

## Doctors With Multi-State Practices Beware: New DEA Regulation Could Affect You

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On January 2, 2007, an amendment to 21 C.F.R. § 1301(b)(12) went into effect. The amended § 1301(b)(12) revises the exception to the requirement of a separate registration for each place of business at which controlled substances are “manufactured, distributed, imported, exported, or dispersed by a person.” The new exception applies to:

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.

Prior to the amendment, arguably, a physician could prescribe in any state provided the physician held a Drug Enforcement Administration (DEA) registration in a single state. The DEA’s position is that the January 2, 2007, amendment clarifies that a “physician, dentist, or veterinarian” must maintain a separate DEA registration for each state in which he or she “prescribes” a controlled substance. Of course, the real question is what does this mean.

21 C.F.R. §1301.12(a) states:

A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

21 U.S.C. §802(21) defines a “practitioner” as follows:

The term “practitioner” means a physician, dentist, veterinarian, scientific in-

vestigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does 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.

21 U.S.C. §802(10) defines the term “dispense” as follows:

The term “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term “dispenser” means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

21 U.S.C. §802 defines the terms “deliver” or “delivery” as follows:

The terms “deliver” or “delivery” means the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

Courts have interpreted the mere writing of a prescription as “dispensing” (*United States v. Roy*, 574 F.2d 386, 393 [7th Cir. 1978]; *United States v. Tigag*, 551 F.2d 18, 19-20 [3rd Cir. 1977]). Thus in order to prescribe a controlled substance, a practitioner must register with the DEA. Under the DEA’s interpretation of this rule, the registration exception for prescribing is only effective intra-state.

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An exception to the requirement for a separate registration for each dispensing site solely for intra-state prescribing is provided by 21 C.F.R. §1301.12(b)(12), quoted above. In other words, a physician with a DEA registration associated with the physician's office in Cleveland, Ohio, can prescribe controlled substances throughout Ohio. (As discussed earlier, the prior iteration of this rule arguably allowed a physician who held a single registration, for example in Ohio, to prescribe in any state in the union.) Under the January 2, 2007, amendment, physicians who, for example, practice in Illinois and Indiana must now maintain a separate DEA registration in both states.

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Commentators raised concerns about the increased regulatory burden this would impose in comments to the proposed rule.<sup>1</sup> The DEA took the position in the comments to the revised rule that, "A DEA registration based on a particular State license cannot authorize dispensing controlled substances in another State." The DEA went on to state, "DEA recognizes that the requirement to

have separate DEA registrations for each State imposes a burden on practitioners who practice in multiple States."<sup>1</sup> Apparently, DEA is prepared to impose that burden.

The requirement for separate registration may also apply to physicians who are registered in one state, but issue prescriptions to persons who are located outside the state via telemedicine, the Internet, or other contact that does not involve a physical visit to the physician's office. Case law involving whether a person has sufficient contacts with a state in order to provide for personal jurisdiction would suggest that a practitioner providing a prescription over the phone or Internet to someone in another state is "dispensing" in both states. For example, DEA may claim that a doctor located in Florida prescribing for a patient located in Maine is prescribing in both Florida and Maine. If the practitioner did not have a DEA registration for both Florida and Maine, DEA may take the position he or she violated the amended rule. Physicians with multi-state practices should consult with their legal counsel to ensure they meet this new regulatory requirement. ■

**REFERENCE**

1. *Federal Register*; E-620334: 69478-69479.