

5. Technical reports and evaluations of any prototype ROVs with enhanced safety designs.

6. Technical information on ROV/vehicle design specific to vehicle handling (e.g., suspension design and the use of sway bars).

7. Minimum and maximum track width considerations in ROV design.

8. Minimum and maximum ground clearance considerations in ROV design.

9. Minimum and maximum speed considerations in ROV design.

10. Information on the center of gravity heights of occupied and unoccupied ROV models currently on the market.

11. Information about the applicability of sensor technology to improve the safety of ROVs.

12. Technical information on technologies for increasing seat belt use.

13. Technical information on technologies for increasing the performance of seat belts.

14. Technical studies and evaluations of three-point, four-point, and five-point seat belts.

15. Technical information on ROPS design as it pertains to ground impact footprint and potential crushing injuries to the occupant.

16. Information on test procedures to evaluate occupant retention and protection performance during roll over.

17. Information on how non-fatal injuries associated with ROVs compare with those associated with ATVs in terms of severity and type of injury.

List of Relevant Documents

1. Briefing memorandum from Caroleene Paul, Project Manager, Directorate for Engineering Sciences, to the Commission, "Advance Notice of Proposed Rulemaking (ANPR) for Recreational Off-Highway Vehicles (ROVs)," September 25, 2009.

2. Memorandum from Caroleene Paul, Division of Mechanical Engineering, CPSC, to Robert J. Howell, Assistant Executive Director for Hazard Identification and Reduction, "Recreational Off-Highway Vehicles (ROVs)," September 25, 2009.

3. Memorandum from Sarah Garland, Mathematical Statistician, Division of Hazard Analysis, CPSC, and Robin Streeter, Mathematical Statistician, Division of Hazard Analysis, CPSC, to Caroleene Paul, Project Manager, Directorate for Engineering Sciences, "Review of Reported Injuries and Fatalities Associated with Recreational Off-Highway Vehicles (ROVs)," September 2009.

4. Memorandum from Robert Franklin, Economist, Directorate for Economic Analysis, CPSC, to Caroleene

Paul, Project Manager, Directorate for Engineering Sciences, "Recreational Off-Highway Vehicles: Market Information," September 25, 2009.

Dated: October 22, 2009.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

[FR Doc. E9-25959 Filed 10-27-09; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-324a]

RIN 1117-AB21

Registration Requirements for Individual Practitioners Operating in a "Locum Tenens" Capacity

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

ACTION: Advance notice of proposed rulemaking.

Summary: On December 1, 2006, the Drug Enforcement Administration (DEA) published in the **Federal Register** a Final Rule "Clarification of Registration Requirements for Individual Practitioners" (71 FR 69478). The Final Rule makes 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. The Final Rule also noted that DEA would address its policy regarding locum tenens practitioners in a separate future document. To adequately address this issue, DEA is publishing this Advance Notice of Proposed Rulemaking to seek information useful to the agency in promulgating regulations regarding locum tenens practitioners.

DATES: Written comments must be postmarked on or before December 28, 2009, and electronic comments must be sent on or before midnight Eastern time December 28, 2009.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-324" on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152. Comments may be sent to DEA 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 attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes because <http://www.regulations.gov> terminates the public's ability to submit comments at midnight Eastern Time on the day the comment period closes. Commenters in time zones other than Eastern Time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; telephone: (202) 307-7297.

SUPPLEMENTARY INFORMATION: *Posting of Public Comments:* Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph

of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

DEA's Legal Authority

DEA implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA), (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes 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 medical, scientific, and other legitimate purposes and to 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 opioids, 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, dispensed, or otherwise disposed of.

Background

The CSA defines "dispense" as meaning "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 * * *" (21 U.S.C. 802(10)). The CSA requires that every person who dispenses controlled substances shall obtain from the Attorney General a registration (21 U.S.C. 822(a)(2)). Authority to issue such registrations has been delegated by the Attorney General to the Administrator of the Drug Enforcement Administration (28 CFR 0.100). DEA has established, by regulation, that the period of registration for persons who dispense controlled substances is three years (21 CFR 1301.13(e)(iv)).

The CSA states that the Attorney General shall register practitioners to dispense controlled substances if the applicant for registration is authorized to dispense controlled substances under the laws of the State in which the applicant practices (21 U.S.C. 823(f)). The Attorney General may deny an application for registration if he determines that the issuance of registration would be inconsistent with the public interest. In determining the public interest, the Attorney General is required to consider the following factors:

- (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.
- (5) Such other conduct which may threaten the public health and safety. (21 U.S.C. 823(f))

The CSA further 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 other locations within the same State,

are not required to register for any other location in that State at which they only prescribe controlled substances.

The exception applies only to additional locations within the same State in which the practitioner maintains his DEA 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 administer, dispense, or prescribe controlled substances and to determine what level of authority practitioners have, that is, what schedules they may administer, dispense, or prescribe. 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.

DEA discussed the intrastate exception extensively in a Notice of Proposed Rulemaking "Clarification of Registration Requirements for Individual Practitioners" [Docket No. DEA–244, RIN 1117–AA89] (69 FR 70576, December 7, 2004) and in a subsequent Final Rule (71 FR 69478, December 1, 2006). This rule clarified that the exception discussed above related only to *intrastate*, as opposed to *interstate*, locations.

Locum Tenens Practitioners

DEA received three comments to its December 7, 2004, Notice of Proposed Rulemaking requesting clarification of the effect of that rule on the practice of "locum tenens" practitioners. Locum tenens is a procedure whereby someone substitutes temporarily for another. Latin for "to hold the place of, to substitute for," locum tenens means, in layman's terms, a temporary physician or other practitioner. Usually, locum tenens practitioners contract with a staffing company to perform medical services for a healthcare organization for a specified length of time. The practitioner is paid by the staffing firm itself, which is then paid by the healthcare facility, *i.e.*, the client.

Groups supportive of locum tenens indicate that the practice of locum tenens benefits both practitioners and healthcare organizations because it provides flexibility for both parties. They note that the industry offers temporary opportunities for medical professionals across the country and worldwide. DEA has found one estimate indicating that there are over 100 locum tenens agencies operating in the United States and over 30,000 locum tenens practitioners. The practitioners in

demand are hospital-based specialties including anesthesiology, psychiatry, radiology, pediatrics, and surgery.

The CSA does not specifically reference or acknowledge the practice of locum tenens. DEA regulations do make clear that under 21 CFR 1301.12(a), "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, or dispensed by a person." When a locum tenens practitioner substitutes for another practitioner on a temporary or sporadic basis at that other practitioner's [DEA registered] place of business, that place of business is considered by DEA to be a "principal place of business or professional practice" for purposes of the locum tenens practitioner's DEA registration (21 CFR 1301.12(a)).

Since DEA individual practitioner registrations are based on State authority to practice and prescribe controlled substances, a practitioner is not authorized to dispense controlled substances outside the State(s) in which he or she is licensed and registered. Therefore, any locum tenens practice that is conducted in a State other than the State in which the practitioner maintains his DEA registration is subject to a separate DEA registration.

DEA believes that two alternatives presently exist to obtain a separate DEA registration in another State to accommodate a locum tenens practice. First, if the practitioner is licensed to practice and to handle controlled substances in that second state, he may submit an address change for his current DEA registration for the temporary practice location. There is no cost to change an address, even temporarily, and it generally takes one week to process. At the end of the locum tenens practice, the practitioner may submit a request to change his address to his new primary place of business, within the same state.

Second, if the locum tenens service is with a hospital or other institution registered with DEA, if the hospital agrees, and if State law allows, the practitioner may use the DEA registration of that hospital or other institution to administer, dispense, or prescribe controlled substances so long as all requirements are met (21 CFR 1301.22(c)). Specifically:

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 himself, provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he is practicing;

(3) The hospital or other institution by whom he is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his employment in the hospital or institution;

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. (21 CFR 1301.22(c))

This waiver places the controlled substance registration and recordkeeping responsibility with the hospital or other institution; therefore, there is no need for individual DEA registration. However, the individual practitioner must still maintain State licensure.

State Regulations

As DEA discussed in its proposed and final rules regarding the clarification of registration by individual practitioners (69 FR 70576, December 7, 2004; 71 FR 69478, December 1, 2006), 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 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

maintains the registration. These principles are discussed extensively in DEA's proposed and final rules referenced above.

While DEA is aware that a few States have legislation or regulations regarding the locum tenens industry, DEA does not believe that the information it has regarding States' legislation and/or regulations is complete. DEA notes that States may address locum tenens under general legislative authority and through a variety of State regulatory entities, including State boards of medicine and State licensing commissions. Therefore, as discussed further below, DEA is specifically seeking information from State regulatory authorities regarding States' legislative and/or regulatory requirements for locum tenens practitioners, agencies, and entities that contract with these persons.

Comments Requested

DEA is soliciting information from the locum tenens industry so that DEA may obtain a better understanding of this industry and how it functions. DEA seeks to clarify the requirements that apply to locum tenens practitioners, especially after considering the December 2006 final rule that specified that only intrastate locations are subject to the exception for registration at separate locations. Commenters are encouraged to include the comment number enumerated below in their response. Although all comments are welcome, DEA is particularly interested in comments regarding the questions listed below. These questions are separated into groups by area of interest. The groups are:

- Locum tenens practitioners
- Those that employ and place locum tenens practitioners
- Institutions that retain the services of locum tenens practitioners
- State regulatory authorities

Locum Tenens Practitioners

1. In your experience, what types of practitioners participate in locum tenens activities (e.g., physicians, dentists, nurse practitioners)? Please specify your type of licensure.

2. How long is the typical locum tenens assignment?

3. Do locum tenens practitioners seek State/Federal licensure or registration prior to accepting a position as a locum tenens practitioner?

4. What is the length of time between hiring for the position and reporting to duty?

5. Do practitioners secure locum tenens positions independently or through an agency?

6. As locum tenens practitioners, do you administer, dispense and prescribe controlled substances? Does your authority to do so vary in the States in which you practice?

7. Can you have more than one locum tenens job at a time?

Those That Employ and Place Locum Tenens Practitioners

8. What role do you have in the locum tenens process?

9. Do you assist with State and Federal licensure/registration? If so, how?

10. What types of practitioners do you employ or place (e.g., physicians, dentists, nurse practitioners)?

11. How do you verify the locum tenens practitioner's credentials?

12. Are criminal background checks performed on locum tenens practitioners?

13. What is the geographical coverage for locum tenens (e.g., local, statewide, multi-state, national)?

14. How much time is there between assignments for one practitioner?

Institutions That Retain the Services of Locum Tenens Practitioners

15. How many locum tenens placement agencies do you contract with?

16. How frequently do you secure locum tenens services?

17. What credentialing checks do you perform on the locum tenens practitioners working for you? Do you perform fewer checks for practitioners supplied by agencies than you do for practitioners you contract with individually?

18. For how long do you secure locum tenens services (i.e., duration)?

19. For what specialties do you use locum tenens practitioners?

20. What authority do you grant locum tenens practitioners? (For example, can they administer, dispense, or prescribe controlled substances? Under whose DEA registration would such an activity occur?)

21. Do you grant locum tenens practitioners the same controlled substance authority that other practitioners using the institution's DEA registration to dispense controlled substances have? If not, why not?

State Regulatory Authorities

22. What are the State requirements for locum tenens practice for practitioners (e.g., physicians, dentists)?

23. Does the State waive State medical licensure (or automatically grant temporary courtesy licensure) for locum tenens practitioners if they are properly licensed in another State? If so, what

checks are performed to confirm State licensure in the other State?

24. If granted, for how long is the waiver or courtesy licensure?

25. What are the State requirements for locum tenens practice for mid-level practitioners (e.g., physician assistants, nurse practitioners)?

26. Does the State waive State licensure (or automatically grant temporary courtesy licensure) for locum tenens practitioners who are mid-level practitioners if they are properly licensed in another State? If so, what checks are performed to confirm State licensure in the other State?

27. If granted, for how long is the waiver or courtesy licensure?

28. If the State requires State licensure with the medical or other professional board, how long is it good for?

29. Does the State grant locum tenens practitioners the same controlled substance authority that it grants to practitioners that are fully licensed by the State professional board? If not, why not?

30. To dispense controlled substances, must a locum tenens practitioner obtain a State controlled substance registration?

31. Does the State medical or other professional board report board actions against locum tenens practitioners to the National Practitioner database and to States in which the locum tenens practitioner holds a license?

Regulatory Certifications

This action is an Advance Notice of Proposed Rulemaking (ANPRM). Accordingly, the requirement of Executive Order 12866 to assess the costs and benefits of this action does not apply. Rather, among the purposes DEA has in publishing this ANPRM is to seek information from the public regarding locum tenens practitioners. Similarly, the requirements of section 603 of the Regulatory Flexibility Act do not apply to this action since, at this stage, it is an ANPRM and not a "rule" as defined in section 601 of the Regulatory Flexibility Act. Following review of the comments received to this ANPRM, if DEA promulgates a Notice or Notices of Proposed Rulemaking regarding this issue, DEA will conduct all analyses required by the Regulatory Flexibility Act, Executive Order 12866, and any other statutes or Executive Orders relevant to those rules and in effect at the time of promulgation.

Dated: October 21, 2009.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E9-25937 Filed 10-27-09; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-331]

Schedules of Controlled Substances: Placement of 5-Methoxy-N,N-Dimethyltryptamine Into Schedule I of the Controlled Substances Act

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

ACTION: Notice of proposed rulemaking; reopening of comment period.

SUMMARY: On August 21, 2009, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking in the **Federal Register**, 74 FR 42217, to place the substance 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) and its salts into schedule I of the Controlled Substances Act (CSA). The original 30-day comment period expired on September 21, 2009. DEA is reopening the comment period for an additional 30-day period.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before November 27, 2009. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-331" on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152. Comments may be sent to DEA 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 Microsoft Word, WordPerfect, Adobe PDF, or Excel files only. DEA will not accept any file format other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern time on the day the comment period closes because