

630 F.3d 17, 31 (1st Cir. 2010). The recordkeeping requirements at issue here have been part of federal law since the enactment of the CSA in 1971. Surely, at some point during the thirty-seven years of his medical career, and preferably before he first started handling controlled substances, Respondent should have familiarized himself with the CSA and DEA regulations.

By themselves, recordkeeping violations can support the revocation of a registration. *See Volkman*, 73 FR at 30644. Here, however, the scope of the proven violations is limited, given that there is no evidence that he dispensed any of the controlled substances he obtained from his patients and that the other evidence in the case suggests that his dispensing activity was limited in scope. So too, while Respondent did not maintain an inventory of the controlled substances he had on hand, the quantities found during the inspection were limited. I thus conclude that Respondent's recordkeeping violations do not warrant revocation but are nonetheless sufficiently egregious to warrant the suspension of his registration.

Moreover, pursuant to the Medical Board's order, Respondent no longer holds authority under state law to prescribe "narcotics, including but not limited to, all opioid analgesics, including buprenorphine and all synthetic opioid analgesics." GX 5, at 13. As explained in the discussion of factor one, under the CSA, the Board's revocation of his authority to prescribe these drugs likewise mandates that the same restriction be imposed on his DEA registration. Therefore, his registration will be restricted to bar him from prescribing the aforementioned drugs and his Identification Number as a DATA-Waiver physician must also be revoked.

Accordingly, I will order that Respondent's application to renew his new registration be granted subject to the following conditions:

(1) Effective on the date on which Respondent's registration is renewed, his registration shall be suspended for period of six months.

(2) Respondent's registration shall be restricted to authorize the dispensing of only non-narcotic controlled substances.

(3) Respondent's Identification Number as a DATA-Waiver physician shall be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that the application of Kenneth Harold Bull,

M.D., to renew his DEA Certificate of Registration as a practitioner be, and it hereby is, granted subject to the condition that he be authorized to dispense only non-narcotic controlled substances. I also order that the Identification Number as a DATA-Waiver physician issued to Kenneth Harold Bull, M.D., be, and it hereby is, revoked. I further order that upon the effective date of this Order, the DEA Certificate of Registration issued to Kenneth Harold Bull, M.D., be, and it hereby is, suspended for a period of six months. This Order is effective November 21, 2013.

Dated: September 22, 2013.

Michele M. Leonhart,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Anthony E. Wicks, M.D. Decision and Order

On June 6, 2012, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Anthony E. Wicks, M.D. (Applicant), of Tampa, Florida. Show Cause Order at 1. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration, because granting his application would be "inconsistent with the public interest." *See id.*; 21 U.S.C. 823(f).

The Show Cause Order specifically alleged that in approximately December 2010, Applicant discontinued his practice in Visalia, California and began practicing in Winter Springs, Florida, and that he issued more than 2,290 controlled-substance prescriptions without being registered at this location, in violation of 21 U.S.C. 822(e) and 21 CFR 1301.12; and that he also failed to notify DEA of the change in his practice location pursuant to 21 CFR 1301.51. Show Cause Order at 1. The Show Cause Order also alleged that after Applicant's registration expired on May 31, 2011, he issued more than 270 controlled-substance prescriptions, in violation of 21 U.S.C. 841(a) and 843(a)(2). *Id.* at 2.

The Show Cause Order further notified Applicant that within thirty days of the date of his receipt of the Order, he had the right to either request a hearing, or to file a waiver of his right to a hearing, together with a written statement of his position on the matters

of fact and law asserted by the Government. *Id.* (citing 21 CFR 1301.43(a) & (c)). In addition, the Order notified applicant that should he "request a hearing and then fail to appear at the . . . hearing, [he would] be deemed to have waived his right to a hearing" and that a final order may be entered "without a hearing based upon the evidence presented to" me. *Id.* (citing 21 CFR 1301.43(d) & (e)).

The Government served the Show Cause Order on Applicant by certified mail addressed to him at the address of his proposed registered location. GXs 1, 16, 17. As evidenced by the signed return receipt card, service was accomplished on June 9, 2012. GX 17.

On July 5, 2012, Applicant, through his counsel, filed a timely request for a hearing. GX 18. The matter was placed on the docket of the Office of Administrative Law Judges (ALJ) and assigned to an ALJ, who proceeded to conduct pre-hearing procedures. GX 22. However, on September 26, 2012, Applicant withdrew his request for a hearing. GX 21. The same day, the ALJ issued an Order granting Applicant's request and cancelled the hearing. GX 22.

On March 13, 2013, the Government submitted the Investigative Record and a Request for Final Agency Action to my Office. As an initial matter, I find that Applicant, by withdrawing his request for a hearing, has waived his right to a hearing on the allegations. *See* 21 CFR 1301.43(d). I therefore issue this Decision and Order based on relevant evidence found in the Investigative Record submitted by the Government. *See id.* 1301.43(e). I make the following findings.

Findings

Applicant previously held DEA Certificate of Registration BW7987184, which authorized him to dispense controlled substances in Schedules II through V, as a practitioner, at the registered address of 400 West Mineral King Blvd., Department of Anesthesia, Visalia, California.¹ GX 2. This registration was issued on April 11, 2008 and expired on May 31, 2011. *Id.* While Applicant was sent two renewal notices, as well as a delinquency notice (after his registration had expired), he failed to renew the registration, and on

¹ Applicant had also previously held a registration which authorized him to dispense controlled substances at the registered location of: Department of Anesthesia, St. Joseph's Hospital, 1105 Shipwatch Circle, Tampa, Florida. GX 4, at 1. This registration expired on May 31, 2005 and was retired when Applicant failed to renew it. *Id.* at 2.

July 1, 2011, it was retired by the Agency. GX 3, at 1; GX 15, at 3, ¶ 11.

On July 19, 2011, Applicant applied for a new registration. GX 1. Applicant sought authority to dispense controlled substances in Schedules II–V at the registered address of 1105 Shipwatch Circle, Tampa, Florida. *Id.*

A Diversion Investigator (DI) subsequently determined that beginning in December 2010, Applicant had begun practicing at a pain clinic located in Winter Springs, Florida. GX 15. However, Applicant neither obtained a registration for this location, nor sought to modify the address of his then-existing registration. Instead, during the ensuing period, which lasted through at least most of June 2011, Applicant issued 3,120 controlled-substance prescriptions,² using DEA registration BW7987184, while listing his address as Pain Management of Winter Springs, 165 W. SR 434, Winter Springs, Florida. GX 15, at 2, ¶¶ 5–6. Applicant never notified the Agency that he had changed his practice address. *Id.* at 2, ¶ 5.

The DI also found that Applicant had issued at least 341³ controlled-substance prescriptions after his registration had expired. GX 15, at 2, ¶ 7; *see also* GX 13. Applicant wrote the prescriptions for oxycodone,⁴ diazepam, and lorazepam.⁵ GX 15, at 2, ¶ 7; GX 13.

Discussion

Under the Controlled Substances Act (CSA), an application for a practitioner's registration may be denied if “the

issuance of such registration . . . would be inconsistent with the public interest.” 21 U.S.C. 823(f). In making the public interest determination, Congress directed that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority;
- (2) The applicant's experience in dispensing, or conducting research with respect to 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; and
- (5) Such other conduct, which may threaten the public health and safety.

21 U.S.C. 823(f).⁶

“[T]hese factors are considered in the disjunctive.” *Robert A. Leslie*, 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 to revoke an existing registration or to deny an application. *Id.* Moreover, while I “must consider each of these factors, [I] ‘need not make explicit findings as to each one.’” *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) (citing *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005)).

The Government has “the burden of proving that the requirements for . . . registration . . . are not satisfied.” 21 CFR 1301.44(d). In this matter, I have considered all of the factors and conclude that the evidence with respect to factors two and four supports the conclusion that granting the application “would be inconsistent with the public interest.”⁷ 21 U.S.C. 823(f).

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Federal and State Laws Related to Controlled Substances

A. The Applicant's Issuance of Prescriptions at an Unregistered Location

Under the CSA, “[e]very person who dispenses⁸ . . . any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.” 21 U.S.C. 822(a)(2). Moreover, “[a] separate registration [is] required at each principal place of business or professional practice where the applicant . . . dispenses controlled substances.” *Id.* § 822(e); *see* 21 CFR 1301.12(a).

In a rulemaking, DEA has explained that “DEA individual practitioner registrations are based on a [s]tate license to practice medicine and prescribe controlled substances.” DEA, *Clarification of Registration Requirements for Individual Practitioners*, 71 FR 69478 (2006) (final rule); *see also* 21 U.S.C. 823(f) (“The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.”).⁹ Therein, the Agency further explained that “[s]tate authority to conduct the above-referenced activities only confers rights and privileges within the issuing State; consequently, the DEA registration based on a [s]tate license cannot authorize controlled substance dispensing outside the State.” 71 FR at 69478.

The evidence shows that Applicant issued thousands of controlled-substance prescriptions while practicing medicine at the Winter Springs, Florida pain clinic and did so over the course of a seven-month period. The evidence thus establishes that Applicant

² Documentary evidence, which the Government acquired through administrative subpoena, includes copies of some of the prescriptions Respondent wrote for controlled substances while practicing at the Winter Springs pain clinic. *See* GXs 7–11. Walgreens' and Albertsons' pharmacies provided the documents. *Id.* Additionally, Walgreens provided a chart summarizing all of Applicant's prescriptions that were filled at their pharmacies after he started practicing at the Winter Springs pain clinic. *See* GX 14.

³ The documentary evidence offered by the Government in support of this figure is contained within GX 13. This exhibit contains 439 pages of documents which were obtained from Walgreens; however, the exhibit contains prescriptions, as well as the labels that were generated for the prescriptions and which are typically placed in the pharmacy's dispensing log. However, even if this exhibit does not support the exact number of controlled substance prescriptions Applicant issued as alleged by the DI, it still provides evidence that he issued several hundred prescriptions after the expiration of his registration. Moreover, in *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 519*, 77 FR 62315, 62316, 62328 (2012), I adopted the ALJ's finding that these stores had dispensed a total of 55 controlled-substance prescriptions for oxycodone 30mg, which Applicant issued after the expiration of his registration.

⁴ Oxycodone is a schedule II controlled substance. *See* 21 CFR 1308.12(b)(1).

⁵ Both Diazepam (Valium) and Lorazepam (Ativan) are schedule IV depressants. 21 CFR 1308.14(c).

⁶ Pursuant to 21 U.S.C. 871(a), the Attorney General has delegated this authority to the DEA Administrator. *See* 28 CFR 0.100(b).

⁷ It is acknowledged that the Government offered no evidence regarding factors one, three, and five. While I have assumed that there is no evidence under any of these three factors that would support the denial of Applicant's application, the Agency has held that findings under a single factor can support the denial of an application. *See MacKay*, 664 F.3d at 817–18 (quoting *Dewey C. MacKay*, 75 FR 49956, 49973 (2010)); *see also Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Jayam Krishna-Iyer*, 74 FR 4590, 462 (2009).

⁸ *See* 21 U.S.C. § 802(10) (“The term ‘dispense’ means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . .”).

⁹ *See also* 21 U.S.C. § 802(21) (defining “[t]he term ‘practitioner’ [as] a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to . . . dispense . . . a controlled substance in the course of professional practice”); *id.* § 824(a)(3) (authorizing the suspension or revocation of a registration based “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 . . . dispensing of controlled substances”).

maintained a principal place of professional practice at the Winter Springs pain clinic. Because the evidence further shows that during this period, Applicant was not registered at this location, or any other location in the State of Florida, I conclude that Applicant violated the CSA's separate registration requirement. 21 U.S.C. 822(e).¹⁰

The CSA further provides that "[e]very registrant . . . shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require." 21 U.S.C. 827(g). Under a DEA regulation, "[a]ny registrant may apply to modify his/her registration . . . to change his/her name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration." 21 CFR 1301.51. Of consequence, this regulation further provides that "[t]he request for modification shall be handled in the same manner as an application for registration." *Id.* Moreover, under 21 CFR 1301.13(a), "[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person."

Because section 827(g) clearly creates a substantive obligation on the part of a registrant to notify the Agency if he changes his professional address, the regulation's use of the words "may apply to modify" cannot alter (and cannot reasonably be read as altering) the binding nature of a registrant's obligation to notify the Agency. *Cf. Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842–43 & n.9 (1984); *see also United States v. Marte*, 356 F.3d 1336, 1341 (11th Cir. 2004) ("When a regulation implements a statute, the regulation must be construed in light of the statute[.]" (citation omitted)). Indeed, because the regulation itself further

states that a modification is "handled in the same manner as an application for registration," and thus, a registrant may "not engage in any activity for which registration is required until the application . . . is granted and a . . . [r]egistration is issued," 21 CFR 1301.13(a), the regulation is also properly construed as imposing, on a registrant who changes his professional address, the binding obligations to both: 1) Notify the Agency, and 2) refrain from dispensing activities until his request is approved. Accordingly, I also conclude that Respondent violated the CSA and DEA regulations when he failed to notify the Agency of the change of his professional address and yet proceeded to dispense controlled substances at his new practice location. *See* 21 U.S.C. § 827(g); 21 CFR 1301.13(a) and 1301.51. These findings, particularly when considered in light of the extent of the Applicant's violations, support the conclusion that granting Applicant's application "would be inconsistent with the public interest." *Id.* § 823(f).

B. The Applicant's Issuance of Prescriptions After His DEA Registration Expired

Under the CSA, it is unlawful for a practitioner to "knowingly or intentionally . . . use in the course of the distribution[] or dispensing of a controlled substance, . . . a registration number which is . . . expired." 21 U.S.C. 843(a)(2); *see also* 21 CFR 1306.03(a) ("A prescription for a controlled substance may be issued only by an individual practitioner who is . . . registered . . ."). Notably, a DEA Certificate of Registration states on its face the date it expires; with respect to Applicant, his registration stated that it expired on May 31, 2011. *See* GX 2. Moreover, other evidence submitted by the Government shows that the Agency sent notices (on March 25 and April 10, 2011) to Applicant notifying him of the impending expiration of his registration. GX 3, at 2.

Here, the evidence shows that while Applicant's registration expired on May 31, 2011, he nonetheless proceeded to use the registration to issue several hundred controlled-substance prescriptions for drugs such as oxycodone 30mg. and Valium 10mg. *See* GX 13. In the absence of any evidence to the contrary, I further find that Applicant knew that his registration had expired and thus violated the CSA and DEA regulations when he continued to use it to issue the prescriptions. 21 U.S.C. 843(a)(2); 21 CFR 1306.03(a).

Here again, the extent of Applicant's misconduct in using an expired

registration to issue prescriptions provides reason to deny his application. *See Larry E. Davenport, M.D.*, 68 FR 70534, 70537–38 (2003), *pet. for rev. denied Davenport v. U.S. Dep't of Justice*, 122 F. App'x 224 (6th Cir. 2005); *James C. LaJevic, D.M.D.*, 64 FR 55962, 55964 (1999). These violations, coupled with the thousands of violations Applicant committed in issuing prescriptions at the Winter Springs pain clinic without being registered at this location, strongly support the conclusion that granting Respondent's application for a new registration "would be inconsistent with the public interest." 21 U.S.C. 823(f). Accordingly, I will order that Applicant's application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Anthony E. Wicks, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective immediately.

Dated: September 30, 2013.

Thomas M. Harrigan,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–17]

Morris W. Cochran, M.D.; Decision and Order

On July 9, 2013, Administrative Law Judge Gail A. Randall (hereinafter, ALJ) issued the attached Recommended Decision. Therein, the ALJ found that there was no dispute over the material fact that Respondent does not hold authority under the laws of the State of Alabama, the State in which he seeks registration with the Agency, to dispense controlled substances. R.D. at 12–13. Applying longstanding agency precedent, which holds 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 prerequisite for obtaining a registration under the Controlled Substances Act (CSA), *id.* at 8–10, the ALJ granted the Government's motion for summary disposition and recommended that I deny Respondent's application for a registration. *Id.* at 13. Neither party filed exceptions to the ALJ's Recommended Decision.

¹⁰ As support for its contention that, "[u]nder DEA regulations, a practitioner is required to report a change of registered address to DEA," the Government cites 21 CFR 823(f)(2). Request for Final Agency Action, at 6. However, a review of the Code of Federal Regulations reveals that the provision cited by the Government does not even exist, and to the extent the Government mistakenly cited to the Code of Federal Regulations rather than the United States Code, 21 U.S.C. 823(f)(2) provides no support for its contention because it is simply a factor to be considered in determining the public interest and is not an independent requirement for registration. *See Penick Corp., Inc., v. DEA*, 491 F.3d 483, 490 (D.C. Cir. 2007) (citation omitted). Indeed, the text of factor two simply directs the Agency to consider "[t]he applicant's experience in dispensing . . . controlled substances" and imposes (unlike numerous other provisions of the CSA) no substantive obligation on an applicant or registrant.