LLC, Wichita, KS; Oriola Defense & Security LLC to Safran Federal Systems, Inc., Rochester, NY; Integrata AG to Cegos Integrata GmbH, Stuttgart, GERMANY; and NovaTech Process Solutions to Valmet Automation Oy, Vespoo, FINLAND.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and TOG intends to file additional written notifications disclosing all changes in membership.

On April 21, 1997, TOG filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on June 13, 1997 (62 FR 32371).

The last notification was filed with the Department on June 29, 2023. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on August 23, 2023 (88 FR 57478).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

[FR Doc. 2023–27558 Filed 12–14–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–48]

APEXX Pharmacy, LLC; Decision and Order

I. Introduction

On August 2, 2022, the Administrator of the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (collectively, OSC) to APEXX Pharmacy, LLC (Respondent), of Hudson, Florida. OSC, at 1, 9. The OSC immediately suspended, and proposes the revocation of, Respondent's DEA registration No. FA5493363, pursuant to 21 U.S.C. 824(d) and (a)(4), and 21 U.S.C. 823(g)(1).[1] *Id.* at 1. The OSC more specifically alleges that Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* It also alleges violations of Florida law. *Supra* n.1.

The hearing Respondent requested was held on December 13 and 14, 2022. Hearing Transcript. The Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (RD) concludes that Respondent's registration should be revoked. RD, at 27. This Decision and Order, based solely on OSC allegations that Respondent filled controlled substances under the names of three individuals who, at the time, were deceased, agrees.[2] Fla. Admin. Code r. 64B16–27.1001(4). Accordingly, the Agency will revoke Respondent's registration. *Infra* Order.

II. Findings of Fact

The Allegation That Respondent Filled Controlled Substance Prescriptions Issued to Deceased Individuals

The OSC alleges, among other things, that Respondent filled controlled substance prescriptions issued to individuals who, at the time, were deceased. OSC, at 9. According to the Government's evidence, Respondent filled at least forty-seven such controlled substance prescriptions. *See, e.g.,* GX 6–GX 8 and GX 12–GX 14.

Respondent does not dispute that it filled the forty-seven Schedule II controlled substance prescriptions. *See, e.g.,* Tr. 366. It does not, however, take responsibility for doing so. Instead, it maintains that it acted properly and suggests, without any documentary or evidentiary support, a complex and layered theory of misconduct by others.

According to the testimony of Respondent's owner/Pharmacist-in-Charge (PIC), whom the Agency finds to be not credible, *infra,* the ''only way'' he can determine the validity of a prescription is to call the issuing doctor and ask whether the doctor wrote the specific elements of the order for the individual to whom the prescription is issued. *Id.* at 368–69. He testified that he does this for all of the prescriptions presented to his pharmacy. *Id.* at 369. He also testified that, for the forty-seven controlled substance prescriptions, each issuing doctor provided the verification. *Id.*

Further, Respondent's owner/PIC testified, for the forty-seven prescriptions, as with all other prescriptions, that ''every patient that comes into the pharmacy ha[s] to have an ID,'' that he ''get[s] their ID,'' and that he has ''to have an ID that matches the person in front of . . . [him].'' Tr. 367. He specifically testified that he ''always'' makes a copy of the IDs to put in the pharmacy's files, and that those prescriptions were not an exception.[3] *Id.*

While he acknowledged the Government-sponsored testimony that no copies of IDs presented for the forty-seven prescriptions were found in Respondent's files, the owner/PIC testified that ''that is impossible'' because ''[f]or every patient there ha[s] to be an ID to match the—the patient. They have to fill the information sheet and they have to give me an ID to match them and the prescription that they are filling.'' *Id.* at 368. He further testified that he was provided IDs for the three deceased individuals' prescriptions, that he made copies of them, and that ''those IDs seem to match the prescriptions that were presented to'' him. *Id.* The owner/PIC could not recall whether, for each of the forty-seven prescriptions, the individual presenting the Schedule II controlled substance prescription provided an ID in hard copy or electronically. *Id.* at 367; *see also* RD, at 23 (owner/PIC's ''testimony is undermined by his statement that he could not remember whether the customer presented a physical identification or emailed him one from a phone application''). Regardless, as already noted, Respondent's owner/PIC testified that he has ''to have an ID that matches the person in front of . . . [him].'' Tr. 367.

When asked for his explanation as to how Respondent filled any of the forty-seven Schedule II controlled substance prescriptions issued to deceased

[1] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

The Federal and state substantive violations alleged in the OSC include 21 U.S.C. 841(a)(2) and 842(a)(1); 21 CFR 1306.04(a) and 1306.06; Fla. Stat. 893.055(3)(a)(3); and Fla. Admin. Code r. 64B16–27.810(1) and (2), Fla. Admin. Code r. 64B16–27.831(1)(b) and (c), (2)(c), and (4), and Fla. Admin. Code r. 64B16–27.1001(4).

[2] The OSC's substantive headings describe the allegations as ''Improper Filling of Prescriptions to Undercover Officers,'' specifically referencing July 7, 2022, July 14, 2022, and July 15, 2022, ''Issuing Prescriptions to Dead Patients,'' and ''Imminent Danger.'' The OSC cites federal and state authorities as the bases of its allegations. *Supra* n.1.

This Decision is adjudicating only OSC allegations that Respondent filled controlled substance prescriptions issued to individuals who were deceased. Because these allegations alone are sufficient to revoke Respondent's registration, the Agency does not reach the other OSC allegations. The other OSC allegations include various references to conduct observed by and involving undercover officers; the record evidence related to those observations and interactions is periodically referenced herein as relevant to the analysis of Respondent's credibility and trustworthiness.

[3] The admitted exhibits do not support the owner/PIC's testimony that he always makes a copy of the IDs. GX 4; GX 5. They indicate that the owner/PIC made copies of controlled substance prescriptions and patient history forms. *E.g.,* GX 5, at 1, 5. They do not indicate, however, that the owner/PIC made a copy of any of the IDs that the undercover officers handed him. *See, e.g.,* GX 5, at 2, 10. Accordingly, the Agency finds that the testimony of Respondent's owner/PIC lacks credibility. *See also infra* section V (credibility discussion).

persons, Respondent's owner/PIC testified that the ''only thing'' he ''can think of is identity theft.'' Tr. 366. In other words, instead of acknowledging the possibility that his actions led, in any way, to the diversion of Schedule II controlled substances ordered on any of the forty-seven prescriptions, Respondent's owner/PIC engaged in speculation and misdirection.

Respondent offered no documentary evidence to support the identity theft theory. Indeed, it should have had evidence to prove or disprove the identity theft theory had Respondent's owner/PIC, as he testified (though not credibly), required the production of an ID that matched the individual presenting any of the forty-seven Schedule II controlled substance prescriptions, copied the ID, and put the copy in the pharmacy's files. *See supra* n.3. The Diversion Investigator (DI), though, credibly testified that he did not see any such IDs in Respondent's files for any of the forty-seven controlled substance prescriptions. Tr. 276–77; *infra.*

Again, though, instead of acknowledging the possibility that its actions or inactions led, in any way, to there being no copies of IDs in the pharmacy's files for any of the forty-seven prescriptions, Respondent suggested that the Government's seizure of its files was the cause. *See, e.g.,* Respondent Prehearing Statement, at 8 (''Proposed Documents—None because the Government seized all APEXX Pharmacy documents without a valid search warrant, as required pursuant to F.S. 465'').

Respondent did not, however, successfully develop its suggestions of Government responsibility for Respondent's allegedly missing pharmacy records. Instead, the Special Agent (S/A) testified about the seizure of Respondent's files, the DI testified about the content of those seized files, and the ALJ explicitly invited Respondent to develop its position through the cross-examination of both Government witnesses. *See, e.g.,* Tr. 123–31, 132–34, 136–37 (S/A testimony); *id.* at 126–27, 130, 134–36, 139, 277 (Administrative Law Judge-Respondent colloquy); *see also id.* at 206–09, (Respondent's cross examination of S/A); *id.* at 272–73, 275–77 (Respondent's cross examination of DI). However, Respondent did not successfully develop, on cross-examination of those two witnesses, its suggestion that Government error is the reason that there are no IDs in Respondent's seized files for any of the forty-seven controlled substance prescriptions. *Supra.* Instead, Respondent's owner/PIC testified that the Government's exhibits, offered as including Respondent's records regarding the forty-seven controlled substance prescriptions, ''match what is on PDMP.'' [4] Tr. 366; *see also id.* at 134. As it is Respondent that submitted these data to E–FORCSE, Florida's PDMP, the fact that Respondent's owner/PIC admits that the data in the Government's exhibits match the data in the PDMP is further evidence of the soundness and legal sufficiency of the Government's seizure of Respondent's files and the lack of credibility of Respondent's claims.

In sum, Respondent is asking the Agency to credit its *post hoc,* concocted sequential claims that: (1) it always copies and files an ID that matches each person presenting a prescription, (2) on forty-seven occasions it was presented with IDs that matched the physical characteristics of the persons presenting the forty-seven prescriptions for Schedule II controlled substances, but those IDs were fake and part of the perpetration of forty-seven incidents of identity theft, (3) Respondent cannot document the forty-seven fake IDs because of unspecified Government errors during the Government's search and seizure of Respondent's files, (4) and Respondent cannot develop the parameters of the unspecified Government errors even though it was given ample opportunity to do so during the hearing. The Agency declines.

After thoroughly reviewing the transmitted record, the Agency concludes that it will afford the testimony of both Government witnesses full credibility, and find that the testimony of Respondent's owner/PIC that conflicts with the Government witnesses' testimonies is not credible or creditable.[5] *Accord* RD, at 4, 5 (Government witnesses); *id.* at 14 (Respondent's witness). Further, when testimony of Respondent's owner/PIC conflicts with the testimony of a Government witness, the Agency will credit the testimony of the Government witness. *Accord* RD, at 14.

Based on the record before it, the Agency finds uncontroverted evidence that Respondent, through Respondent's owner/PIC, filled forty-seven controlled substance prescriptions issued to individuals who, at the time, were deceased.[6] *See, e.g.,* GX 6–GX 8 and GX 12–GX 14; *infra* section III. The Agency further finds uncontroverted record evidence that, due to these fillings, Respondent diverted 1,040 hydromorphone 8 mg tablets and 966 oxycodone HCL 30 mg tablets, or a total of 2006 Schedule II controlled substance tablets.[7] *Id.* The Agency concludes, based on substantial record evidence, that, since the individuals to whom these controlled substance prescriptions were issued were deceased, Respondent could not have ''dispensed'' the prescribed controlled substances to the individuals to whom the prescriptions were issued, and necessarily ''dispensed'' each of these forty-seven controlled substance prescriptions to a ''third party'' instead. GX 12–14; *accord* RD, at 24.

The Agency also finds substantial record evidence that Respondent's owner/PIC did not explain credibly why Respondent's seized files do not contain any of the alleged copies of the deceased customers' identifications that its owner/PIC testified he made when filling the forty-seven Schedule II controlled substance prescriptions. *Supra.*

III. Florida Legal Prohibition on ''Dispensing'' Prescriptions to ''Third Parties''

Among its other statutes and regulatory provisions concerning pharmacy standards of practice, Florida prohibits the ''dispensing'' of controlled

[4] PDMP stands for Prescription Drug Monitoring Program.

[5] The credibility of Respondent's owner/PIC is further eroded by his relentless pursuit of controlled substances sales and his willingness to violate legal requirements. *See, e.g.,* GX 5, at 7 (Respondent's owner/PIC telling the undercover sponsor which days during the following week to bring in ''some more people'' whom the sponsor will be ''taking to the doc''), GX 5, at 3, 4 (showing how Respondent's owner/PIC coached undercover sponsors and undercover officers on what to do to get the controlled substances from him that they want), and *infra* section V (addressing Respondent's owner/PIC's decision to close, permanently, the pharmacy's back door).

[6] Based on all of the above, the Agency does not credit Respondent's submissions to E–FORCSE that the individuals who dropped off the forty-seven prescriptions and picked up the filled controlled substances were the individuals to whom the controlled substance prescriptions were issued. GX 6, at 4, GX 7, at 4, and GX 8, at 4.

Further, a violation of the Florida regulation that this Decision is applying, according to the regulation's text, simply occurs when a pharmacy physically ''dispenses'' a controlled substance to a ''third party,'' not to the individual in whose name the prescription is written. *Cf., e.g., United States* v. *Green Drugs,* 905 F.2d 694, 698 (3d Cir. 1990) (''The defendants further argue that the result we enunciate here would allow the government to hold virtually any pharmacy liable for the most minor infraction even where the greatest care has been exercised and good faith demonstrated. This is a consequence that Congress likely accepted in enacting the [Controlled Substances] Act, and perhaps should be considered together with the broad discretion the district court has in assessing fines.'').

[7] Some prescriptions were written for Dilaudid 8 mg and were filled with hydromorphone HCL 8 mg. *See, e.g.,* GX 10, at 9–10, 13–18, and 25–28; GX 11, at 3–4, 19–20, 23–26, and 31–32.

substances to a ''third party.'' Fla. Admin. Code r. 64B16–27.1001(4) (2010) (''The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.''). According to the clear text of the regulation, nothing beyond the physical ''dispensing'' to a ''third party'' constitutes a violation. This regulation was in effect for the entire time covered by the OSC's allegations and, therefore, applies to Respondent's actions during that period.

Having thoroughly analyzed all of the record evidence, the Agency finds substantial and undisputed record evidence that Respondent ''dispensed'' controlled substances, pursuant to prescriptions issued to deceased individuals, to ''third parties'' at least forty-seven times. *See, e.g.,* GX 6–GX 8 and GX 12–GX 14.

IV. Discussion

Under Section 304 of the CSA, ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''pharmacy,'' Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A–E). The five factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

According to Agency decisions, the Agency ''may rely on any one or a combination of factors and may give each factor the weight [it] deems appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (*citing Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016)); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U. S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while 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.

According to DEA regulations, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. 824(a) . . . are satisfied.'' 21 CFR 1301.44(e).

In this matter, while all of the 21 U.S.C. 823(g)(1) factors have been considered, the Government's evidence in support of its *prima facie* case regarding the forty-seven prescriptions is confined to Factors B and D.[8] Government's Proposed Findings of Fact and Conclusions of Law, at 19; *see also* RD, at 16.

Factors B and/or D—Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Florida regulations explicitly prohibit pharmacies from ''dispensing'' to ''third parties.'' Fla. Admin. Code r. 64B16–27.1001(4) (2010); *supra* sections II and III. The record evidence is uncontroverted that, at least forty-seven times, Respondent filled Schedule II controlled substance prescriptions when the persons to whom the prescriptions were issued were deceased. Due to these fillings, Respondent diverted 1,040 hydromorphone 8 mg tablets and 966 oxycodone HCL 30 mg tablets, or a total of 2006 Schedule II controlled substance tablets to ''third parties.'' *Supra* sections II and III. The Agency finds that, as a result of this ''dispensing'' to ''third parties,'' Respondent repeatedly violated applicable law, supporting the revocation of its registration. 21 U.S.C. 824(a)(4) and Fla. Admin. Code r. 64B16–27.1001(4) (2010).

Accordingly, the Agency finds that Respondent's continued registration is inconsistent with the public interest. 21 U.S.C. 824(a)(4) and 823(g)(1)(B) and (D).

[8] Neither Respondent nor the Government argues that it offered evidence relevant to Factors A, C, or E. Although the Agency considered Factors A, C, and E, it finds that they are not relevant to this adjudication. *Accord* RD, at 16.

V. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest due to its numerous violations pertaining to controlled substances, the burden shifts to the Respondent to show why it can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882 (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). 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. *Id.* A registrant's acceptance of responsibility must be unequivocal. *Id.* 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.* Furthermore, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* DEA Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Id.*

Regarding these matters, there is no record evidence that Respondent, or its owner/PIC, takes responsibility, let alone unequivocal responsibility, for the founded, egregious violations involving the diversion of 2006 Schedule II controlled substance tablets. *Supra* sections II and IV. Instead, Respondent's case consists of one debunked and failed attempt after another to shift the blame for the unlawful filling of at least forty-seven controlled substance prescriptions away from itself.[9]

The interests of specific and general deterrence weigh in favor of revocation. Respondent has not convinced the Agency that it understands that its controlled substance prescription filling fell short of the applicable legal standards and that this substandard filling has serious negative ramifications for the health, safety, and medical care of individuals who come to it for medicine. *See, e.g., Garrett Howard Smith, M.D.,* 83 FR 18910 (collecting cases). As such, it is not reasonable to

[9] The testimony offering these serial attempts reflects poorly on the candor of Respondent's owner/PIC. *Supra* section II.

believe that Respondent's future controlled substance prescription filling will comply with legal requirements.[10] Indeed, Respondent's owner/PIC's own testimony suggests that he has no intention of complying with the CSA in the future because he believes compliance is unduly burdensome.[11]

Further, 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.

The Agency finds that it cannot entrust Respondent with a registration.[12] It finds that Respondent's actions were motivated by profiting while avoiding DEA's detection and lacked any genuine care for the health and welfare of its customers. For example, the record evidence shows that Respondent coached customers regarding what to write on their forms in order to get the desired controlled substances, *see, e.g.,* GX 5, at 3, 4, and shows the complete willingness of Respondent's owner/PIC to continue to fill the controlled substance prescriptions that S/A and undercover officer ''sponsors'' were bringing him. GX 5, at 1, 7.[13]

Respondent's owner/PIC's testimony regarding those matters further erodes the Agency's trust in the truthfulness of Respondent's owner/PIC and in the ability of Respondent to maintain a registration in compliance with the law.

In sum, the record supports the imposition of a sanction because Respondent did not unequivocally accept responsibility for its egregious and extensive violations, and has not convinced the Agency that it can be entrusted with a registration.

Accordingly, the Agency shall order the sanction the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4), I hereby revoke DEA registration No. FA5493363 issued to APEXX Pharmacy, LLC. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending application of APEXX Pharmacy, LLC, for a DEA Registration in Florida. This Order is effective January 16, 2024.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 7, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–27524 Filed 12–14–23; 8:45 am]

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[10] The Agency notes the record evidence, in GX 5, of two incidents when Respondent's owner/PIC declined to provide the undercover officers with additional controlled substances without a prescription. GX 5, at 6, 8–9. These incidents do not excuse Respondent's owner/PIC's otherwise laser-focused pursuit of controlled substances sales regardless of legal requirements. *Supra* section II.

[11] Respondent's owner/PIC testified that ''filling controls is a lot of headache. You have to record it down, you have to go through a lot of process, and nobody wants to deal with that.'' Tr. 297. Respondent's owner/PIC further testified that when he worked for larger pharmacies in the past, he would tell customers that controlled substances were not in stock because he got paid the same amount whether he filled controlled or non-controlled substances. *Id.* He testified, ''why would pharmacies . . . want to fill a control medication for somebody when it can come back to haunt him when he can say I don't have it, I will fill just the non-controls.'' *Id.*

[12] While only the evidence relating to the found violation, *supra,* was used to determine that the Government made a *prima facie* case, the entire record supports the Agency's determination that Respondent's owner/PIC is not credible and that, therefore, the Agency cannot entrust Respondent with a registration.

[13] GX 5, at 1 (''S/A: 'Can I drop you some more scripts?' . . . . Respondent's owner/PIC: 'How many is there?' ''); GX 5, at 7 (''Undercover Officer: 'I got some more people I'm taking to the doc. you good with me bringing them here again? Um next week.' . . . . Respondent's owner/PIC: 'Next week, yeah, next week that's fine.' '').

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Gary R. Wisner, M.D.; Decision and Order

On March 1, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Gary R. Wisner, M.D. (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 3. The OSC proposed the revocation of Registrant's Certificates of Registration (COR) Nos. FW8432471 and AW2971073 at the registered addresses of 621 S. Ham Ln., Ste. A, Lodi, California 95242, and 16246 N. Locust Tree Road, Lodi, California 95240, respectively. *Id.* at 1. The OSC alleged that Registrant's registrations should be revoked because Registrant was ''without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of California, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing, *inter alia,* 21 U.S.C. 824(a)(3); 21 CFR 1301.37(b)).

The OSC notified Registrant of his right to file with DEA a written request for hearing, and that if he failed to file such a request, he would be deemed to be in default. *Id.* at 2 (citing 21 CFR 1301.43(c)(1)). Here, Registrant did not request a hearing. RFAA, at 1.[1] ''A default, unless excused, shall be deemed to constitute a waiver of the [registrant's] right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . 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). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 1.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, ''[e]ffective January 30, 2023, as part of an agreement with the [Medical Board of California] . . . [Registrant] surrendered [his] license to practice medicine in the State of California.'' RFAAX 1, at 1–2.

According to California's online records, of which the Agency takes official notice, the status of Registrant's physician and surgeon license (type A) is listed as surrendered, and he is not permitted to practice.[2] California

[1] Based on the Government's submissions in its RFAA dated August 3, 2023, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the included declaration by a DEA Diversion Investigator (DI) indicates that on March 13, 2023, the DI personally ''served [Respondent] a copy of the [OSC] by hand delivery.'' RFAAX 2, at 1.

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a