corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.46.

Findings of Fact

REGISTRANT'S DEA REGISTRATION

Registrant is the holder of DEA Certificate of Registration No. AL1804409 at the registered address of 2392 N. Euclid Ave, Upland, CA 91784. RFAAX 1 (Registrant's DEA Certificate of Registration). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration will expire on its own terms on March 31, 2022. *Id.*

THE STATUS OF REGISTRANT'S STATE LICENSE

On March 5, 2019, Registrant and the Medical Board of California entered into a Stipulated Surrender of License and Order, whereby Registrant surrendered his California medical license. RFAAX 3. The Medical Board of California's online records, of which I take official notice, document that Registrant's license is still surrendered. [1] Medical Board of California License Verification, *https://www.mbc.ca.gov/Breeze/License_Verification.aspx* (last visited date of signature of this Order).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in California, the state in which Registrant is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

According to California statute, ''[n]o person other than a physician . . . shall write or issue a prescription.'' Cal. Health & Safety Code § 11150 (West 2020). Further, ''physician,'' as defined by California statute, is a person who is ''licensed to practice'' in California. *Id.* at § 11024.

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. AL1804409 issued to King Wong, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of King Wong, M.D. to renew or modify this registration. This Order is effective January 11, 2021.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–27232 Filed 12–10–20; 8:45 am]

BILLING CODE 4410–09–P

[1] 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 party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (*dea.addo.attorneys@dea.usdoj.gov*).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Zeljko Stjepanovic, M.D.; Decision and Order

On May 1, 2018, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration to Zeljko Stjepanovic, M.D. (hereinafter, Registrant). Government's Request for Final Agency Action Exhibit (hereinafter, RFAAX) 3, at 1 (Order to Show Cause and Immediate Suspension Order (hereinafter, collectively OSC)). The OSC informed Registrant of the immediate suspension of his DEA Certificate of Registration FS3042885 pursuant to 21 U.S.C. 824(d), ''because [his] continued registration constitutes an imminent danger to public health and safety.'' *Id.*

The substantive ground for the proceeding, as alleged in the OSC, is that Registrant's ''continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.* Specifically, the OSC alleges that on August 31, 2017, January 19, 2018, February 16, 2018, and March 15, 2018, Registrant unlawfully prescribed controlled substances in violation of 21 U.S.C. 841(a) and 842(a). The OSC further alleges that on those dates, Registrant prescribed controlled substances to individuals that he ''knew were not for a legitimate medical purpose and were not in the usual course of [his] professional practice,'' because he issued them ''without establishing bona fide practitioner-

patient relationships'' and ''issued prescriptions in the name of one patient for use by another patient, despite acknowledging the illegality of this behavior, in violation of federal and state law.'' *Id.* at 2 (citing 21 CFR 1306.04(a); Va. Code Ann. §§ 54.1–3303.A, 54.1–2915.A(3), (8), (13), (16), (17), and 18.2.248).

In issuing the OSC, which immediately suspended the registration, the former Acting Administrator concluded that Registrant's ''continued registration is inconsistent with the public interest'' based on a preliminary finding that Registrant ''issued prescriptions for controlled substances that [Registrant] knew were illegal, without a legitimate medical purpose and outside the usual course of professional practice'' and that were ''indicative of [Registrant's] general illegitimate practice of prescribing controlled substances in violation of State and Federal laws.'' *Id.* at 7. Citing 21 U.S.C. 824(d), he also made the preliminary finding that Registrant's ''continued registration during the pendency of the proceedings would constitute an imminent danger to the public health or safety because of the substantial likelihood that [Registrant] will continue to unlawfully prescribe controlled substances, thereby allowing the diversion of controlled substances unless [Registrant's] DEA COR is suspended.'' *Id.* The former Acting Administrator authorized the DEA Special Agents and Diversion Investigators serving the OSC on Registrant to place under seal or remove for safekeeping all controlled substances Registrant possessed pursuant to the immediately suspended registration. *Id.* (citing 21 U.S.C. 824(f) and 21 CFR 1301.36(f)). The former Acting Administrator also directed those DEA employees to take possession of Registrant's Certificate of Registration FS3042886 and any unused prescription forms. *Id.* at 8.

According to the Declaration of a DEA Diversion Investigator (hereinafter, DI) from the Richmond District Office, the DI personally served the OSC on Registrant on May 4, 2018, at his registered address. RFAAX 5, at 2. Based on the DI's Declaration, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on May 4, 2018. The OSC notified Registrant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. OSC at 7–8 (citing 21 CFR 1301.43(c)).

On July 25, 2018, the Government forwarded a Request for Final Agency Action (hereinafter, RFAA), along with the evidentiary record for this matter, to my office, and asserted that the Government had not received a request for a hearing. RFAA, at 2. I find that more than thirty days have now passed since the Government accomplished service of the OSC. I further find, based on the Government's written representations, that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, or submitted a written statement while waiving Registrant's right to a hearing. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement. 21 CFR 1301.43(d). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Registrant committed acts rendering his continued registration inconsistent with the public interest. I also find that Registrant has submitted no evidence that he accepts responsibility for his failures to meet the responsibilities of a registrant nor presented any evidence of mitigation or remedial measures. Accordingly, I conclude that the appropriate sanctions are (1) for Registrant's DEA registration to be revoked; and (2) for any pending application by Registrant to be denied.

Based on the representations of the Government in its RFAA, I make the following findings of fact.

I. Findings of Fact

A. Registrant's DEA Registration

Registrant is registered with DEA as a practitioner in schedules II through V under DEA Certificate of Registration No. FS3042885, at the registered address of 2004 Bremo Rd, Suite 200, Richmond, VA 23226. RFAAX 1. This registration expires on February 28, 2021. *Id.* The registration was suspended pursuant to the Immediate Suspension Order dated May 1, 2018. OSC, at 7.

B. The Investigation of Registrant

In 2017, the Richmond District Office (hereinafter, RDO) of the DEA Washington Field Office began an investigation of Registrant that included the use of undercover investigators. RFAAX 5, at 1–2. Two RDO Task Force Officers (hereinafter, TFO One and TFO Two) were assigned to investigate Registrant. *Id.* at 2. According to the Government, TFO One first visited Registrant posing as a patient on August 31, 2017, while Registrant was working for a practice located in Fredericksburg, VA. RFAAX 6 (Declaration of TFO One), at 1. TFO Two next went undercover to visit Registrant with TFO One on January 19, 2018 and February 16, 2018 in Registrant's Richmond Office. *Id.* at 2. Finally, TFO Two went undercover to visit Registrant by herself on March 15, 2018. RFAAX 7 (Declaration of TFO 2), at 2.

The Government submitted declarations from TFO One and TFO Two, which summarize the events of the undercover visits to Registrant. *See* RFAAX 6 and 7. The Government also submitted copies of controlled substance prescriptions written by Registrant to the aliases used by TFO One and TFO Two that support their accounting of their visits with Registrant, RFAAX 4 (Copies of prescriptions), and a partial transcript of a recording of the February 16 undercover visit.[1] RFAAX 2 (Transcript of February 16, 2018 undercover visit with Registrant).

1. August 31, 2017 Undercover Visit

TFO One first visited Registrant posing as a patient on August 31, 2017. RFAAX 6, at 1. At the time, Registrant was working for a practice located in Fredericksburg, VA. *Id.* During the August 31 visit, Registrant provided TFO One with a prescription for Tramadol (50 mg, QTY 84).[2] RFAAX 4 (copy of prescription); RFAAX 6, at 2.

TFO One said that she ''specifically asked for Tramadol by name because it made [her] feel good.'' RFAAX 6, at 2. When Registrant checked the Virginia Prescription Monitoring Program and discovered that TFO One did not have a previous prescription for Tramadol, TFO One told Registrant that she ''had previously been using [her] ex-boyfriend's Tramadol prescription.'' *Id.* According to TFO One, Registrant did

[1] The DI assigned to Registrant's case declared that TFO One and TFO Two recorded all of their visits with Registrant. RFAAX 5, at 2. The Government, however, has only provided a partial transcript from the recording of one of those visits. *See* RFAAX 2 (Transcript of February 16, 2018 undercover visit with Registrant). Exhibit Two to the Government's RFAA is three pages of a twenty-four page transcript of the recording of the February 16, 2018 visit. *Id.* The Government has provided no explanation for only including certain pages from the February 16, 2018 visit transcript and for not including any of the recordings or transcripts of the recordings from the other three visits. Although I do not have the recordings for the majority of the undercover visits in the evidence before me, there is no evidence in the record that contradicts the Government's presentation of the facts in this matter.

[2] Tramadol is a schedule IV controlled substance. 21 CFR 1308.14(b).

not conduct a physical exam, use diagnostic tools, or complete a urinalysis during the August 31 visit. *Id.* TFO One also declared that she did not provide any medical records from a previous medical provider. *Id.*

2. January 19, 2018 Undercover Visit

On January 19, 2018, TFO One visited Registrant again in an undercover capacity at Registrant's office in Richmond, Virginia. RFAAX 6, at 2. TFO One was accompanied on this visit by TFO Two, acting in an undercover capacity.[3] *Id.* Registrant saw TFO One and Two together, in the same room, during the visit. *Id.*

During the January 19 visit, TFO One asked Registrant for another prescription for Tramadol. *Id.* According to the declaration of TFO One, Registrant replied that he ''could not write [TFO One] [her] own prescription due to [her] status as a former Fredericksburg patient.'' *Id.* Instead, according to TFOs One and Two, Registrant issued TFO Two a double dose of oxycodone so TFO One and TFO Two ''could share a prescription until [their] next office visit to [Registrant].'' RFAAX 6, at 2; RFAAX 7, at 2. A copy of the prescription from the January 19 visit shows that Registrant wrote TFO Two (in the name of her alias) a prescription for oxycodone (10mg, QTY 90).[4] RFAAX 4.

3. February 16, 2018 Undercover Visit

TFO One and TFO Two visited Registrant in an undercover capacity together for a second time on February 16, 2018.[5] RFAAX 6, at 2. Registrant saw TFO One first, by herself, in Registrant's office. *Id.* TFO One stated that the office was not an examination room—that it contained a desk, computer, and chairs but no examination bed or medical equipment. *Id.* Registrant again stated that he could not write TFO One a prescription due to her status as a former Fredericksburg patient and offered to write TFO One a Tramadol prescription in TFO Two's name. *Id.; see also* RFAAX 2 (Excerpts from transcript of February 16 visit), at 2. The transcript of the recording made of the visit demonstrates that Registrant said, ''What I was thinking in the beginning according [sic], that you are so nice, and I know that it is illegal, but I technically can write down those medications on her name.'' RFAAX 2, at 2.

TFO Two was then summoned into Registrant's office with Registrant and TFO One. RFAAX 6, at 2. Registrant told TFO Two that he had been discussing with TFO One writing a Tramadol prescription for TFO One in TFO Two's name. RFAAX 7, at 2. Registrant sought to confirm that TFO Two was comfortable with having the Tramadol prescription for TFO One written in TFO Two's name. *Id.;* RFAAX 2, at 3. After TFO Two said that it was fine, Registrant told TFO Two what to say if a pharmacist questioned her on why a doctor was prescribing two short acting drugs. RFAAX 2, at 3. According to the transcript, Registrant then asked, ''Is that Okay? I'm sorry is illegal, but you know.'' *Id.*

Registrant issued two prescriptions to TFO Two, one for oxycodone (10mg, QTY 90) and one for Tramadol (50mg, QTY 90). RFAAX 6, at 2; RFAAX 7, at 2; RFAAX 4. Registrant then advised TFO Two that she should fill the prescriptions at the same pharmacy as the January 19, 2018 prescription to avoid any scrutiny. RFAAX 6, at 2; RFAAX 7, at 2; RFAAX 4. He said ''just don't change, because they're looking if you're changing doctors or changing pharmacies . . . .'' RFAAX 2, at 4. According to TFO Two, Registrant did not perform any type of physical exam on her during the February 16 visit. RFAAX 7, at 2.

4. March 15, 2018 Undercover Visit

TFO Two visited Registrant by herself on March 15, 2018, and met with Registrant in his office. RFAAX 7, at 2. According to TFO Two, Registrant asked ''if I wanted him to 'do the same stuff'' and ''if I wanted him to issue another Tramadol prescription for TFO [One] in [TFO Two's] name.'' *Id.* Registrant then asked if she had any problems with the pharmacy filling the previous prescriptions for oxycodone and Tramadol. *Id.* When TFO Two told him there were no problems, Registrant ''again advised [her] that to avoid scrutiny of the illegal prescriptions he was writing, [she] should not change providers or pharmacies.'' *Id.*

Registrant wrote TFO Two a prescription for oxycodone (10mg, QTY 90) and a prescription for Tramadol (50mg, QTY 90). *Id.;* RFAAX 4. TFO Two declared that during the visit Registrant ''asked generally, how [she] was feeling but did not perform any physical examination.'' RFAAX 7, at 2.

In summary, based on the substantial evidence in the record, I find that Registrant issued a total of six prescriptions for controlled substances to TFO One and TFO Two without performing a physical examination of either undercover officer. I also find that Registrant wrote two controlled substance prescriptions for TFO One in TFO Two's name even though he verbally stated that doing so was illegal.

II. Discussion

Under the Controlled Substances Act (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 under 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 ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

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

(2) The [registrant]'s experience in dispensing . . . controlled substances.

(3) The [registrant]'s conviction record under Federal or State laws relating to the . . . distribution[ ] or dispensing of controlled substances.

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

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f). These factors are considered separately. *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharm., 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.

[3] TFO One declared that this visit occurred on January 19, 2018, while TFO Two declared that this visit occurred on January 18, 2018. RFAAX 7, at 2. I find that the one-day discrepancy between the two accounts of the date of this visit does not detract from TFO Two's credibility, given the other supporting evidence for this visit, and is ultimately irrelevant in this matter. The Government presents the visit as having occurred on January 19, 2018, and a prescription Registrant issued during the visit supports a finding of that date; therefore, I am concluding that the visit occurred on that January 19, 2018.

[4] Oxycodone is a schedule II controlled substance. 21 CFR 1308.12(1).

[5] In their declarations, TFO One and TFO Two state that this visit occurred on February 26, 2018. RFAA 6, at 2; RFAAX 7, at 2. The Government stated in the RFAA that the date in the declarations was a typo and should read February 16, 2018. RFAA, at 4. The transcript of the recording of the interview states that the recording was made on February 16, 2018. RFAAX 2. I find that the date in the declarations was a typo and that the visit occurred on February 16, 2018. I find that this date discrepancy was a scrivener's error and does not detract from the overall credibility of the Government's evidence.

2016)); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *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 I am required to consider each of the factors, I ''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, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

The Government has the burden of proving that the requirements for revocation of a DEA registration in 21 U.S.C. 824(a) are satisfied. 21 CFR 1301.44(e). When the Government has met its *prima facie* case, the burden then shifts to the registrant to show that revoking the registration would not be appropriate, given the totality of the facts and circumstances on the record. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

In this matter, while I have considered all of the Factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four.[6] I find the Government has satisfied its *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

A. Factors Two and/or Four—The Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

The Government alleges that on August 31, 2017, January 19, 2018, February 16, 2018, and March 15, 2018, Registrant prescribed controlled substances to undercover officers posing as patients without establishing a bona fide practitioner-patient relationship, without a legitimate medical purpose, and outside the usual course of his professional practice in violation of 21 CFR 1306.04(a) and Va. Code Ann. § 54.1–3303.A. RFAA, at 8; OSC, at 2. The Government further alleges that Registrant's actions violated 21 U.S.C. 841(a), which states, in relevant part, that it is unlawful for any person to knowingly or intentionally dispense a controlled substance except as authorized by the CSA. OSC, at 2.

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). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.* The Supreme Court has stated that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

DEA has consistently stated that a practitioner must establish and maintain a bona fide doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Ralph J. Chambers,* 79 FR 4962, 4970 (2014) (citing *Paul H. Volkman,* 73 FR 30,629, 30,642 (2008), *pet. for rev. denied Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 223–24 (6th Cir. 2009)); *see also U.S.* v. *Moore,* 423 U.S. 122, 142–43 (1975) (noting that evidence established that the physician exceeded the bounds of professional practice, when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against . . . misuse and diversion''). In recognition of the State's primary role in regulating the practice of medicine, the CSA generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. *Mackay,* 75 FR at 49,973; *Volkman,* 73 FR at 30,642.

The law of the Commonwealth of Virginia, the state in which Registrant is registered with DEA, to which the Government cited in the OSC, echoes the CSA requirement that a practitioner may only issue a prescription to a person with whom the practitioner has ''a bona fide practitioner-patient relationship.'' Va. Code Ann. § 54.1–3303A (West 2018).[7] At the time of the events at issue here, Virginia law defined a bona fide practitioner-patient relationship as ''one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice.'' *Id.* The Virginia law further states that

> A bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects.

Id.

The Government typically establishes that a practitioner issued prescriptions without a legitimate medical purpose or outside the usual course of professional practice in violation of 21 CFR 1306.04(a) through, or with the support of, expert testimony. However, DEA decisions have found that the nature of the allegations and the evidence on the record can establish violations of Section 1306.04(a) without necessitating

[6] As to Factor One, the Government alleged that Registrant holds a valid state medical license, and there is no evidence in the record of any recommendation from Registrant's ''State licensing board or professional disciplinary authority.'' *See* OSC, at 2. State authority to practice medicine is ''a necessary, but not a sufficient condition for registration . . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15,230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19,434, 19,444 (2011).

As to Factor Three, there is no evidence in the record that Registrant has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49,956, 49,973 (2010), *pet. for rev. denied, MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808 (10th Cir. 2011). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[7] Virginia amended this portion of the code in 2018 and 2020. This Decision cites to the law that was in effect during the time when Registrant issued the subject prescriptions to the undercover officers and when the OSC was issued.

the support of expert opinion.[8] *Lawrence E. Stewart, M.D.,* 81 FR 54,822, 54,839 (2016). DEA has not required expert testimony to establish a violation of 21 CFR 1306.04(a) in past matters under factual circumstances that include: Where a prescriber engaged in drug deals; where a prescriber did not conduct a physical exam of the patient as required by law; where a controlled substance prescription was based on a patient's request rather than the result of the application of the physician's medical judgment; and where a prescriber falsified patients' charts. *See e.g., Stewart,* 81 FR at 54,839–41 (finding, without expert testimony, that prescriptions were issued outside the usual course of professional practice, where the physician failed to perform and document a physical exam, and lacked a legitimate medical purpose, where a physician prescribed controlled substances based on a patient's request); *Morris W. Cochran, M.D.,* 77 FR 17,505, 17,519–20 (2011) (finding, without expert testimony, that prescriptions lacked a legitimate medical purpose, where a physician noted in patient medical records that patients had no pain, did not document any findings to support a diagnosis, and yet diagnosed patients as having chronic pain); *Robert F. Hunt, D.O.,* 75 FR 49,995, 50,003 (2010) (finding, without expert testimony, that a physician lacked a legitimate medical purpose based on statements made during undercover visits and falsification of patient chart). *See also T.J. McNichol, M.D.,* 77 FR 57,133, 57,147–48 (2012), *pet. for rev. denied,* 537 Fed. Appx. 905 (11th Cir. 2013).

I find that, with respect to the prescriptions Registrant issued to the undercover officers, expert testimony is not necessary to prove that Registrant lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing them. Virginia law clearly states that to establish a practitioner-patient relationship, the practitioner must ''perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically.'' Va. Code Ann. § 54.1–3303A(iii). The uncontested evidence in this matter shows that Registrant issued prescriptions for controlled substances to TFOs One and Two without performing any physical examination or using any diagnostic tools. By issuing prescriptions to TFOs One and Two without first establishing a bona fide practitioner-patient relationship, Registrant violated Va. Code Ann. § 54.1–3303A and thus acted outside the usual course of his professional practice.

I also find that Registrant did not issue the prescriptions to the undercover officers for legitimate medical purposes. First, there is substantial evidence that Registrant knew that TFO One was not seeking treatment for a legitimate medical condition but was either engaged in self-abuse or diversion. During her first visit with Registrant on August 31, 2017, TFO One asked Registrant for a prescription for Tramadol ''because it made [her] feel good'' and told Respondent that she had been taking Tramadol that was not prescribed to her. Previous DEA decisions have found, without the support of expert testimony, that controlled substance prescriptions did not have a legitimate medical purpose when practitioners prescribed them based on a patient request rather than for the treatment of a legitimate medical condition. *See Stewart,* 81 FR at 54,841; *Henri Wetselaar M.D.,* 77 FR 57,126, 57,132 (2012).

Second, Registrant's statements to TFOs One and Two during the course of their visits make clear that Registrant was prescribing controlled substances to TFO Two to intentionally divert drugs to TFO One. On their first visit together to Registrant on January 19, 2018, Registrant told the undercover officers that he was prescribing TFO Two a double dose of oxycodone, so that they ''could share a prescription until [their] next office visit to [Registrant].'' RFAAX 6, at 2; RFAAX 7, at 2. Then, during the undercover officers' second visit together to Registrant on February 16, 2018, Registrant told the undercover officers that he would write a prescription for Tramadol in TFO Two's name for TFO Two to give to TFO One. RFAAX 2 at 2; see also RFAAX 4 (prescription for Tramadol in TFO Two's name). When TFO Two visited Registrant by herself on March 15, 2018, Registrant again issued TFO Two a prescription for Tramadol so that she could give the drugs to TFO One. RFAAX 7, at 2. Registrant's actions ''completely betrayed any semblance of legitimate medical treatment.'' *Jack A. Danton, D.O,* 76 FR 60,900, 60,904 (quoting *United States* v. *Feingold,* 454 F.3d 1001, 1010 (9th Cir. 2006)). Therefore, the evidence clearly supports a finding that Registrant issued the prescriptions without a legitimate medical purpose and outside the usual course of his professional practice in violation of 21 CFR 1306.04(a).

Finally, despite Registrant's failure to take his responsibilities as a registrant seriously, he did understand the potential legal consequences for his action and undoubtedly knew his actions were wrong. Registrant repeatedly stated that the prescriptions he wrote for TFO Two to give to TFO One were ''illegal.'' [9] RFAAX 2, at 2–3. He also gave the undercover officers instructions on how to evade scrutiny when filling the prescriptions. RFAAX 2, at 3; RFAAX 7, at 2. This evidence supports the conclusion that Registrant knowingly engaged in an outright drug deal in violation of 21 U.S.C. 841(a).

In summary, I find that Registrant committed flagrant violations of 21 CFR 1306.04(a); violated state law, Va. Code Ann. § 54.1–3303.A; [10] and displayed an appalling disregard of a registrant's duty under the CSA to prescribe controlled substances based on a legitimate doctor-patient relationship.

B. Registrant's Registration Is Inconsistent With the Public Interest and Presented an Imminent Danger

Violations of the prescription requirement strike at the core of the CSA's purpose of preventing the diversion of controlled substances. *See United States* v. *Moore,* 423 U.S. 122, 135 (1975) (''Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. It was aware that registrants,

[8] Numerous federal courts have found in criminal cases, which require a higher standard of proof than is required in these proceedings, that expert testimony is not required to establish a violation of 21 U.S.C. 841 or 21 CFR 1306.04(a) based on the particular facts of the case. *See, e.g., United States* v. *Pellman,* 668 F.3d 918, 924 (7th Cir. 2012) (holding that even without expert testimony there was ''ample evidence'' for a reasonable jury to determine the physician-defendant acted outside the usual course of his professional practice and not for a legitimate purpose); *U.S.* v. *Armstrong,* 550 F.3d 382, 389 (5th Cir. 2008), *overruled on other grounds by United States* v. *Balleza,* 613 F.3d 382 (5th Cir. 2010) (''While expert testimony may be both permissible and useful, a jury can reasonably find that a doctor prescribed controlled substances not in the usual course of professional practice or for other than a legitimate medical purpose from adequate lay witness evidence surrounding the facts and circumstances of the prescriptions.''); *U.S.* v. *Word,* 806 F.2d 658 663–64 (6th Cir. 1986).

[9] In the transcript of recording from the February 16, 2018 visit, regarding prescribing in TFO Two's name for TFO One, Registrant stated, ''I know that is illegal, but I technically can write down those medications on her name,'' and ''Is that Okay? I'm sorry is illegal, but you know.'' RFAAX 2, at 2–3.

[10] The Government also alleged that Registrant's actions violated Va. Code Ann. § 54.1–2915.A(3), (8), (13), (16), and (17), which provide grounds for which the Virginia Medical Board may refuse to issue, suspend, or revoke a medical license. While I find that these provisions buttress the Government's argument that Registrant was acting outside the usual course of his professional practice, I do not find that they establish independent violations of state law and, as such, I am not including them in my findings herein.

who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.''). The Agency has previously found that proof of a single act of intentional or knowing diversion is sufficient to satisfy the Government's *prima facie* burden of showing that a practitioner's continued registration is inconsistent with the public interest. *McNichol,* 77 FR at 57,145–46 (2012); *see also, Alan H. Olefsky,* 57 FR 928, 928–29 (1992) (revoking registration based on physician's presentation of two fraudulent prescriptions to pharmacist in single act where physician failed to acknowledge his misconduct). Accordingly, I find that the evidence in this matter establishes Registrant ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' *See* 21 U.S.C. 824(a)(4).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Registrant ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant'' under the CSA. 21 U.S.C. 824(d)(2). The substantial evidence that Registrant was issuing prescriptions for controlled substances without a legitimate medical purpose and outside the usual course of professional practice also establishes that there was ''a substantial likelihood [that an] . . . abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension'' of Registrant's registration. *Id.* As I found above, the recording of the February 16, 2018 visit between Registrant and the undercover officers and the undercover officers' accountings of their other visits establish that Registrant unlawfully prescribed controlled substances to the officers without conducting physical examinations and wrote controlled substance prescriptions in TFO Two's name for her to give to TFO One. Thus, at the time the Government issued the OSC, the Government had clear evidence of Registrant's violations of law.

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that a Registrant's continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases). Registrant did not present any evidence of remorse for his past misconduct or evidence of rehabilitative actions taken to correct his past unlawful behavior. Further, he provided no assurances that he would not engage in such conduct in the future. Absent such evidence and such assurances in this matter, I find that continued registration of Registrant is inconsistent with the public interest. Registrant's silence weighs against his continued registration. *Zvi H. Perper, M.D.,* 77 FR 64,131, 64,142 (2012 (citing *Med. Shoppe-Jonesborough,* 73 FR at 387); *see also Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007). Accordingly, I find that the factors weigh in favor of sanction, and I shall order the sanctions the Government requested, as contained in the Order below.

IV. Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration FS3042885 issued to Zelijko Stjepanovic, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Zelijko Stjepanovic, M.D. to renew or modify this registration. This Order is effective January 11, 2021.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Anindita Nandi, M.D.; Decision and Order

On January 31, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Anindita Nandi, M.D. (hereinafter, Registrant) of Jersey City, New Jersey. OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. FN5040136. *Id.* It alleged that Registrant has ''no state authority to handle controlled substances.'' *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that, ''[o]n September 25, 2018, the New Jersey State Board of Medical Examiners (hereinafter, BME) issued an Order of Temporary Suspension of License, suspending . . . [Registrant's] license to practice medicine and surgery in the State of New Jersey, effective September 12, 2018.'' OSC, at 2. The OSC further alleged that Registrant's ''State of New Jersey C[ontrolled] D[angerous] S[ubstance] (hereinafter, CDS) license is in an 'Inactive' status, having expired on October 31, 2018.'' *Id.* The OSC concluded that ''[c]onsequently, the DEA must revoke . . . [her] DEA registration based on . . . [her] lack of authority to handle controlled substances in the State of New Jersey.'' *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a sworn Declaration, dated May 21, 2020, a DEA Diversion Investigator assigned to the Newark Division Office (hereinafter, DI) stated that he attempted personal service of the OSC on Registrant at the Hudson County Correctional Facility. Request for Final Agency Action (hereinafter, RFAA), EX 5 (DI Declaration), at 1. Registrant, however, refused to meet with DI. *Id.*

DI, therefore, sent the OSC to Registrant certified mail, return receipt requested. *Id.* He attached the executed return receipt card, dated February 26, to his Declaration. *Id.* at Attachment C. Further evidence of the adequacy of the Government's service is Registrant's proposed Corrective Action Plan (hereinafter, CAP) and waiver of hearing dated March 4, 2020. RFAA EX 6 (CAP), at 1. Accordingly, I find that the Government's service of the OSC was adequate.

Registrant's Proposed CAP

As already discussed, Registrant timely submitted a proposed CAP and waiver of hearing. *Id.* In her CAP, Registrant asked that this proceeding be discontinued or postponed. *Id.* She alleged that she received notification of the reactivation of her medical license in July 2019. *Id.* at 2. Further, she alleged that she timely renewed her ''second State of NJ CDS Account.'' *Id.*

I find that Registrant waived her right to a hearing and proposed a CAP. I find that the Assistant Administrator, Diversion Control Division, denied Registrant's CAP request that the administrative proceeding be discontinued or deferred. RFAA EX 7 (Letter Denying Proposed CAP), at 1. I also find that the Assistant Administrator concluded that ''there is no potential modification of . . . [her proposedCAP] that could or would alter