



UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jose Raul S. Villavicencio, M.D.

Decision and Order

On June 24, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Jose Raul S. Villavicencio, M.D. (hereinafter, Registrant), of Parkersburg, West Virginia. GX 1. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration and denial of any applications for renewal or modification of the registration, and any applications for any other DEA registration, on the ground that his continued "registration would be inconsistent with the public interest." Id. at 1 (citing 21 U.S.C. 823(f) and 824(a)(4)).

The Show Cause Order alleged that Registrant is registered as a practitioner in Schedules II through V, pursuant to DEA registration number BV3249643, at the location of 1909 Dudley Avenue, Parkersburg, West Virginia, and that his registration does not expire until May 31, 2016. Id. The Show Cause Order alleged that Registrant had previously been registered at 1761 High Street, Columbus, Ohio, and that on September 27, 2012, the Agency had approved his request for a change from his previous registered address. Id. The Show Cause Order also alleged that Registrant's DEA registration authorizes him to dispense schedule III drugs to patients for maintenance or detoxification treatment, and that since July 12, 2007, Registrant has been authorized to treat up to one hundred patients, pursuant to 21 U.S.C. 823(g)(2)(A) and (2)(b)(iii). Id.

The Show Cause Order then alleged that on September 12, 2012, the State Medical Board of Ohio permanently revoked Registrant's medical license following a hearing. Id. The Show

Cause Order alleged that the Ohio Board's Order was based on his failure to comply with applicable state law pertaining to the prescribing of schedule II through IV controlled substances for chronic pain, and that upon its review of sixteen (16) patient files, the Board found that he "failed to maintain minimal standards applicable to the administration or selection of drugs" for fourteen (14) of the patients, and that his "care of all [sixteen (16)] patients was 'a departure from, or the failure to conform to, minimal standards of care of similar practitioners,' in violation" of Ohio Revised Code Sections 4731.22(B)(2) and 4731.22 (B)(6). Id. at 1-2. The Show Cause Order then alleged that the Ohio Board's findings with respect to the sixteen patients establish that Registrant prescribed controlled substances without a legitimate medical purpose and outside of the usual course of professional practice in violation of 21 CFR 1306.04(a). Id. at 2.

Next, the Show Cause Order alleged that a review of data obtained from the Ohio Automated Rx Reporting System (OARRS), the state database to which all Ohio pharmacies are required to report their dispensings of controlled substances, showed that on at least five separate occasions between September 1, 2010 and March 1, 2012, Registrant was treating over 100 patients with Suboxone or Subutex prescriptions at a time. Id. The Show Cause Order thus alleged that Registrant violated 21 U.S.C. 823(g)(2)(B)(iii) and 21 CFR 1301.28(f). Id.

The Show Cause Order further alleged that on March 9, 2013, DEA served an administrative inspection warrant at Registrant's registered location seeking to inspect all of his controlled substance records pertaining to his prescribing of Subutex and Suboxone for maintenance or detoxification treatment. Id. The Show Cause Order alleged that Investigators found that Registrant committed numerous violations of two DEA regulations, 21 CFR 1304.03(c) and 1306.05(a), including that: 1) on 116 occasions, he "failed to record dosage units

prescribed”; 2) on five occasions, he “failed to record the date on which the prescriptions were signed”; 3) on three occasions, he “failed to record the drug name”; and 4) on sixteen occasions, he “failed to record any prescription information.” Id. (citing 21 CFR 1304.03(c) and 1306.05(a)). The Order also alleged that Registrant issued eleven Subutex or Suboxone prescriptions to patients from a location at which he was not registered. Id. (citing 21 U.S.C. 822(e)). Id. at 2.

Finally, the Show Cause Order also alleged that Registrant had not been candid in providing material information in violation of 21 U.S.C. 823(f)(5). Specifically, the Order alleged that: 1) the Ohio Board found that he “provided questionable, self-serving testimony during the hearing” in three respects; 2) that on an application to a drug distributor, he had falsely stated that his medical license or registration had never been subject to “sanction or disciplinary action”; 3) and that during an inspection by an Investigator for the West Virginia Board of Medicine, Registrant had stated that he had not ordered any drugs for dispensing when he had done so two days earlier.

Finally, the Show Cause Order notified Registrant of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for doing either, and the consequence for failing to do either. Id. at 3-4 (citing 21 CFR 1301.43).

On July 8, 2013, a Diversion Investigator (DI) served the Show Cause Order on Registrant by electronic mail to the email address he had provided to the Agency on his registration application. GX 4, at 1 (Declaration of Diversion Investigator). The DI received an electronic response stating that the email had been delivered on the same date. Id. Also, the DI faxed a copy of the Order to Show Cause to the facsimile number provided by Registrant on his registration application. Id. The DI then called the telephone number listed on Registrant’s

application and confirmed that Registrant had received the Order. Id. at 1-2. The DI also informed Registrant that a hearing request form had been included in both transmissions and that he had thirty days in which to request a hearing. Id. at 2. According to the DI, “Registrant responded that he understood.” Id.

Since the date of service of the Show Cause Order, more than thirty days have now passed and neither Registrant, nor anyone purporting to represent him, has requested a hearing or submitted a written statement in lieu of a hearing. I therefore find that Registrant has waived his right to a hearing or to submit a written statement in lieu of hearing, and issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings of fact.

FINDINGS

Registrant is registered as a practitioner in Schedules II through V pursuant to DEA registration number BV3249643, at the registered address of 1909 Dudley Avenue, Parkersburg, West Virginia. GX 2. Registrant is also authorized to dispense Schedule III drugs, as a DATA-waived practitioner, to up to 100 patients for maintenance or detoxification treatment pursuant to 21 U.S.C. 823(g)(2)(A) and (2)(b)(iii). Id. Registrant’s previous registered address was 1761 High Street, Columbus, Ohio. Id. at 3.

However, by letter dated September 26, 2012, Registrant requested that his registered location be changed from his Ohio office to a location at 1900 Dudley Ave., Parkersburg, West Virginia. GX 7. In the letter, Registrant explained that his West Virginia medical license was active and that “I lost my Ohio license recently over alleged improper prescribing in 2005.” Id. Nonetheless, the following day, Registrant’s request was approved. GX 2, at 3. On May 30,

2013, Registrant submitted a timely renewal application; his registration is not due to expire until May 31, 2016. GX 2, at 1.

As noted above, Registrant previously held an Ohio Medical License. However, on April 13, 2011, the Ohio Board notified Registrant that it was proposing to take action against his license. GX 5, at 1. On May 10, 2011, Registrant requested a hearing, and on January 17-18 and 23-27, 2012, a state Hearing Examiner conducted a hearing at which both the Board and Registrant were represented by counsel.

Following the hearing, the Hearing Examiner issued a 164-page Report and Recommendation. GX 5. Therein, the Hearing Examiner found that between 2005 and 2008, Registrant “provided care and treatment for” sixteen patients and that he had “inappropriately treated and/or failed to appropriately treat and/or failed to appropriately document his treatment of these patients.” *Id.* at 142. With respect to these patients, the Hearing Examiner further found that Registrant:

- 1) “repeatedly and/or continually treated patients by excessively and/or inappropriately prescribing medications” and “continued to prescribe controlled substances without appropriately pursuing or documenting the pursuit of alternative non-narcotic therapies”;
- 2) “failed to record in the patients’ medical records the reason(s) he prescribed medication and/or the need . . . for prescribing multiple medications”;
- 3) “repeatedly and/or continually treated patients without performing and/or documenting appropriate physical examinations or evaluations, and/or without utilizing and/or documenting appropriate diagnostic testing or other methods of evaluating the patients’ health conditions, and/or without devising and/or documenting treatment plans, and/or without periodically reassessing or documenting the reassessment of the effectiveness of treatment for illnesses”;
- 4) “failed to adequately and/or appropriately diagnose and/or document an adequate or appropriate diagnosis of the patients’ medical conditions”;
- 5) “failed to document in the patient record adequate findings to support his diagnoses”;

- 6) “repeatedly and/or continually treated patients without making appropriate and/or timely referrals to specialists”; and
- 7) “failed to keep and maintain adequate records reflecting his care and treatment of the patients[,]” because “[t]he entries in the medical records frequently appeared verbatim from one office visit to the next and from one patient to another, with few or no changes.”

Id. The Hearing Examiner then set forth specific examples of each finding with respect to the sixteen patients, including the testimony and opinion of the Board’s expert witness with regard to each of the patients. Id. at 143-160.

The Hearing Examiner thus concluded, inter alia, that Registrant’s acts, conduct and/or omissions constituted: 1) the “failure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease,” as set forth in Ohio Rev. Code 4731.22(B)(2); and 2) a “departure from or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,” as set forth in Ohio Rev. Code 4731.22(B)(6). GX 5, at 160-161.

The Hearing Examiner further concluded that Registrant “provided questionable, self-serving testimony during the hearing” and specifically found that “he provided conflicting testimony” as to whether he had terminated one patient from his practice. Id. at 163. She also found “disingenuous” his “attempt to explain away his notation that [another patient] was ‘caught selling cocaine.’” Id. While the Hearing Examiner noted that Registrant had presented some “mitigating evidence,” she concluded that “[t]he evidence overwhelmingly establishes that [his] treatment of these patients place[d] them in serious danger.” Id. at 163-64. She therefore recommended that Registrant’s Ohio medical license be permanently revoked. Id. at 164.

On September 12, 2012, the Ohio Board adopted the Hearing Examiner’s Report and Recommendation and ordered that Registrant’s medical license be permanently revoked. GX 6,

at 1. The Board further ordered that the revocation be effective immediately upon the mailing of its Order. Id. Registrant appealed the decision to the Ohio Court of Common Pleas, which affirmed the Board's revocation order on July 29, 2013. GX 18, at 21.

As found above, on September 26, 2012, Registrant wrote to a Diversion Investigator in the Charleston, West Virginia office requesting that he "expedite the transfer" of his DEA registration from Ohio to West Virginia. GX 7. The next day, Registrant's request was approved. GX 2, at 3.

On March 9, 2013, a DEA DI (along with other DEA personnel), accompanied by a West Virginia Medical Board Investigator, went to Registrant's Parkersburg office where the DI served him with an Administrative Inspection Warrant. GX 8; see also GX 3, at 1. Pursuant to the warrant, the DI seized 149 patient files and miscellaneous photocopies of prescriptions, as well as related notes and claim forms. GX 3, at 3. Registrant told the DI that all records of the controlled substances he prescribed in the course of providing treatment for addiction since September 2012 were in the medical charts, but that his Suboxone records for the period prior to September 2012 were stored electronically on an off-site computer server. Id. However, when asked by the DI to access those records, Registrant was unable to do so, and as of the date of the DI's affidavit (July 14, 2014), he had not submitted any such records to the DI. Id.

The evidence submitted by the Government includes excerpts from 78 patient files which include Subutex and Suboxone prescriptions issued by Registrant between September 29, 2012 and March 9, 2013. See GXs 11-15. The evidence includes 55 patient file excerpts, which the DI stated show that for 118 prescriptions issued during this period, Registrant failed to record the quantity of the Suboxone or Subutex prescribed.¹ See GX 11. The evidence also includes

¹ Pages 1-3 of the exhibit consist of an itemized list prepared by the DI specifying each patient (by a number assigned by the DI), the date of the prescription, the drug (Subutex or Suboxone) and the specific violation

undated visit notes for seven patients, which document that Registrant prescribed Suboxone or Subutex, see GX 12, as well visit notes for two patients on which Registrant failed to record the name of the drug prescribed (Suboxone or Subutex). GX 13.

The evidence also includes patient file excerpts for five individuals, along with printouts obtained from the Ohio Automated Rx Reporting System (OARRS) and the West Virginia Controlled Substance Monitoring Program (WVCSMP). See GX 14. This evidence shows that on twenty-nine occasions, Registrant failed to record in the patients' files any information regarding the Suboxone or Subutex prescriptions he issued. Id. In one instance, the OARRS printout shows that Registrant issued twelve prescriptions for Suboxone or buprenorphine to a patient between June 8, 2012 and January 12, 2013. Id. at 1 & 9. Yet none of the prescriptions are documented in the patient's file. Id. at 1, 6-9.

The Government also submitted evidence tending to show that notwithstanding that his Ohio license had been revoked and that Registrant had changed the address of his DEA registration to Parkersburg, West Virginia, he continued to issue prescriptions from his prior DEA-registered location at the South German Village Medical Center, Columbus, Ohio. GX 15. More specifically, the evidence shows that between November 28, 2012 and March 5, 2013, Registrant issued ten prescriptions for Suboxone or Subutex which he faxed from the South German Village Medical Center. See also GX 3, at 5. Facsimile records for two additional Suboxone prescriptions purportedly issued to one individual show that they were faxed within Ohio on February 2, 2013. Id., see also GX 15, at 12.

The evidence also includes a list of patients to whom Registrant prescribed buprenorphine, along with the dates of the first and last such prescription. GX 16. According to

(generally that he "did not record dosage units"). See GX 11. However, the list contains a patient file (#59) whose file is not included in the exhibit. According to the itemized list, Patient 59's prescription for buprenorphine on January 21, 2013 did not include a recorded dosage unit. Id. at 3.

the DI, this list was compiled based on data obtained from the prescription monitoring programs of Ohio and West Virginia, and shows that “on five specific dates,” Registrant exceeded the 100-patient limit on the number of patients to whom he could prescribe Suboxone and Subutex as a DATA-Waived physician. GX 3, at 5-6; see also 21 U.S.C. 823(g)((2)(B)(iii). More specifically, the DI asserted that on September 1, 2010, Registrant “was treating 148 buprenorphine patients.” GX 3, at 6.² Consistent with the DI’s findings, Registrant testified before the Ohio Medical Board that: “[w]e also currently have 150 patients in our Suboxone program. This program has actually allowed us to return to function a fair number of nurses, businessmen, teachers, computer programmers, and homemakers.” GX 5, at 137 (citation omitted).

As found above, an Investigator from the West Virginia Board of Medicine was also present during the execution of the Administrative Inspection Warrant at Registrant’s Parkersburg office on March 9, 2013. GX 10, at 1. When the Investigator advised Registrant that she would be conducting an on-site dispensing inspection, he stated that he was not ready to dispense and that he did not have any dispensing equipment. Id. at 1. The Investigator’s report states that Registrant had applied for a Dispensing Registration from the West Virginia Board of Medicine on February 25, 2013, and had telephoned the Board again on March 6, 2013 requesting that the registration be faxed as soon as possible. Id. According to the report, Registrant told the Investigator that he had not ordered any pharmaceuticals because the “packagers Dr. Dispense and Advantage RX need a copy of my dispensing license before they will process the pharmaceuticals and provide me with the scanner, label maker, everything I need to dispense.” Id. at 1-2.

² According to the exhibit, as of January 1, 2011, Registrant was treating 158 buprenorphine patients; as of June 1, 2011, he was treating 143 buprenorphine patients; as of January 1, 2012, he was treating 118 buprenorphine patients; and as of March 1, 2012, he was treating 110 such patients. GX 16, at 7.

The evidence also includes a copy of a customer application Registrant submitted on February 20, 2013, to Smith Medical Partners, a distributor of controlled substances. GX 9, at 5-6. On the application, Registrant wrote that his business was an “addiction clinic” and that it “dispenses only schedule III drugs, Suboxone & Subutex.” Id. at 5.

On the application, Registrant was also required to answer the following question: “[h]as any sanction or disciplinary action been taken regarding any license, permit, or registration issued to the applicant, officer, owner member, partner, [or] physician . . . involving the operations or ownership of a clinic?” Id. at 6. Notwithstanding that the Ohio Medical Board had revoked his medical license five months earlier, Registrant answered “No.” Id.

Registrant was approved as a customer, and on or about March 7, 2013, ordered both buprenorphine and Suboxone from Smith, which shipped the drugs by UPS to his Parkersburg office. Id. at 4. The drugs, however, were returned to Smith by UPS after Registrant failed to pick up them up at UPS per an arrangement he had made with it. Id. at 3. During a phone call with a Smith employee, Registrant told her that because his Parkersburg office was open only “on Saturdays . . . he need[ed] to pick up his product from a UPS location.” Id.

Finally, the evidence includes a copy of a Final Order issued by the West Virginia Board of Medicine and a copy of the Hearing Examiner’s Proposed Findings of Fact, Conclusions of Law, and Recommendation. GX 17. These documents establish that on or about June 8, 2013, the West Virginia Medical Board issued a Complaint and Notice of Hearing to Registrant, which sought to revoke his medical license, and that following a hearing, the Hearing Examiner concluded that the evidence “clearly and convincingly established that [Registrant]’s practice of medicine in West Virginia renders him unqualified for continued licensure based upon his violations” of state law and that his license should be revoked. Id. at 50. _The evidence further

shows that on November 18, 2013, the Board adopted the Hearing Examiner’s report (albeit with one minor modification to a single finding of fact) and concluded that Registrant “is unfit to practice medicine and surgery in the state of West Virginia.” Id. at 2. The Board thus revoked Registrant’s medical license effective on entry of its order. Id.

DISCUSSION

The Public Interest Analysis

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to “dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a)(4). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing . . . controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, 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.

Id. § 823(f).

“These factors are . . . considered in the disjunctive.” Robert A. Leslie, M.D., 68 FR 15227, 15230 (2003). I “may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked.” Id.; see also Volkman v. DEA, 567 F.3d 215, 222 (6th Cir. 2009). While I must

consider each factor, I am “not required to make findings as to all of the factors.” Volkman, 567 F.3d at 222; see also Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

However, even where a Registrant fails to request a hearing on the allegations, the Government has the burden of proving, by substantial evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. § 824(a) are met. 21 CFR 1301.44(e).³ Having considered the Government’s evidence, I find that the Government has established that Registrant “has committed such acts” as to render his registration “inconsistent with the public interest.”⁴ 21 U.S.C. 824(a)(4).

Factors II and IV - The Applicant's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Relevant to these factors, the Government has alleged that Registrant violated federal law by: 1) issuing controlled substance prescriptions which lacked a legitimate medical purpose, 2) exceeding the 100-patient limit on his authority to treat narcotic dependent patients under the Drug Addiction Treatment Act of 2000, and 3) failing to maintain required records when he prescribed Subutex and Suboxone for maintenance and detoxification purposes. GX 1, at 1-2. As discussed below, each of these allegations is supported by substantial evidence.

The Violations of 21 CFR 1306.04(a)

³ Where the Government seeks to deny an application for a practitioner’s registration, it also has “the burden of proving that the requirements for such registration . . . are not satisfied.” 21 CFR 1301.44(d).

⁴ Regarding factor three, there is no evidence that Respondent has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. However, as there are a number of reasons why a person may never be convicted of an offense falling under this factor, let alone be prosecuted for one, “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and thus, it is not dispositive. David A. Ruben, 78 FR 38363, 38379 n. 35 (2013) (citing Dewey C. MacKay, 75 FR 49956, 49973 (2010), pet. for rev. denied MacKay v. DEA, 664 F.3d 808 (10th Cir. 2011)).

As for factor one, while there is no recommendation in the record from the West Virginia Medical Board, it is noted that the State has revoked his medical license. The consequence of the Board’s action is discussed more fully later in this Decision.

To effectuate the dual goals of conquering drug abuse and controlling both the legitimate and illegitimate traffic in controlled substances, “Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” Gonzales v. Raich, 545 U.S. 1, 13 (2005). Consistent with the maintenance of the closed regulatory system, a controlled substance may only be dispensed upon a lawful prescription issued by a practitioner. Carlos Gonzalez, M.D., 76 FR 63118, 63141 (2011).

Fundamental to the CSA’s scheme is the Agency's longstanding regulation which states that “[a] prescription for a controlled substance [is not] effective [unless it 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 relating to controlled substances.” Id.

As the Supreme Court has explained, “the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)); United States v. Alerre, 430 F.3d 681, 691 (4th Cir. 2005), cert. denied, 574 U.S. 1113 (2006) (the prescription requirement stands as a proscription against doctors acting not “as a healer[,] but as a seller of wares.”).

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act “in the usual course of . . . professional practice” and to issue a prescription for a “legitimate medical purpose.” Paul H. Volkman, 73 FR 30629, 30642 (2008), pet. for rev. denied, 567 F.3d 215, 223-24 (6th Cir. 2009); see also Moore, 423 U.S. at 142-43 (noting that evidence established that 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”). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a legitimate doctor-patient relationship. Volkman, 73 FR at 30642.

As support for this allegation, the Government submitted the decisions and orders of the Ohio and West Virginia medical boards.⁵ Under the doctrine of collateral estoppel, the Ohio Board’s findings of fact and conclusions of law are entitled to preclusive effect in this

⁵ Noting that the West Virginia Board’s Order was not issued until after the OTSC was issued, the Government asks that I take official notice of its various factual findings related to Registrant’s prescribing of Suboxone. Req. for Final Agency Action, at 16. I take official notice of the Order only to the extent it establishes that Registrant is no longer authorized to practice medicine in West Virginia, the State in which he is registered. Pursuant to 5 U.S.C. § 556(e) Registrant is entitled to show to the contrary by filing a properly supported motion for reconsideration within fifteen (15) days of the date of service of this Order which shall begin on the date of mailing.

I otherwise decline to take official notice of the findings of fact and conclusions of law set forth in the West Virginia Board’s Order. While it is true that the Order was not issued until after the Show Cause Order was issued, the West Virginia Board issued its complaint two weeks before the Show Cause Order was issued. Moreover, the Board issued its Final Order eight months before the Government filed its Request for Final Agency Action. Yet, at no point did the Government provide notice to Registrant that it was also alleging that his prescribing to the nine patients who were at issue in the West Virginia proceeding would also be at issue here. While it is true that even if he had notice, the doctrine of collateral estoppel would likely foreclose any challenge to those findings in this proceeding, I nonetheless conclude that he was entitled to notice that the Government also intended to rely on these additional allegations. Cf. Fed. R. Civ. P. r 5(a)(2) (“No service is required on a party who is in default for failing to appear. But a pleading that asserts a new claim for relief against such a party must be served on that party . . .”).

By contrast, because possessing state authority is an essential condition for maintaining a practitioner’s DEA registration, and the Agency has long held that it lacks authority to continue a practitioner’s registration where a practitioner no longer holds state authority to dispense controlled substances, the Agency has consistently taken official notice of state board decisions suspending or revoking a practitioner’s state authority notwithstanding that the state did not take action until after the issuance of a Show Cause Order. In such cases, adequate notice is provided either by the Government’s filing of a Motion for Summary Disposition (in a case where a hearing was requested) or by taking official notice and providing the applicant/registrant with the opportunity to refute the finding (when no hearing request was filed).

proceeding if Registrant had an adequate opportunity to litigate the issues in the state proceeding. See Thomas Neuschatz, 78 FR 76322, 76325 (2013) (citing Robert L. Dougherty, M.D., 76 FR 16823, 16830 (2011)); Univ. of Tenn. v. Elliot, 478 U.S. 788, 797-98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata[.]") (internal quotations and citations omitted).

Here, having reviewed the Ohio Board's decision, I conclude that Registrant had an adequate opportunity to litigate (and did litigate) the issues raised in that proceeding. Accordingly, I give preclusive effect to the Board's findings of fact and conclusions of law. See Neuschatz, 78 FR at 76325; Dougherty, 76 FR at 16830.

As found above, the Ohio Board adopted its Hearing Examiner's findings of fact that with respect to sixteen patients, Registrant:

- 1) "repeatedly and/or continually treated patients by excessively and/or inappropriately prescribing medications" and "continued to prescribe controlled substances without appropriately pursuing or documenting the pursuit of alternative non-narcotic therapies";
- 2) "failed to record in the patients' medical records the reason(s) he prescribed medication and/or the need . . . for prescribing multiple medications";
- 3) "repeatedly and/or continually treated patients without performing and/or documenting appropriate physical examinations or evaluations, and/or without utilizing and/or documenting appropriate diagnostic testing or other methods of evaluating the patients' health conditions, and/or without devising and/or documenting treatment plans, and/or without periodically reassessing or documenting the reassessment of the effectiveness of treatment for illnesses";
- 4) "failed to adequately and/or appropriately diagnose and/or document an adequate or appropriate diagnosis of the patients' medical conditions";
- 5) "failed to document in the patient record adequate findings to support his diagnoses";

- 6) “repeatedly and/or continually treated patients without making appropriate and/or timely referrals to specialists”; and
- 7) “failed to keep and maintain adequate records reflecting his care and treatment of the patients[,]” because “[t]he entries in the medical records frequently appeared verbatim from one office visit to the next and from one patient to another, with few or no changes.”

GX 5, at 142.

The Ohio Board thus found that Registrant, in treating the sixteen patients, violated Ohio law in that he failed to “maintain minimal standards applicable to the selection or administration of drugs, or . . . to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease.” *Id.* at 160 (citing Ohio Rev. Code § 4731.22(B)(2)). And the Ohio Board also found that Registrant’s acts, conduct and/or omissions constituted a “departure from or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances.” *Id.* at 161 (citing Ohio Rev. Code 4731.22(B)(6)).

It is acknowledged that the State Board did not charge, and the Board did not find, that Registrant violated the provision of the Ohio Code which most closely tracks the standard of the CSA’s prescription requirement. See Ohio Rev. Code 4731.22(b)(3) (authorizing sanction of medical license holder for “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and therapeutic purposes”). Cf. Kenneth Harold Bull, 78 FR 62666, 62674 n.9 (2013) (dictum). However, while the State Board’s legal conclusion sounds in malpractice, I nonetheless conclude that the Board’s factual findings support the conclusion that Respondent’s prescribing went well “beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence” and thus establish that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to the sixteen patients. Laurence T. McKinney, 73 FR 43260, 43266 (2008) (quoting United States v. McIver, 470 F.3d 550, 559 (4th Cir. 2006));

see also United States v. Feingold, 454 F.3d 1001, 1010 (9th Cir. 2006) (“[T]he Moore Court based its decision not merely on the fact that the doctor had committed malpractice, or even intentional malpractice, but rather on the fact that his actions completely betrayed any semblance of legitimate medical treatment.”).

Numerous decision of the courts (including the Supreme Court in Moore) and this Agency have recognized that the prescribing of a controlled substance (and the continued prescribing of a controlled substance) under the following circumstances establishes that a physician lacked a legitimate medical purpose and acted outside of the usual course of professional practice and therefore violated the CSA:

- without performing an appropriate physical examination,
- without utilizing appropriate diagnostic testing,
- failing to devise and document a written treatment plan,
- failing to periodically reassess the effectiveness of the treatment,
- continuing to prescribe controlled substances without pursuing alternative therapies,
- repeatedly and continually prescribing without referring the patient to appropriate specialists, and
- failing to keep and maintain records which contain adequate findings to support a diagnosis and the need to prescribe one or more medications.

See, e.g.; Paul H. Volkman, 73 FR 30630 (2008), pet. for rev. denied, 567 F.3d. 215 (6th Cir. 2009); see also David A. Ruben, 78 FR 38363 (2013); Henri Wetselaar, 77 FR 57126 (2012); Jack A. Danton, 76 FR 60900 (2011); George C. Aycock, 74 FR 17529, 17544 (2009).

Accordingly, I hold that the Ohio Board's findings support the Government's allegation that Respondent violated 21 CFR 1306.04(a) when he prescribed to the sixteen patients discussed in the Board's Order.

Other CSA Violations

As found above, DEA's investigation of Registrant established that he has committed numerous additional violations of the CSA related to his prescribing as a DATA-Waived practitioner. First, the evidence shows that notwithstanding that Registrant was only authorized to provide maintenance or detoxification treatment to 100 patients at a time, he was in violation of this limit on multiple dates. Indeed, in the Ohio Board proceeding, Respondent admitted that he "currently ha[d] 150 patients in our Suboxone program." GX 5, at 137. Thus, Respondent violated the conditions imposed by federal law on the prescribing of Suboxone and Subutex for maintenance or detoxification treatment. See 21 U.S.C. 823(g)(2) (A) & (B)(iii); 21 CFR 1301.28(b)(iii).

The DI also found evidence that Registrant committed numerous violations of the recordkeeping requirement applicable to the prescribing of Suboxone and Subutex in the course of maintenance or detoxification treatment. See 21 U.S.C. 827(c)(1)(a) Records and Reports of Registrants); see also 21 CFR 1304.03(c) (requiring registered practitioners to keep records of controlled substances that are prescribed in the course of maintenance or detoxification treatment).

The DI's review of OARRS and WVCSMP records found that on twenty-nine (29) occasions, Registrant failed to record any information in his patient files for prescriptions issued

for Suboxone and Subutex, in violation of 21 U.S.C. 827(a)(3) & (c)(1)(a) and 21 CFR 1304.03(a) & (c). Also, the DI's review of the patient files found that between September 9, 2012 and March 9, 2013, Registrant issued 118 prescriptions for Suboxone and Subutex, without recording the quantity prescribed in the patient's file. See 21 U.S.C. 827(a)(3) (requiring the maintenance of a complete and accurate record of each controlled substance delivered by him); 21 CFR 1304.22(c) (requiring dispenser's records to include "[t]he name of the substance," the "finished form," "the number of units or volumes of such finished form dispensed, . . . the name and address of the person to whom it was dispensed, the date of the dispensing, [and] the number of units or volume dispensed"). Cf. 21 CFR 1306.05(a) ("All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.").

In addition, the DI found that in seven instances, Registrant had issued Suboxone or Subutex prescriptions but had not documented the date of the prescription (whether in a log, on the progress note, or by making a copy of the prescription and keeping it in the patient's file), as well as that in three instances, Registrant failed to document whether he had prescribed Suboxone or Subutex.

The evidence also showed that subsequent to September 26, 2012, Registrant issued ten prescriptions for Subutex and/or Suboxone to patients, which were faxed from his office at the South German Village Medical Center in Columbus, Ohio. Notably, this was after the Ohio Board had revoked his medical license and after Registrant had changed his DEA registered address to his office in Parkersburg, West Virginia. In doing so, Registrant violated the separate

registration requirement of 21 U.S.C. 822(e), which provides that “[a] separate registration shall be required at each principal place of business or professional practice where the [registrant] distributes or dispenses controlled substances.” See also 21 CFR 1301.12(a).

The evidence also shows that when Registrant applied for an account with Smith Medical Partners so that he could purchase controlled substances, he provided a false answer to the application’s question which asked whether “any sanction or disciplinary action [had] been taken regarding any license, permit, or registration issued to” him. Thereafter, Registrant was approved as a customer and ordered both buprenorphine and Suboxone from Smith. However, the drugs were returned to Smith after Registrant failed to pick them up.

Pursuant to 21 U.S.C. 843(a)(3), it is “unlawful for any person knowingly or intentionally . . . to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deceptions or subterfuge.” Here, while Registrant never actually obtained possession of the drugs, the CSA also provides that “[a]ny person who attempts . . . to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt.” 21 U.S.C. 846.

At the time Registrant submitted his application to Smith, he clearly knew that the Ohio Board had revoked his medical license. See GX 7 (Registrant’s letter of Sept. 26, 2012 to DI stating that “I lost my Ohio license recently over alleged improper prescribing in 2005”). And by falsifying the application, and then proceeding to order the controlled substances, Registrant clearly attempted to obtain the drugs by “misrepresentation, fraud, . . . deception, or subterfuge.” Given that the question was clearly part of Smith’s process for screening its potential new customers, I further conclude that the falsification was capable of influencing Smith’s decision to approve him as a customer and was therefore material. I therefore find that Registrant violated

federal law when he attempted to procure controlled substances by falsifying his application to become a customer of Smith Medical Partners.

As the forgoing demonstrates, Registrant's experience in dispensing controlled substances is characterized by his violations of multiple provisions of federal law. These include: 1) his violations of the prescription requirement, see 21 CFR 1306.04(a); 2) his violations of the 100-patient limit on his authority to prescribe as a DATA-Waived practitioner, see 21 U.S.C. 823(g)(2)(B)(iii); 3) his violations of the separate registration requirement, see 21 U.S.C. 822(e); 4) his numerous violations of recordkeeping requirements applicable to the prescribing Suboxone and Subutex for the purpose of providing maintenance and detoxification treatment, see 21 U.S.C. 827(a)(3) & 21 CFR 1304.22(c); and 5) his attempt to procure controlled substances by misrepresentation and fraud. 21 U.S.C. 843(a)(3) & 846.

I therefore conclude that the Government's evidence with respect to factors two and four establishes that he has committed such acts as would render his registration "inconsistent with the public interest." Id. § 824(a)(4). I further conclude that the proven misconduct is egregious and supports the revocation of Registrant's registration.⁶

Loss of State Authority Grounds

⁶ The Government also alleged that Registrant has not "been candid in providing material information in violation of 21 U.S.C. § 823(f)(5) based on: 1) the application he submitted to Smith Medical Partners, 2) testimony he gave on several issues before the Ohio Board, and 3) a false statement he made to the West Virginia Board Investigator. GX 1, at 2-3. Putting aside that section 823(f)(5) is simply a public interest factor and creates no substantive rule of conduct, I have concluded that Registrant's submission of his false customer application to Smith Medical Partners is properly considered under factor four.

As also found above, the Ohio Board's Hearing Examiner did find Registrant's testimony on several issues to be disingenuous. This provides some additional support under factor five (not that it is needed) for the conclusion that Registrant has committed such acts as to render his registration "inconsistent with the public interest." 21 U.S.C. § 824(a)(4).

As for the allegation that on March 9, 2013, Registrant made a false statement to a West Virginia Board Investigator, the Board itself apparently did not pursue the allegation, and given the extensive evidence of Registrant's misconduct, I deem it unnecessary to address it.

The Government also seeks the revocation of Registrant's registration on the separate and independent ground that he no longer holds a valid medical license in West Virginia, and thus lacks authority to dispense controlled substances in the State in which he is registered with DEA. Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to revoke or suspend a registration "upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . distribution or dispensing of controlled substances." With respect to a practitioner, "DEA has repeatedly 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." James L. Hooper, 76 FR 71371, 71371 (2011) (citing Leonard F. Faymore, 48 FR 32886, 32887 (1983)), pet. for rev. denied, Hooper v. Holder, 481 Fed. Appx. 826, 828 (4th Cir. June 6, 2012) (unpublished).

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) (emphasis added).

Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the Act, DEA has held repeatedly that revocation of a

practitioner's registration is the appropriate sanction if the practitioner is no longer authorized to dispense controlled substances under the laws of the State in which he practices medicine. See, e.g., Calvin Ramsey, 76 FR 20034, 20036 (2011); Sheran Arden Yeates, M.D., 71 FR 39130, 39131 (2006); Dominick A. Ricci, 58 FR 51104, 51105 (1993); Bobby Watts, 53 FR 11919, 11920 (1988).

Here, I have taken official notice of the West Virginia Medical Board's Final Order which revoked Registrant's medical license effective with the entry of the Order. Accordingly, I conclude that Registrant is without authority under West Virginia law to handle controlled substances in the State in which he holds his registration. Because Registrant no longer meets the CSA's requirement that he be currently authorized to dispense controlled substances in the State in which he holds his registration, I will order that his registration be revoked for this reason as well. See Craig Bammer, 73 FR 34327, 34329 (2008); Richard Carino, M.D., 72 FR 71955, 71956 (2007) (citing cases).

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(3) & (4), as well as 28 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration BV3249643, issued to Jose Raul S. Villavicencio, M.D., be, and it hereby is, revoked. I further order that any application of Jose Raul S. Villavicencio, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effectively **immediately**.⁷

Dated: December 30, 2014.

Thomas M. Harrigan,
Deputy Administrator.
BILLING CODE: 4410-09-P

⁷ Based on the extensive and egregious nature of the misconduct proved by the Government, I conclude that the public interest necessitates that this Order be effectively immediately. 21 CFR 1316.67.

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