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With the ever increasing proliferation of multiple state healthcare practices, providers must be aware of the need for separate DEA licenses in each state in which they practice.

CIVIL PENALTIES

In *U.S. v. Butterbaugh*, the government sued Dr. Barton Butterbaugh (“Butterbaugh”) for prescribing controlled substances without a Drug Enforcement Administration (“DEA”) registration in Washington State.¹ Butterbaugh was both an Arizona licensed physician and DEA registrant.² Through his employment with a Florida based company, eClinicMD, Butterbaugh volunteered to temporarily service patients in Washington after its Washington provider relocated to California.³ Between October 2010 and November 2012, Butterbaugh treated and prescribed medications to approximately 80 individuals in Washington.⁴ Prior to treating patients in Washington, Butterbaugh applied for and received a Washington medical license.⁵ However, he did not register with the DEA to dispense, administer, or distribute controlled substances in the state of Washington. During the 2 year period, Butterbaugh wrote over 1300 prescriptions for controlled substances for over 200 people.⁶

¹ *United States of America v. Barton Butterbaugh*, No. C14-515 TSZ, slip op. at 3 (W.D. Wash. Aug. 5, 2015) 2015 WL 4660096. See also, *Arizona Doctor Sued for Prescribing Controlled Substances without DEA Registration in Washington State*, U.S. DEP’T. OF JUSTICE (Apr. 8, 2014) <https://www.justice.gov/usao-wdwa/pr/arizona-doctor-sued-prescribing-controlled-substances-without-dea-registration>.

² *Id.* at p. 2-3.

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.* at p. 3.

In imposing a civil penalty,⁷ the District Court found Butterbaugh failed to comply with 21 U.S.C. sections 822(a)(2) and 822(e)(1) of the Controlled Substances Act (“CSA”), which requires that a person register with the DEA in each state that they dispense, administer or distribute a controlled substance in.⁸ The District Court reasoned that by employing both 21 U.S.C. sections 802(8) and (11) to define “distribute,” it meant the “actual, constructive, or attempted transfer of a controlled substance” other than by administering or dispensing.⁹ Thus, “because ‘prescription’ is not statutorily defined, a regulation provides that a prescription may be issued only by ‘an individual practitioner’ who is ‘[a]uthorized to prescribe controlled substances by the jurisdiction in which he [or she] is licensed to practice’ and is either registered with the DEA or exempt from registration. See 21 C.F.R. 1306.03(a).¹⁰ In that sense, “prescribing” is akin to “distributing” a controlled substance.

CRIMINAL PENALTIES

The Act also provides that it is unlawful for any person to knowingly or intentionally dispense a controlled substance in a manner not authorized under the Act. See 21 U.S.C. §841. Factors considered in cases against provider registrants, in which the DEA was involved, resulting in the arrest and prosecution of the registrant, include, but are not limited to: the controlled substance at issue, the crime alleged, whether the prescription was made for a valid medical purpose, and severity of outcome of the provider’s misconduct.

Further, under California’s Health and Safety Code §11157, a provider shall not issue a prescription that is false or fictitious in any respect. Violation of this section is deemed a misdemeanor under §11161(a). It is the responsibility of the provider to properly prescribe and dispense controlled substances. Anyone who knowingly violates §11157 shall be punished by imprisonment for one year or by a fine not exceeding \$20,000, or both. (Health & Safety Code § 11153 (a) – (b); Penal Code §1170.)

SEPARATE DEA LICENSE NEEDED FOR EACH STATE

Butterbaugh, like many providers in California, and nationally are at risk of civil penalties or prosecution if they prescribe controlled substances in a jurisdiction where they have not registered with the DEA or are not exempt from DEA registration. Although the final rule promulgated by the DEA clarifying registration requirements for individual practitioners went into effect on January 2, 2007,¹¹ many providers are unclear on what it means for their multi-state practice. It should be noted that the process of obtaining

⁷ The Act makes it unlawful for any provider to dispense a controlled substance in violation of any regulation relating to writing prescriptions and can subject any such provider to a penalty of up to \$25,000. See 21 U.S.C. § 842.

⁸ *Id.* at p. 8.

⁹ *Id.* at p. 7.

¹⁰ *Id.* at p. 7-8.

¹¹ *Clarification of Registration Requirements for Individual Practitioners*, U.S. DEP’T OF JUSTICE (2006), http://www.dea diversion.usdoj.gov/fed_regs/rules/2006/fr1201.htm.

DEA registration is the same regardless of what state a provider practices in, but for the purpose of this article, the state of California will be referenced.

For a provider that has a multi-state practice in California and another state(s), he/she¹² as an initial matter must be licensed to practice medicine in California and each of the other state(s) in which he/she has an office or location from which he/she practices medicine.¹³ Moreover, if the provider is prescribing controlled substances, then under the CSA, it must register the location¹⁴ with the DEA in California and each separate location in other state(s) that it prescribes from.¹⁵ Because DEA registration is tied to a provider's California license to practice medicine, (and a state medical license in general) having a DEA registration in California does not allow the provider to prescribe a controlled substance in offices located in other states where the provider does not hold both a medical license and DEA registration.¹⁶

EXEMPTIONS

The limited exceptions to the registration requirements are as follows:

- 1) Where a provider uses a hospital or clinical setting's DEA registration instead of registering with the DEA independently if the hospital or clinic agrees and the situation warrants it.¹⁷ 21 C.F.R. § 1301.22(c);

¹² *Practitioner's Manual – Section II*, U.S. DEP'T OF JUSTICE ("Under the CSA, the term 'practitioner' is defined as a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the practitioner practices or performs research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research. Every person or entity that handles controlled substances must be registered with DEA or be exempt by regulation from registration.")

<http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm> (2006).

¹³ See 21 U.S.C. § 822(a)(2) (2014) ("(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.")

¹⁴ However, a provider who registers at one location, but practices at others within the same state, is not required to register for the locations where he/she maintain offices at which he/she **only prescribe**, but do not administer or dispense, controlled substances.

(<http://www.deadiversion.usdoj.gov/drugreg/faq.htm#4>)

¹⁵ *Id.* See also, 21 U.S.C. § 822(e)(1) (2014) ("(1) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals."); See also, Registration Requirements, 21 U.S.C. § 823(f) (relating to the registration of Manufacturers, Distributors, and Dispensers of Controlled Substances).

¹⁶ *Clarification of Registration Requirements for Individual Practitioners*, *supra*, fn. 10.

¹⁷ Exemption of agents and employees; affiliated practitioners, 21 C.F.R. § 1302.22(c) ("An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself"). For example, a New York provider accepts a one-year fellowship working San Francisco Memorial Hospital treating underserved communities. The New York provider with, or without a DEA registration in

- 2) Where a provider decides to transfer their existing DEA registration in one state to another.¹⁸ 21 C.F.R. § 1301.51; and
- 3) Where providers prescribe controlled substances from multiple locations within the same state, need only register one location with the DEA.¹⁹ 21 C.F.R. § 1302.12(b)(3);

[Note from Donna: The first exception applies to in-person visits; the rules are different for remote / telepsychiatry treatment.]

In order to register with the DEA, a provider must apply using a DEA Form 224. Once approved, the DEA Certificate of Registration (DEA Form 223) must be maintained at the designated location and be made available for inspection upon request.

New York can seek permission from San Francisco Memorial Hospital to dispense, administer or distribute under the hospital's DEA registration number.

¹⁸ Modification in registration, 21 U.S.C. § 1301.51. For example, Dr. Jane Smith is DEA registered in the state of Michigan. Dr. Smith also has licenses to practice medicine in the states of California and Michigan. Dr. Smith receives an opportunity to join Candyland Hospital in California. Dr. Smith calls the DEA Registration and Program Support and requests a change in registration. Once approved, Dr. Smith will get a new DEA Certificate of Registration to use at her new place of practice.

¹⁹ Separate registrations for separate locations, 21 C.F.R. § 1302.12(b)(3) (“(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed: . . . (3) An office used by a practitioner (who is registered at another location in the same State or jurisdiction of the United States) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.”). For example, Dr. Meredith Blue has her own private practice in California in which she dispenses, administers, and distributes controlled substances. She has both a valid medical license and is DEA registered. In her spare time, Dr. Blue likes to volunteer at two different clinics, one in Westwood, and the other in Orange County. On some occasions, Dr. Blue has prescribed controlled substances from these locations. Dr. Blue's single registration with the DEA is sufficient because each location that she practices medicine in and on occasion, distributes, dispenses and administers controlled substances from, are in California.