that her records of Tucson clinic testosterone and Phentermine dispensings do not include the strength of the testosterone and Phentermine dispensed. *Id.* at 320, 338. Elsewhere, however, Respondent's testimony states that there is only one strength of testosterone pellets. *Id.* at 321-22. Then, shortly after so testifying, Respondent again testifies that testosterone pellets come in a range of strengths, and that liquid testosterone "absolutely" comes in different "dosage bottles." *Id.* at 322, 336.

¹⁹ The Agency notes other differences between Respondent's dispensing logs prior to and on November 10, 2023, but does not see discussion of those differences in the hearing transcript. RX D, at 22-23. Regardless, the Agency finds substantial record evidence that drug strength still is not noted on Respondent's RX D dispensing logs. *Id.*; Tr. 321.

discussed, the Agency acknowledges that Respondent added the patient address to her dispensing logs as of November 10, 2023. RX D, at 23. While the inclusion of the required patient address is an improvement, Respondent's dispensing logs still do not include all of the required elements, such as the strength and the form of the dispensed controlled substance. *Id.*; Tr. 321. For the above reasons, the Agency finds substantial record evidence that Respondent's "updated" dispensing logs in RX D continue not to comply with the regulations. The Agency rejects Respondent's tenth factual Exception, and specifically disagrees that Respondent's failures are "inconsequential."

Having read and analyzed all of the record evidence, the Agency finds substantial record evidence that Respondent's Tucson clinic's controlled substance dispensing logs, for the period germane to the OSC/ISO, do not include the requisite data points. *Supra.*

IV. DISCUSSION

A. The Controlled Substances Act and Implementing Regulations

Pursuant to the CSA, "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(g)(1). The section further provides that an application for a practitioner's registration may be denied upon a determination that "the issuance of such registration . . . would be inconsistent with the public interest." *Id.* Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A-E).²⁰ Congress directed the Attorney General to consider the same

²⁰ 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.

five factors when determining whether to suspend or revoke a practitioner’s registration due to the practitioner’s commission of “such acts as would render his registration under . . . [21 U.S.C. 823] inconsistent with the public interest.” 21 U.S.C. 824(a)(4).

The five factors are considered in the disjunctive. *Gonzales v. Oregon*, 546 U.S. at 292-93 (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 15,227, 15,230 (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 37,507, 37,508 (1993).

The Agency “may rely on any one or a combination of factors and may give each factor the weight [it] deems appropriate. *Morall*, 412 F.3d at 185 n.2; *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)); *Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman 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

-
- (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.

(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.

While the Agency considered all of the 21 U.S.C. 823(g)(1) factors in this matter, the Agency finds that the Government’s evidence in support of its *prima facie* cases is confined to factors B and D. Government’s Closing Brief, at 12; OSC/ISO, at 2; see also RD, at 21.²¹

According to DEA regulations, the Government has the burden of proof in this proceeding. 21 CFR 1301.44(d) (granting or denying an application), 21 CFR 1301.44(e) (revoking or suspending a registration). Both parties submitted documentary evidence. The Agency agrees with the Chief ALJ’s rulings on the admissibility of the offered evidence.

B. Allegations that Respondent’s Tucson Registration and Proposed GVC Registration Are Inconsistent with the Public Interest

Factors B and/or D – Respondent’s Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

The OSC/ISO alleges that Respondent violated multiple provisions of the CSA and its implementing regulations concerning controlled substance registration and

²¹ The Government argues that Factor E includes a respondent’s candor and forthrightness with DEA investigators. Government’s Closing Brief, at 11; see also RD, at n.55. The Agency declines to adopt the Government’s Factor E arguments in this matter.

recordkeeping requirements. These registration and recordkeeping requirements go to the heart of federal controlled substance law and this Agency's law enforcement mission.

Having thoroughly analyzed the record evidence and applicable law, the Agency finds substantial record evidence that Respondent administered controlled substances from an unregistered location, in violation of 21 CFR 1301.12(a). *Supra* section III.A. Accordingly, the Agency concludes that the Government presented a *prima facie* case that Respondent dispensed controlled substances from GVC, an unregistered location, and that Respondent tried, but failed, to rebut that *prima facie* case. *Id.* Next, the Agency finds substantial record evidence that Respondent failed to maintain, readily retrievable from her ordinary business records, a complete and accurate record of each controlled substance received at her Tucson clinic, in violation of 21 U.S.C. 827(a)(3) and 827(b) and 21 CFR 1304.04(a) and 1304.21(a). *Supra* section III.B. Accordingly, the Agency concludes that the Government presented a *prima facie* case that Respondent did not maintain, readily retrievable from her ordinary business records at her Tucson clinic, a complete and accurate record of each controlled substance received at that clinic, and that Respondent tried, but failed, to rebut that *prima facie* case. *Id.* Finally, the Agency finds substantial record evidence that Respondent did not maintain the requisite controlled substance dispensing logs, in violation of 21 CFR 1304.22(c). *Supra* section III.C. Accordingly, the Agency concludes that the Government presented a *prima facie* case that Respondent failed to maintain the requisite controlled substance dispensing logs, and that Respondent tried, but failed, to rebut that *prima facie* case.

Accordingly, the Agency finds that Factors B and D weigh in favor of revocation of Respondent's Tucson registration and denial of her GVC application because her

continued registration is inconsistent with the public interest. 21 U.S.C. 824(a)(4) and 823(g)(1).

V. SANCTION

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued Tucson registration and her being granted a registration for GVC are inconsistent with the public interest, the burden shifts to Respondent to show why she 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 18,882 (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 46,968, 46,972 (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 unequivocally accept responsibility for those acts and demonstrate that she will not engage in future misconduct. *Jones Total Health Care Pharmacy*, 881 F.3d at 831-33 (citing, among other authority, *Alra Labs., Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995) ("An agency rationally may conclude that past performance is the best predictor of future performance.")). "[T]hat consideration is vital to whether continued registration is in the public interest," and the acceptance of responsibility must be unequivocal. *MacKay v. Drug Enf't Admin.*, 664 F.3d at 820, 830-31. Further, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. DEA

Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR 46,972-73.

Regarding these matters, while Respondent stated, during her hearing testimony, that she does not want to give the “implication that . . . [she is] not accepting responsibilities [sic],” the Agency finds substantial record evidence that she minimizes her unlawfulness. For example, Respondent testified that she “know[s] that . . . [she] should have known . . . [the] regulations and had . . . [her] paperwork in order.” Tr. 354. She immediately affirms that she “know[s] that and it will happen.” *Id.* She then immediately continues, apparently even attempting to minimize her unlawfulness, stating that she “was not dealing with any other substance than testosterone and Phentermine.”²² *Id.*

In addition, the Agency finds substantial record evidence that Respondent blames DEA staff for her unlawfulness. Even after having the opportunity to improve by, for example, making her dispensing logs legally compliant, she never fully complies with the requirements incumbent on her as a registrant. Tr. 354. Instead, she shifts the blame for her failure to comply with legal requirements. For example, regarding her dispensing logs, she blames the DEA Investigators for not giving her an exemplar. She testified that “anytime . . . [she] had interactions with diversion investigators, . . . [she] was never really given a [dispensing] log. . . [I]t would be really easy and simple to say, Svetlana, this is what needs to happen, and it would have happened like in a matter of hours.” *Id.* at 353.

²² The Agency takes seriously the mishandling, abuse, and the potential for abuse of testosterone and Phentermine.

Further, Respondent is unwilling, or unable, to understand the responsibilities of a registrant, a matter with troubling ramifications. For example, she does not know the meanings of “administer” and “dispense,” two terms defined in the CSA. 21 U.S.C. 802(2), 802(10). *Supra* sections II.A. and III.A. Instead of citing the statutory meaning of those terms, she testified that “[i]n . . . [her] mind, dispensing is something that occurs with shipping to you and you – you account for the drug in that location.” Tr. 292 (emphasis added). Based on her incorrect definition of those terms, she told the DEA Investigators that she was not “dispensing” from GVC, an unregistered location. *Id.* at 291. Yet, her multiple testimonial and documentary admissions belie her denial of dispensing controlled substances at GVC. *E.g., id.* at 285, 297, 308; GX 13, GX 14. Thus, in addition to her not being willing or able to understand the responsibilities of a registrant, any DEA Investigator in the future, based on the experience of the DEA Investigators who interacted with Respondent in this matter, would not be able to trust the accuracy of Respondent’s statements.

Respondent’s record testimony indicates that she did not understand the reasons why the CSA and its implementing regulations require that controlled substances only be dispensed from registered locations. For example, Respondent “didn’t think that it would be a big deal at all” to have controlled substances at GVC as she “was under the impression . . . [that her] license [was] coming any day, really.” Tr. 305. The Agency cannot entrust a registration to an individual who does not think that it is a “big deal” to violate one of the foundational principles of the CSA.

Accordingly, the Agency finds substantial record evidence that Respondent did not unequivocally accept responsibility for her unlawfulness.²³ As such, Respondent has not convinced the Agency that she can be entrusted with a registration.

The interests of specific and general deterrence weigh in favor of the revocation of Respondent's Tucson registration and the denial of her Green Valley registration application. The Agency finds substantial record evidence that Respondent's testimony and controlled substance records establish that she failed to comply, over an extended time period, with registration and recordkeeping requirements that go to the heart of federal controlled substance law. *E.g.*, Tr. 354 ("I know that I should have known my regulations and had my paperwork in order. I know that, and it will happen."); Tr. 291-92; *supra* n.11 (Respondent's confusion about the meaning of "dispense" and her eighth factual Exception). The principle of specific deterrence requires the Agency to take action to deter Respondent who, despite over a decade of experience as a registrant and multiple, recent interactions with, and specific instructions from, DEA Investigators, continued to dispense controlled substances from an unregistered location, among other things. Tr. 260. Further, Respondent seemed not to take the DEA inspection seriously as she testified that she is unaware of the inspection's findings and whether the DEA Inspection Team received all of the documents it requested. *Supra* section III.B. Respondent's willing unawareness of the results of the inspection of her Tucson clinic does not indicate Respondent's future compliance with the CSA and the CSA's implementing regulations.

²³ For all of the above reasons, the Agency does not agree with Respondent's second legal Exception. Exceptions, at 20-24.

As the Agency does not consider remedial measures in the absence of unequivocal acceptance of responsibility, the Agency does not accept Respondent's third legal Exception. Exceptions, at 24.

For all of the above reasons, it is not reasonable to rely on Respondent's promise of her future compliance with the requirements incumbent on a registrant. Given the foundational nature of Respondent's violations, a sanction less than revocation would send a message to her, and to the existing and prospective registrant community, that compliance with the law is not a condition precedent to maintaining a registration. *E.g.*, *Jones Total Health Care Pharmacy*, 881 F.3d at 834 and n.4; *Garrett Howard Smith, M.D.*, 83 FR 18,910 (collecting cases).

Accordingly, the Agency shall order the revocation of Respondent's Tucson registration and the denial of her GVC application as contained in the Order below.

ORDER

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificate of Registration No. MB2645767 issued to Svetlana Burtman, N.P. 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 the pending application, Control No. W231061194M, of Svetlana Burtman, N.P., for registration in Green Valley, Arizona.

In addition, 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 to renew or modify DEA Certificate of Registration No. MB2645767, as well as any other pending application of Svetlana Burtman, N.P., for registration in Arizona. This Order is effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on April 16, 2025, by Acting Administrator Derek Maltz. 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. 2025-06882 Filed: 4/21/2025 8:45 am; Publication Date: 4/22/2025]