

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.

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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.

On June 30, 2014, the New Mexico Medical Board issued a Decision and Order which adopted nearly all of the findings of a state Hearing Officer. GX 4, at 1. The Board suspended Respondent's medical license "effectively immediately," based upon "the deficiencies noted in" a report by the Center for Personalized Education for Physicians (CPEP), which had assessed his clinical skills, as well as the Hearing Officer's "finding of manifest incompetence." *Id.* The Board further ordered that the suspension would remain in effect until Respondent "successfully completes a Board approved retraining in a residency or residency-like program to address the deficiencies noted in the CPEP report," and that upon completion, he "may petition. . . for reinstatement of his medical license." *Id.*

The Government states that Respondent's medical license remains suspended, and Respondent does not deny this in his written statement. GX 8, at 2. Moreover, a search of the online records of the New Mexico Medical Board shows that Respondent's medical license remains suspended. See <http://cgi.docboard.org/cgi-shl/nhayer.exe>.

Respondent's written statement summarizes his academic and professional career, noting that he has been practicing for more than 40 years.³ *Id.* at 1–2. Respondent disputes the allegation of the Order to Show Cause that his medical license has been revoked, arguing that "the Board suspended [his] license pending [his] attending a residency-like program." *Id.* at 2. While Respondent is correct, as a practical matter, this is a distinction without a material difference.

Respondent further states that he "strongly disagrees with the Board's findings and conclusions, but has accepted them." *Id.* Continuing, he states that he "has freely accepted and described without reservation the mistakes he had made as a practitioner, but disagrees [that] he is 'manifestly incompetent.'" *Id.*

Respondent then engages in a collateral attack on the Board's Order. He argues:

[T]he Medical Board's prosecution rested its case entirely on unsworn hearsay evidence in the form of a report issued by a Colorado physician assessment organization

³ Respondent states that he is the holder of a DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V, including narcotic controlled substances, as a practitioner. GX 8, at 2. Although his statement notes that his registration was the subject of a previous DEA show cause proceeding, it does not accurately state the outcome of that proceeding, which restricted his registration to authorize the dispensing of only non-narcotic controlled substances. See 78 FR at 62676.

called the . . . CPEP. The report was based on approximately three hours of interview time with [him] done by unidentified physician consultants who conducted a review of a tiny fraction of his total patient records (24 records out of hundreds of cases). [Respondent] also participated in two 30 minute simulated patient intake interviews with actors playing the patients. The New Mexico Medical Board based its suspension on its conclusion [that he] required a residency-type program to continue practicing psychiatry, a claim [his] expert witness disagreed with strongly.⁴ *Id.*

Respondent then argues that "there is no claim [he] engaged in any sort of financial impropriety, diversion of medications, boundary issues, or harmed a patient in any manner." Stating that he "intends to ask the Board to modify its order in the near future to allow him to resume practice," Respondent asks that I delay consideration of the matter "until this occurs." *Id.* Finally, Respondent notes that "New Mexico is a notoriously underserved medical community" and that he provided care for patients "in desperate need of psychiatric services" and "with severe behavioral problems and extremely serious mental illness," and that "[h]e will not be able to do so without a DEA registration." *Id.* at 3.

Discussion

In its Request for Final Agency Action, the Government asserts two grounds to revoke Respondent's registration. RFAA, at 4. With respect to the public interest ground, the Government contends that, "in the present proceeding, [I] can give *res judicata* effect to the prior DEA final order," and therefore, "the prior findings of fact and conclusions of law in [that] proceeding may be incorporated into the present final order." *Id.*

The Government does not explain, however, why the factual findings and legal conclusions of the prior Agency Decision and Order now support the revocation of Respondent's registration on public interest grounds. Notably, in that proceeding, the prior Administrator found that Respondent had accepted responsibility and demonstrated that he would not engage in future misconduct with respect to the misconduct that "was properly at issue in the proceeding." 78 FR at 62675. Moreover, the prior Administrator did not find the misconduct that was proven on the record of the proceeding to be sufficiently egregious to warrant revocation. *Id.* at 62676.

⁴ Respondent also included a copy of the Post-Hearing Brief filed on his behalf in the Board proceeding.

Presumably, Respondent served his suspension without incident, and notably, the Government makes no allegation in this proceeding that Respondent has, since the first proceeding, engaged in any further misconduct related to controlled substances. See GX 1, at 1–2 (Show Cause Order). Indeed, in its Request for Final Agency Action, the Government states that Show Cause Order "did not allege that [the Board's] final order entails findings that reveal violations related to [Respondent's] DEA registration." RFAA, at 3. Given the Government's position that the State Board proceeding does not involve misconduct related to his registration and the absence of evidence of misconduct related to controlled substances since the first proceeding, there is no basis to invoke the Agency's public interest authority to revoke his registration.⁵

There is, however, no dispute that Respondent lacks authority to handle controlled substances in New Mexico, the State where he is currently registered, and 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 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.

⁵ It is noted that the Hearing Officer found that "[t]he CPEP Assessment was designed to evaluate Respondent's practice of outpatient adolescent and adult psychiatry, including the prescribing of controlled substances within a psychiatry practice," and the CPEP Assessment involved a review of Respondent's medical charts, interviews of Respondent, and "simulated patient-physician interactions." GX 5, at 8. Moreover, the Board adopted the Hearing Officer's findings that Respondent's "[c]linical judgment and reasoning were not adequate, particularly his prescribing of controlled substances within the context of a psychiatric practice" and "[h]is documentation in the patient charts submitted for review was not adequate." *Id.* The Board also adopted the Hearing Officer's finding regarding Respondent's use of cheek swabs rather than urine drug screening "[t]o address the addiction and diversion issues in his patients." *Id.* at 9. However, the Government does not argue that these findings support a finding that Respondent has committed such acts as would render his registration inconsistent with the public interest and, in adjudicating this matter, I rely solely on the Board's action in suspending his medical license and the fact that the suspension remains in effect.

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).

Thus, the Agency has held that revocation is warranted even where, as here, the state board has suspended (as opposed to revoked) a practitioner’s dispensing authority and that authority may be restored at some point in the future through further proceedings. *See Ramsey* 76 FR at 20036 (citations omitted). As the Agency has held, the controlling question is not whether a practitioner’s license to practice medicine in the state is suspended or revoked; rather, it is whether the Respondent is currently authorized to handle controlled substances in the state. *James L. Hooper*, 76 FR 71371 (2011) (collecting cases), *pet. for rev. denied, Hooper v. Holder*, 481 Fed. Appx. 826 (4th Cir. 2012).

Respondent further argues that I should consider that the Medical Board’s case “rested entirely on unsworn hearsay evidence in the form of” the CPEP Report and that his expert witness “disagreed with” the Board’s conclusion that he should undergo a “residency-type program to continue practicing. GX 8, at 2. This argument is simply a collateral attack on the State Board proceeding. The Agency has held, however, “that a registrant cannot collaterally attack the result of a state criminal or administrative proceeding in a proceeding under section 304, 21 U.S.C. 824, of the CSA.” *Muzaffer Aslan*, 77 FR 37068, 37069 (2012) (other

citations omitted). “Rather, Respondent’s challenge to the validity of the [New Mexico Board’s] Order must be litigated in the forums provided by the State of [New Mexico], and his contentions regarding the validity of the [Board’s] order are not material to this Agency’s resolution of whether he is entitled to maintain his DEA registration in” New Mexico. *Id.*

Because it is undisputed that Respondent’s New Mexico medical license remains suspended, I find that he no longer has authority under the laws of New Mexico, the State in which he is registered, to dispense controlled substances. Therefore, he is not entitled to maintain his DEA registration. *See* 21 U.S.C. 802(21), 823(f), 824(a)(3). Accordingly, I will order that his registration be revoked and that any pending application to renew or modify his registration be denied.⁶

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 AB5662552, issued to Kenneth Harold Bull, M.D., be, and it hereby is, revoked. I further order that any application of Kenneth Harold Bull, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.⁷

Dated: January 18, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–02129 Filed 2–3–16; 8:45 am]

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⁶ While Respondent also asked that I delay the resolution of this matter, “in circumstances similar to those raised by Respondent, DEA has repeatedly denied requests to stay the issuance of a final order of revocation, noting that [u]nder the Controlled Substances Act, a practitioner must be currently authorized to handle controlled substances in the jurisdiction in which [he] practices in order to maintain [his] DEA registration.” *Gregory F. Saric*, 76 FR 16821, 16822 (2011) (internal quotations and citations omitted). Of further note, Respondent’s state medical license was suspended more than 18 months ago, and yet his license still remains suspended.

Finally, while Respondent asserts that New Mexico is a medically underserved area, in the case of individual practitioners, DEA has held that community impact evidence is irrelevant in the public interest determination as it is in a proceeding based on a loss of state authority. *See Linda Sue Cheek*, 76 FR 66972, 66972 (2011); *Gregory Owens*, 74 FR 36751, 36757 (2009). So too, Respondent’s statement regarding his acceptance of responsibility is not a defense to a revocation based on the loss of state authority, because the CSA mandate that a practitioner possess such authority to obtain and maintain a DEA registration.

⁷ Based on the findings of fact and conclusions of law which led the NMMB to immediately suspend Registrant’s license until he successfully completes Board approved re-training,” GX 4, at 1; I conclude that the public interest requires that this Order be effective immediately. *See* 21 CFR 1316.67.

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Partial Consent Decree Under the Clean Water Act

On January 28, 2016, the Department of Justice lodged a proposed Partial Consent Decree with the United States District Court for the Northern District of Mississippi in the lawsuit entitled *United States and the State of Mississippi v. City of Greenville, Mississippi*, Civil Action No. 4:16–cv–00018–DMB–JMV.

The United States and the State of Mississippi filed this lawsuit under the Clean Water Act and the Mississippi Air and Water Pollution Control Law. The complaint seeks injunctive relief and civil penalties for violations in connection with the City’s sanitary sewer system. The City has grouped mini-systems within the sewer system into three different groups and prioritized Sewer Group 1 and Sewer Group 2 for sewer assessment and rehabilitation work. The Partial Consent Decree provides for the City to conduct early action projects; capacity, management, operations, and maintenance program; and assessment and rehabilitation of Sewer Groups 1 and 2. The partial settlement will not resolve the claims for civil penalties or for injunctive relief related to Sewer Group 3, as those will be the topics of future negotiation among the parties.

The publication of this notice opens a period for public comment on the Partial Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the State of Mississippi v. City of Greenville, Mississippi*, D.J. Ref. No. 90–5–1–1–10932. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

| To submit comments: | Send them to: |
|---------------------|---|
| By email | pubcomment-ees.enrd@usdoj.gov . |
| By mail | Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611. |

During the public comment period, the Partial Consent Decree may be examined and downloaded at this Justice Department Web site: <http://www.justice.gov/enrd/consent-decrees>. We will provide a paper copy of the Partial Consent Decree upon written