

the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on December 3, 2015, Pharmacore, Inc., 4180 Mendenhall Oaks Parkway, High Point, North Carolina 27265 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Oxymorphone (9652)	II
Noroxymorphone (9668)	II

The company plans to manufacture the listed controlled substances as active pharmaceutical ingredients (APIs) for clinical trials.

Dated: January 27, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016-02128 Filed 2-3-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

David W. Bailey, M.D.; Decision and Order

On September 9, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to David W. Bailey, M.D. (Registrant), of Hesperia, California. The Show Cause order proposed the revocation of Registrant's Certificate of Registration FB4421474, and the denial of any applications to renew or modify this registration or for any other registration on two grounds. GX 1, at 1.

First, the Show Cause Order alleged on April 3, 2015, the Medical Board of California (MBC or Board) revoked his state medical license, and that therefore, Registrant is "without authority to handle controlled substances in California, the [S]tate in which [he is] registered with the DEA. *Id.* (citing 21 U.S.C. 802(21), 823(f), and 824(a)(3)).

Second, the Order alleged that Registrant's registration "is inconsistent with the public interest" because he failed to "comply with applicable state and Federal law[s]" related to controlled substances. *Id.* at 2.

With respect to the latter contention, the Show Cause Order alleged that in the MBC proceeding, the MBC Administrative Law Judge (ALJ) found that Registrant admitted to eighteen occasions on which he issued clonazepam prescriptions to his wife but had the drugs dispensed to himself for his "own abuse." *Id.* at 2. The Show Cause Order also alleged that the MBC's ALJ found that Registrant "started a treatment program for alcohol and clonazepam abuse but completed only five days of the thirty-day program," and that "[a]n expert physician testified that [his] diagnosis included benzodiazepine dependence and that [he was] not currently undergoing any recovery. *Id.* The Order alleged these findings establish that Registrant violated 21 U.S.C. 844(a) and 843(a)(3), as well as various provisions of the California Business and Professions Code. *Id.* The Order thus alleged that the MBC ALJ's findings prove that Registrant's registration "is inconsistent with the public interest under 21 U.S.C. 824(a)(4) and 823(f)(4)." *Id.*

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 electing either option, and the consequence for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). On September 16, 2015, DEA Diversion Investigators (DIs) travelled to Registrant's address and after verifying his identity, personally served him with the Show Cause Order. GX 5, at 2 (Declaration of DI).

On December 1, the Government filed its Request for Final Agency Action along with various exhibits. In its Request, the Government states that since the date of service of the Show Cause Order, neither Registrant, "nor anyone representing him[,] has requested a hearing or sent any other correspondence to" the Agency. Request for Final Agency Action, at 9.

Based on the Government's submission, I find that 30 days have now passed since the date of service of the Show Cause Order, and neither Registrant, nor anyone purporting to represent him, has either requested a hearing on the allegations or submitted a written statement in lieu of a hearing. See 21 CFR 1301.43(a) and (c). Accordingly, I find that Registrant has waived his right to a hearing or to submit a written statement in lieu of

hearing. *Id.* § 1301.43(c) and (d). I therefore issue this Decision and Final Order based on the Investigative Record submitted by the Government. *Id.* § 1301.43(e). I make the following findings of fact.

Findings

Registrant is a physician authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of LaSalle Medical Associates, 16455 Main St., Suite 1, Hesperia, California. GX 2. His registration is not due to expire until July 31, 2016. *Id.*

On March 6, 2015, the MBC issued an order revoking Registrant's Physician's and Surgeon's License to practice medicine in the State of California, effective April 3, 2015. GX 4. The MBC's revocation was based on the decision of a state ALJ who found, based on clear and convincing evidence, that Registrant: (1) Is alcohol and benzodiazepine dependent, (2) used alcohol and controlled substances in a manner dangerous to himself and others, (3) prescribed a controlled substance to another with the intention of using that substance himself, (4) self-administered a controlled substance that he had prescribed in the name of another, (5) violated the California Medical Practice Act, and 6) engaged in unprofessional conduct.¹ GX 3, at 1.

More specifically, the state ALJ found, by clear and convincing evidence, that Registrant:

engaged in unprofessional conduct by violating state laws related to the prescription and use of Klonopin as follows: [he] repeatedly issued prescriptions for Klonopin in [his wife's] name with the intent of self-administering the Klonopin obtained from the prescriptions; he engaged in fraud and deceit in order to obtain Klonopin; he provided a false name to obtain Klonopin; he repeatedly used Klonopin in violation of the

¹ Notwithstanding that Registrant failed to appear at the MBC hearing, the MBC's findings of fact and conclusions of law are entitled preclusive effect in this proceeding. The MBC found that Registrant was properly served with the Accusation and, in fact, several days before the hearing telephoned the MBC's counsel "and advised her that he was not going to appear." GX 3, at 2. Thus, notwithstanding that he defaulted, Registrant had a full and fair opportunity to challenge the MBC's allegations. See *Jose G. Zavaleta*, 78 FR 27431, 27434 (2013) (collecting cases holding that findings made in a proceeding against a party in default are entitled to preclusive effect if the party could have appeared and defended if he had wanted to); see also *id.* (quoting *Gottlieb v. Kest*, 141 Cal. App. 4th 110, 149 (Cal. Ct. App. 2006) ("A default judgment conclusively establishes, between the parties so far as subsequent proceedings on a different cause of action are concerned, the truth of all material allegations contained in the complaint in the first action, and every fact necessary to uphold the default judgment.") (int. quotations and citations omitted)).

law; and he repeatedly used and possessed Klonopin that was not obtained with a legitimate prescription.

Id. at 19 (citing Cal. Bus. & Prof. Code sec. 2238(a)).

The state ALJ also found that Registrant “intentionally created medical records—prescriptions to [his wife] for Klonopin—that were false because he intended to use the Klonopin obtained from the prescription for himself.” *Id.* (citing Cal. Bus. & Prof. Code § 2262). The state ALJ further found that Registrant violated the California Medical Practice Act when he “used dangerous drugs in a manner that was dangerous to himself, violated state laws related to dangerous drugs and controlled substances, knowingly made false representation of fact, and created false medical records with a fraudulent intent.” *Id.* (citing Bus. & Prof. Code sec. 2234).

The ALJ then concluded that Registrant: suffers from alcohol dependence and benzodiazepine dependence, and his substance abuse presents a substantial risk of harm to himself, patients and the public. [H]e does not appear to be able or willing to become abstinent of alcohol despite his treatment with psychiatrists and psychologists and despite his brief participation in substance abuse programs.

Id. at 20. The state ALJ thus concluded that “[u]nder all the circumstances, the outright revocation of respondent’s certificate is the only disciplinary option available at this time that will protect the public.” *Id.*

On March 6, 2015, the MBC adopted the proposed decision, and on April 3, 2015, Registrant’s Physician’s and Surgeon’s Certificate was revoked. GX 4. According to the online records of the MBC, Registrant’s license remains revoked. *See also* www.breeze.ca.gov.

Discussion

The Loss of State Authority Ground

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823, “upon a finding that the Registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” Moreover, DEA has held repeatedly 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*, 76 FR 71371 (2011),

pet. for rev. denied, 481 Fed Appx. 826 (4th Cir. 2012).

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 Act, 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 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). *See also Hooper v. Holder*, 481 Fed. Appx. at 828.

Based on the MBC’s revocation of his medical license, I find that Registrant lacks authority to dispense controlled substances in California, the State in which he holds his DEA registration. According, I will order that Registrant’s registration be revoked and that any pending applications be denied. 21 U.S.C. 824(a)(3).

The Public Interest Ground

Section 304(a) of the Controlled Substances Act (CSA) also 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). And while I must consider each factor, I “need not make explicit findings as to each one and can ‘give each factor the weight [I] determine[] is appropriate.’ ” *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009)); *see also Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005)); *see also Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005) (same). In this matter, I concluded that the evidence with respect to Factors Two and Four establishes that Registrant has committed acts which render his registration inconsistent with the public interest.

The Government contends that the MBC ALJ’s findings of fact and conclusions of law establish that Registrant violated state and federal laws related to controlled substances.² I agree that the State’s findings establish that Registrant committed several violations of state laws that are actionable under Factor Four. Specifically, Respondent violated Cal. Bus. & Prof. Code sec. 2239(a), which provides that “[t]he use or prescribing for or administering to himself. . . of any controlled substance; or the use of any of the dangerous drugs. . . to the extent, or in such a manner as to be dangerous or injurious to the licensee, or to any other persons or to the public, or to the extent that such use impairs the ability of the licensee to practice

² As for Factor One, while the State has not made a recommendation to the Agency, the State has revoked Respondent’s medical license and thus, he no longer meets the CSA’s requirement that he is authorized to dispense controlled substances in the State where he is registered.

As for Factor Three, the record contains no evidence that Registrant has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances.

As for Factor Five, even though the evidence shows that Respondent engaged in the self-abuse of controlled substances, the Government did not set forth any argument that Respondent’s conduct is also actionable under this Factor. Thus, I make no findings under this Factor.

medicine safely. . . constitutes unprofessional conduct.” See also Cal. Bus. & Prof. Code sec. 2238 (“A violation of any federal statute or regulation, or any of the statutes or regulations of this state regulating dangerous drugs or controlled substances constitutes unprofessional conduct.”).

I further conclude that the MBC’s findings establish that Registrant violated the CSA when he issued fraudulent prescriptions in his wife’s name for Klonopin (clonazepam), a schedule IV controlled substance, which he then used and abused. See 21 U.S.C. 843(a)(3) (“It shall be unlawful for any person knowingly or intentionally. . . to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge.”); see also *id.* sec. 844(a) (“It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice.”); 21 CFR 1306.04(a) (“A prescription for a controlled substance. . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”). Not only is this conduct actionable under Factor Four, it is also relevant in assessing Registrant’s experience in dispensing controlled substances (Factor Two).

Accordingly, I find that the evidence establishes Registrant “has committed such acts as would render his registration. . . inconsistent with the public interest.” See 21 U.S.C. 824(a)(4). Because Registrant failed to respond in any manner to the Show Cause Order, I will order that his registration be revoked and that any pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FB4421474, issued to David W. Bailey, M.D., be, and it hereby is, revoked. I further order that any pending application of David W. Bailey, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective March 7, 2016.

Dated: January 18, 2016.

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2016-02127 Filed 2-3-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Kenneth H. Bull, M.D.; Decision and Order

On August 21, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Kenneth H. Bull, M.D. (Respondent), of Albuquerque, New Mexico. GX 1, at 1. The Show Cause Order proposed the revocation of Respondent’s DEA Certificate of Registration AB5662552, and the denial of any applications for renewal or modification of the registration, as well as for any other registration, on two grounds: (1) That he lacks authority to handle controlled substances in New Mexico, the State in which he is registered with DEA, and (2) his “registration would be inconsistent with the public interest.” *Id.* (citing 21 U.S.C. 823(f), 824(a)(3) and (4)).

The Show Cause Order alleged that Respondent is registered as a practitioner in schedules IIN, IIIN, IV and V, at the registered address of 3500 Comanche Blvd., Building Suite 6, Albuquerque, New Mexico. *Id.* The Order also alleged that his registration does not expire until July 31, 2017. *Id.*

As grounds for the proposed action, the Show Cause Order alleged that effective June 30, 2014, the New Mexico Medical Board (Board) issued a Decision and Order which revoked Respondent’s medical license, thus rendering him without authority “to order, dispense, prescribe or administer any controlled substances” in New Mexico, the State in which he holds his registration. *Id.* Continuing, the Order asserted that “the DEA must revoke [Respondent’s] registration based upon [his] lack of authority to handle controlled substances in” New Mexico. *Id.* (citing 21 U.S.C. 802(21), 823(f), and 824(a)(3)).

As further ground, the Government alleged that Respondent’s “registration is inconsistent with the public interest because [he] did not comply with applicable Federal law related to controlled substances, in violation of 21 U.S.C. 824(a)(4) and 823(f)(4).” *Id.* The Government based this allegation on the factual findings and legal conclusions of a prior agency proceeding, which suspended his DEA registration for six months and restricted his registration to non-narcotic controlled substances. *Id.* at 2 (citing *Kenneth Harold Bull, M.D.*, 78 FR 62666 (2013)). The Show Cause Order then set forth several of the 2013 Order’s findings of the violations found

during a November 2009 administrative inspection.¹ *Id.*

The Show Cause Order was served on Respondent by registered mail sent to his registered location; according to the Government, the return receipt card showed that the mailing was received on September 16, 2015. Request for Final Agency Action (RFAA), at 2; GX 7. Thereafter, on September 22, 2015, Respondent, through his attorney, filed a written response to the Show Cause Order. GX 8.

Therein, Respondent expressly waived his right to a hearing but submitted a written statement for my consideration. GX 8, at 1 (citing 21 CFR 1301.43(c)). Thereafter, the Government submitted a Request for Final Agency Action with supporting documents; in its submission, the Government also included Respondent’s written statement.

Based on Respondent’s submission, I find that he has waived his right to a hearing on the allegations of the Show Cause Order. 21 CFR 1301.43(c). However, I will consider Respondent’s statement along with the evidence submitted by the Government in this matter. I make the following findings of fact.

Findings

Respondent, who is a psychiatrist in the State of New Mexico, is the holder of DEA Certificate of Registration AB5662552, pursuant to which he is currently authorized to dispense controlled substances in Schedules IIN, IIIN, IV and V; his registration does not expire until July 31, 2017. GX 2, at 1. Respondent was previously authorized to dispense controlled substances in Schedules II through V, as well to dispense buprenorphine as a DATA-Waiver physician. See *Bull*, 78 FR at 62669. However, on September 22, 2013, the then-Administrator issued a Decision and Order which suspended Respondent’s registration for six months; the Order also revoked Respondent’s DATA-Waiver Identification Number and restricted his dispensing authority to non-narcotic controlled substances only.² *Id.* at 62676; GX 2.

¹ The Show Cause Order also notified Respondent of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence of failing to elect either option. GX 1, at 2 (citing 21 CFR 1301.43).

² Pursuant to an earlier Board Order, Respondent did not, at the time of the prior Agency proceeding, possess state authority “to prescribe narcotics, including but not limited to, all opioid analgesics, including buprenorphine and all synthetic opioid analgesics.” *Id.* at 62676.