

MEDICAL CONTROLLED SUBSTANCES TRANSPORTATION
ACT OF 2017

JUNE 23, 2017.—Committed to the Committee of the Whole House on the State of
the Union and ordered to be printed

Mr. WALDEN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 1492]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1492) to amend the Controlled Substances Act to direct the Attorney General to register practitioners to transport controlled substances to States in which the practitioner is not registered under the Act for the purpose of administering the substances (under applicable State law) at locations other than principal places of business or professional practice, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

The bill would amend the Controlled Substances Act (CSA) to authorize a practitioner, who is registered under section 303(f) of the CSA, to transport and administer controlled substances to patients outside of the State in which they are registered under subsection (f) at locations other than a principal place of business or professional practice. In order to do so, the practitioner would need to have a separate registration issued by the Drug Enforcement Administration (DEA) pursuant to section 303(k), as added by this bill, and meet a number of conditions.

BACKGROUND AND NEED FOR LEGISLATION

The CSA currently prohibits the transportation and administration of controlled substances away from the location registered with DEA. Therefore, the statute does not permit registered practitioners with inherently mobile practices, such as emergency medical services personnel traveling to a disaster area, to transport and administer pain or anti-seizure medication. This legislation would establish a separate registration process at DEA to authorize such transportation and administration while providing for appropriate oversight.

COMMITTEE ACTION

The Committee on Energy and Commerce has not held hearings on the legislation, though a previous version of the bill was the subject of a hearing during the 114th Congress and was favorably reported to the House by a voice vote.

On June 7, 2017, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 1492 favorably reported to the House, without amendment, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 1492 reported.

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee has not held hearings on this legislation.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 1492 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to establish a registration process at DEA to allow practitioners to transport and administer controlled substances at locations other than their principal place of business or professional practice under certain conditions.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 1492 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 1492 contains no earmarks, limited tax benefits, or limited tariff benefits.

DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the Committee finds that H.R. 1492 contains no directed rule makings.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the “Medical Controlled Substances Transportation Act of 2017”.

Section 2. Registration for transport of controlled substances to states in which the practitioner is not registered under the Controlled Substances Act for the purpose of administering the substances at locations other than principal places of business or professional practice

Section 2 would amend section 303 of the CSA by adding a new subsection (k) that would authorize DEA, upon application by a practitioner who is registered under subsection (f), to issue a separate registration authorizing the practitioner to transport controlled substances from the practitioner's registered location for the purpose of administering the substances at locations other than a principal place of business or professional practice.

In order for a practitioner to transport and administer controlled substances pursuant to this registration, the practitioner must be licensed, registered, or otherwise permitted by the State in which the substances are administered to carry out such activity at the location where it occurs. In addition, the practitioner must limit the time of transport to not more than 72 consecutive hours and return any such substances not administered to their registered location from which they were obtained. Further, the practitioner must maintain records of the transporting and administering. DEA would maintain the authority to deny or revoke a registration.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

* * * * *

TITLE II—CONTROL AND ENFORCEMENT

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

REGISTRATION REQUIREMENTS

SEC. 303. (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such con-

trolled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 306.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(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.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately

safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a). Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this title.

(g)(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 307) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

- (II) appropriate counseling and other appropriate ancillary services.
- (iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.
- (II) The applicable number is 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients.
- (III) The Secretary may by regulation change such applicable number.
- (IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.
- (C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:
- (i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.
- (ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.
- (D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:
- (I) The notification under subparagraph (B) is in writing and states the name of the practitioner.
- (II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).
- (III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).
- (ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).
- (iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall

make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term “group practice” has the meaning given such term in section 1877(h)(4) of the Social Security Act.

(ii) The term “qualifying physician” means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

- (aa) opioid maintenance and detoxification;
- (bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;
- (cc) initial and periodic patient assessments (including substance use monitoring);
- (dd) individualized treatment planning, overdose reversal, and relapse prevention;
- (ee) counseling and recovery support services;
- (ff) staffing roles and considerations;
- (gg) diversion control; and
- (hh) other best practices, as identified by the Secretary.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(iii) The term “qualifying practitioner” means—

- (I) a qualifying physician, as defined in clause (ii); or

- (II) during the period beginning on the date of enactment of the Comprehensive Addiction and Recovery Act of 2016 and ending on October 1, 2021, a qualifying other practitioner, as defined in clause (iv).
- (iv) The term “qualifying other practitioner” means a nurse practitioner or physician assistant who satisfies each of the following:
- (I) The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.
 - (II) The nurse practitioner or physician assistant has—
 - (aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or
 - (bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner or physician assistant to treat and manage opiate-dependent patients.
 - (III) The nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

- (I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.
- (II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.
- (III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

(I) Notwithstanding section 708, nothing in this paragraph shall be construed to preempt any State law that—

(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 102(39)(A). In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the appli-

cant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.

(j) In this section, the phrase “factors as may be relevant to and consistent with the public health and safety” means factors that are relevant to and consistent with the findings contained in section 101.

(k) REGISTRATION FOR TRANSPORT OF CONTROLLED SUBSTANCES TO STATES IN WHICH THE PRACTITIONER IS NOT REGISTERED FOR THE PURPOSE OF ADMINISTERING THE SUBSTANCES AT LOCATIONS OTHER THAN PRINCIPAL PLACES OF BUSINESS OR PROFESSIONAL PRACTICE.—

(1) IN GENERAL.—Upon application by a practitioner (other than a pharmacy) who is registered under subsection (f), the Attorney General shall issue a separate registration to the practitioner authorizing the practitioner—

(A) to transport one or more controlled substances in schedule II, III, IV, or V from the practitioner’s registered location in a State to one or more States in which the practitioner is not registered under subsection (f) for the purpose of the practitioner administering the substances at locations other than a principal place of business or professional practice; and

(B) to so administer the substances.

(2) REQUIREMENTS.—For a practitioner to be authorized to transport and administer controlled substances pursuant to a registration issued under paragraph (1), all of the following conditions must be satisfied:

(A) The practitioner must be licensed, registered, or otherwise permitted by the State in which the controlled substances are administered to carry out such activity at the location where it occurs.

(B) The practitioner must—

(i) limit the time of transport and administering of any controlled substance pursuant to such registration to not more than 72 consecutive hours; and

(ii) by the conclusion of such 72 hours, return any such controlled substance so transported but not administered to the registered location from which such substance was obtained.

(C)(i) The practitioner must maintain records of the transporting and administering of any controlled substance pursuant to this subsection.

(ii) Such records shall be maintained, in accordance with the requirements of section 307(b), at the practitioner’s registered location from which the controlled substances were obtained and shall include—

(I) the location where the controlled substance was administered; and

(II) such other information as may be required by regulation of the Attorney General with respect to records for dispensers of controlled substances.

(iii) *Notwithstanding clause (ii), the exception in subsection 307(c)(1)(B) shall not apply to records required by this subparagraph.*

(3) *GROUNDS FOR DENIAL OR REVOCATION.—The Attorney General may deny an application for registration under this subsection, or a renewal thereof, or revoke such registration, based on the criteria listed in section 304(a), except that the applicant shall not be required, as a condition of initially obtaining such registration, to present proof of State authorization to administer controlled substances.*

(4) *AUTOMATIC TERMINATION.—A registration issued under this subsection shall automatically terminate if the practitioner no longer has an active registration under subsection (f) due to revocation, suspension, surrender, or other termination.*

(5) *DEFINITION.—In this subsection, the term “registered location” means, with respect to each registration issued to a practitioner under subsection (f), the address that appears on the certificate of registration.*

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