DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–244P]

RIN 1117–AA89

Clarification of Registration Requirements for Individual Practitioners

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to amend its registration regulations to make it clear that when an individual practitioner who practices and is registered in one state seeks to practice and prescribe controlled substances in another state, he/she must obtain a separate DEA registration for the subsequent state. The current regulation was intended to apply to intrastate offices only, but has been misunderstood by some practitioners to apply to interstate offices. To avoid any further misinterpretation, DEA is proposing to modify its current regulation to indicate that it applies only to separate locations maintained within one state for which the practitioner possesses state licensure and DEA registration.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before February 7, 2005.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–244'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCD. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/CCD, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept electronic comments containing MS word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Purpose of This Proposed Rule

There is confusion regarding whether a practitioner who practices and is registered in one state and wishes to practice and prescribe in another state must register with DEA in the second state. DEA proposes to amend its regulations to make it clear that when an individual practitioner who practices and is registered in one state seeks to practice and prescribe controlled substances in another state, he/she must obtain a separate DEA registration for the subsequent state.

Background

The Controlled Substances Act (CSA) requires that a separate registration be obtained for each location at which controlled substances are manufactured, distributed, or dispensed (21 U.S.C. 822(e)). Under this requirement, an individual practitioner must have a separate DEA registration, predicated on a separate state license, if he/she practices in offices that are located in different states and administers, dispenses directly, or prescribes controlled substances from both offices. However, DEA has provided in the regulations (21 CFR 1301.12(b)(3)) that ''an office used by a practitioner (who is registered at another location) 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,'' is not a location for which a registration must be obtained. This regulation is intended to apply only to secondary locations within the same state in which the practitioner maintains his/her DEA registration. However, because the language in Section 1301.12(b)(3) does not specify that it pertains to intrastate locations only, individual practitioners have been applying the regulation to interstate situations, which is contrary to the intent of the regulation, the CSA, and the underlying principles that apply to individual practitioner registration.

State Licensure

The issuance by DEA of an individual practitioner registration is predicated, in part, on the practitioner being authorized (*e.g.* licensed) to dispense controlled substances by the state in which he/she practices (21 U.S.C. 823(f)). Valid state authority to dispense controlled substances is a necessary, but not sufficient, condition for obtaining a DEA registration. DEA will not register a practitioner at a particular location within a state if the practitioner lacks valid state authority to dispense controlled substances in that state. DEA registration serves, in part, to reflect that the individual practitioner has been granted some level of controlled substances authority by the state. In light of the above, a DEA registration is considered to be related directly and exclusively to the license issued to the practitioner by the state in which he/she maintains the registration.

Explanation of DEA Registration Predicated on State Authority

There are problems associated with use of a single DEA registration in different states. For instance, if a practitioner licensed in the State of North Carolina and possessing a DEA registration predicated on that state license subsequently opened an office in Virginia, then any controlled substance prescriptions he/she wrote in Virginia would be invalid for the following reason.

To be valid in a particular jurisdiction, a controlled substance prescription must be written by a practitioner who possesses valid state authority in that jurisdiction and, equally important, the practitioner must possess a DEA registration predicated upon valid state authority in that jurisdiction (or be exempted from the registration requirement) (21 CFR 1306.03(a)). In the example cited above, the practitioner possesses valid state authority in North Carolina and a DEA registration based upon that state authority. Therefore, the practitioner's controlled substance prescriptions would be valid in North Carolina. Because the practitioner lacks a DEA registration based on valid state authority in Virginia, the practitioner's controlled substance prescriptions in Virginia would be invalid.

Similarly, if an optometrist licensed in the State of Virginia and possessing a DEA registration predicated on said license subsequently opened an office in North Carolina prescribing oxycodone with acetaminophen (a Schedule II controlled substance) the prescription would be invalid. This is due to the fact that the DEA registration was issued pursuant to Virginia authority while the prescription was written based on North Carolina state licensure and authority.

North Carolina and Virginia authorize different levels of prescribing authority to optometrists. In Virginia, optometrists are only permitted to prescribe analgesics in Schedules III and IIIN, while in North Carolina optometrists are authorized to prescribe Schedules II through V controlled substances. Therefore, the prescription for oxycodone with acetaminophen would also be invalid due to the fact that Virginia authority is more restrictive than North Carolina's and does not allow the prescribing of Schedule II controlled substances by optometrists.

Title 21 U.S.C. 823(f) states that the Attorney General (as delegated to DEA) shall register practitioners to dispense controlled substances if the applicant is authorized to dispense the controlled substances under the laws of the state in which the applicant practices. Title 21 U.S.C. 841(a) prohibits any person from knowingly or intentionally dispensing a controlled substance except as permitted by the CSA. As previously stated, controlled substances may not be dispensed without state authorization to do so.

Reason for Modification of Existing Regulation

To avoid any further misinterpretation, DEA is proposing to modify its current regulation found in 21 CFR 1301.12(b)(3) by adding the words ''in the same state or jurisdiction of the United States'' to the parenthetical statement. This would make clear that the regulation applies only to separate locations maintained within one state for which the practitioner possesses state licensure and DEA registration. The practitioner must maintain separate state licensure and DEA registration for separate locations in a different state.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This proposed rule merely clarifies existing regulations regarding the registration by individual practitioners conducting business in more than one state.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). This rule has been determined to be a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget. This proposed rule merely clarifies existing regulations regarding the registration by individual practitioners conducting business in more than one state.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Paperwork Reduction Act

This Notice of Proposed Rulemaking merely clarifies that DEA registration must be obtained by practitioners for each state in which a practitioner conducts business, except under certain specific circumstances. While it is possible that the amendment of the regulations could cause certain persons who were not previously registered to register with the Administration, it is not possible for DEA to determine how many persons might be affected by this circumstance. It is important to note that this rule serves merely as a clarification; the Controlled Substances Act, which establishes the requirement of registration, has not been changed, and the requirement of registration addressed by this rulemaking remains consistent. Therefore, persons who would register as a result of publication of this clarification should have been previously registered with the Administration but were not registered due to confusion regarding registration requirements. Thus, at this time, as DEA is not able to determine the impact of this rulemaking on the registrant population, DEA will make any necessary revisions to the affected information collection at the time of renewal of the collection.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

For the reasons set forth above, 21 CFR 1301 is proposed to be amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 951, 952, 953, 956, 957.

2. Section 1301.12(b)(3) is proposed to be revised to read as follows:

§ 1301.12 Separate registrations for separate locations.

* * * * *

(b) * * *

(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.

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Dated: November 30, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

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