

"T.D. 01-86 extended by CBP Dec. 06-26".

Deborah J. Spero,

Acting Commissioner, Bureau of Customs and Border Protection.

Approved: November 27, 2006.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-244F]

RIN 1117-AA89

Clarification of Registration Requirements for Individual Practitioners

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its registration regulations to make it clear that when an individual practitioner practices in more than one State, he or she must obtain a separate DEA registration for each State. This amendment will make it easier for practitioners to understand the requirements of the Controlled Substances Act and its implementing regulations.

DATES: The rule is effective January 2, 2007.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA enforces the Controlled Substances Act (21 U.S.C. 801-971) (CSA), as amended. DEA publishes the implementing regulations for this statute in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to end. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical and scientific purposes and deter the diversion of controlled substances to illegal purposes. Controlled substances are drugs that have a potential for abuse and

psychological and physical dependence; these include substances classified as opiates, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances. DEA lists controlled substances in 21 CFR Part 1308. The substances are divided into five schedules: Schedule I substances have a high potential for abuse and have no accepted medical use in treatment in the United States. These substances may only be used for research, chemical analysis, or manufacture of other drugs. Schedule II-V substances have an accepted medical use and also have a potential for abuse and psychological and physical dependence.

The CSA mandates that DEA establish a closed system of control for manufacturing, distribution, and dispensing of controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt), keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.

Background

The CSA requires that a separate registration be obtained for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed (21 U.S.C. 822(e)). DEA has provided a limited exception to this requirement (21 CFR 1301.12(b)(3)): practitioners who register at one location, but practice at others within the same State, are not required to register for any other location in that State at which they only prescribe controlled substances. If they maintain supplies of controlled substances, administer, or directly dispense controlled substances at a location, they must register for that location (21 U.S.C. 823(f)).

The exception applies only to secondary locations within the same State in which the practitioner maintains his/her DEA registration. However, because the language in § 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. DEA individual practitioner registrations are based on a State license to practice medicine and prescribe controlled

substances. DEA relies on State licensing boards to determine that practitioners are qualified to dispense, prescribe or administer controlled substances and to determine what level of authority practitioners have, that is, what schedules they may dispense, prescribe, or administer. State authority to conduct the above-referenced activities only confers rights and privileges within the issuing State; consequently, the DEA registration based on a State license cannot authorize controlled substance dispensing outside the State.

To clarify the regulation, DEA issued a Notice of Proposed Rulemaking (NPRM) on December 7, 2004 (69 FR 70576), proposing to revise § 1301.12(b)(3) to make explicit that the exception from registration requirements is limited to other locations in the same State or jurisdiction of the United States, and seeking comments on the proposed revision.

Discussion of Comments

Nine commenters submitted comments on the proposed rule; all of the commenters were practitioners or represented practitioners.

General Objections. One physician stated that he had licenses in three States and asserted that because the licensed entity was the physician, it was contradictory to impose different Federal licenses on the same individual. Another commenter noted that practitioners are required to comply with State laws whether DEA issues a State-specific or a national registration.

Other commenters stated that requiring multiple registrations would result in physicians writing the wrong DEA number on prescriptions and in patients receiving unwarranted law enforcement scrutiny because they receive a prescription in one State and fill it in another. One pharmacist stated that multiple DEA registration numbers for practitioners would increase the burden on pharmacies. Two commenters stated that separate DEA registrations would make it difficult to mine data on pharmacy claims for Medicare, whose regions include more than one State; there would be no way to determine whether practitioners with the same name prescribing in multiple States are the same person. The commenters stated that holding multiple DEA registrations would hinder attempts to identify excessive prescribing of controlled substances. One commenter suggested registering each practice site, collecting fees for each State, but using a single DEA number. Another commenter stated the

system is contrary to efforts to move toward a uniform and centralized health care information system. The commenter stated that the proposed Department of Health and Human Services National Health Information Network would include prescription information, including the registration number under which the prescription was issued; requiring the system to recognize multiple registrations for a practitioner would introduce unnecessary complexity into the system.

Two commenters believed that requiring registrations for separate States would increase their costs. One commenter stated that he could not recoup the cost of registering more than one location through reimbursement fees or other charges passed on to patients.

DEA Response: As mandated in the CSA, DEA issues registrations based on the State license to practice medicine and dispense controlled substances. Section 823(f) of Title 21, U.S. Code, states that DEA shall register a practitioner to dispense controlled substances if the applicant is authorized to dispense controlled substances under the laws of the State in which the applicant practices. Just as a license to practice medicine in one State does not authorize a practitioner to practice in any other State, a DEA registration based on a particular State license cannot authorize dispensing controlled substances in another State. As DEA pointed out in the NPRM, different States may provide a practitioner with different prescribing authority; State medical licenses may be suspended or revoked in one State, but not another. A single DEA registration would, in effect, divorce the DEA registration from State authorizations. Although, as one commenter noted, practitioners have separate legal obligations under State laws, separate DEA registrations provide a means of taking action against those practitioners who ignore their State authorizations and whose licenses are suspended or revoked in a single State. In addition, linking the DEA registration to State authority allows pharmacies to rely on the DEA registration to determine whether the prescriber is authorized to issue a controlled substance prescription in the State. If the DEA registration was not based on authority from a specific State, the burden on pharmacies to verify the eligibility of practitioners to authorize prescriptions would increase significantly.

DEA recognizes that the requirement to have separate DEA registrations for each State imposes a burden on practitioners who practice in multiple

States. However, DEA notes that it received only nine comments from practitioners or their representatives; currently, DEA has almost 1.1 million practitioner registrants. This may indicate that most practitioners operating in multiple States already hold appropriate DEA registrations.

DEA also recognizes that multiple registrations make it difficult to use prescription records to identify practitioners who may be overprescribing. That problem, however, is not unique to those operating in multiple States. Under the CSA, practitioners who administer or directly dispense controlled substances must maintain a separate DEA registration at each location where they handle controlled substances. Consequently, many practitioners already hold multiple DEA registrations even when they practice within a single State. DEA currently has almost 1.1 million practitioner registrants; based on the number of practitioners in the United States, it is likely that at least 200,000 registrants have multiple DEA registrations. Although this may create problems for databases and other healthcare information systems, the CSA requires this approach to maintain control over the dispensing of controlled substances.

The CSA requires persons handling controlled substances in more than one State to be registered with the DEA in each State in which they practice. The CSA also requires DEA to recover the full costs of the Diversion Control Program through registration and reregistration application fees. Thus, DEA must abide by its statutory mandates by collecting registration fees for each registered location.

Locum Tenens: Three commenters raised the issue of multiple registrations for practitioners who serve as locum tenens practitioners in multiple States. They stated that adding separate DEA registrations for each of the States would be confusing and costly.

DEA Response: The revision of the regulation will not affect DEA's approach on locum tenens practitioners. DEA will be addressing policies regarding locum tenens practitioners in other documents to be published in the **Federal Register**.

Other Issues: Several commenters noted that they practice close to State borders and see patients who live in other States. One commenter asked if a practitioner would need a separate registration if the patients were from another State. Two commenters asked if a practitioner's prescription could legally be filled in another State. One commenter asked if he needed multiple

registrations in a single State if he administers controlled substances in two locations.

DEA Response: A practitioner must have a DEA registration for any State in which he or she is dispensing (including prescribing) controlled substances. A practitioner must have a separate registration for each location at which he or she stores, administers, or directly dispenses controlled substances.

Summary

The CSA requires that a separate registration be obtained for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed (21 U.S.C. 822(e)). DEA has historically provided an exception that a practitioner who is registered at one location, but also practices at other locations, is not required to register separately for any other location at which controlled substances are only prescribed (21 CFR 1301.12(b)(3)). If the practitioner maintains supplies of controlled substances, administers, or directly dispenses controlled substances at the separate location the practitioner must register for that location. The exception applies only to a secondary location within the same State in which the practitioner maintains his/her registration. DEA individual practitioner registrations are based on State authority to practice medicine and prescribe controlled substances. Since a DEA registration is based on a State license, it cannot authorize controlled substance dispensing outside that State. Hence, the separate registration exception applies only to locations within the same State in which practitioners have their DEA registrations.

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 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 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 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 in a State to register with DEA, 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 register as a result of publication of this clarification should have been previously registered with DEA, 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 \$118,000,000 or more in any one year, and will not significantly or uniquely affect small

governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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 part 1301 is 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 is amended by revising paragraph (b)(3) 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: October 21, 2006.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E6-20334 Filed 11-30-06; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This rule amends Appendix D to the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans by adding the maximum guaranteeable pension benefit that may be paid by the PBGC with respect to a plan participant in a single-employer pension plan that terminates in 2007. The amendment is necessary because the maximum guarantee amount changes each year, based on changes in the contribution and benefit base under section 230 of the Social Security Act. The effect of the amendment is to advise plan administrators, participants and beneficiaries of the increased maximum guarantee amount for 2007.

DATES: *Effective Date:* January 1, 2007.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024. (TTY/TDD users may call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

SUPPLEMENTARY INFORMATION: Section 4022(b) of the Employee Retirement Income Security Act of 1974 provides for certain limitations on benefits guaranteed by the PBGC in terminating single-employer pension plans covered under Title IV of ERISA. One of the limitations, set forth in section 4022(b)(3)(B), is a dollar ceiling on the amount of the monthly benefit that may be paid to a plan participant (in the form of a life annuity beginning at age 65) by the PBGC. The ceiling is equal to "\$750 multiplied by a fraction, the numerator of which is the contribution and benefit base (determined under section 230 of the Social Security Act) in effect at the time the plan terminates and the denominator of which is such contribution and benefit base in effect in calendar year 1974 [\$13,200]." This formula is also set forth in § 4022.22(b) of the PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022). Appendix D to Part 4022 lists, for each year beginning with 1974, the maximum guaranteeable benefit payable by the