(2) a manufacturer, distributor, or reverse distributor of prescription medications;

(3) a retail pharmacy;

(4) a registered narcotic treatment program;

(5) a hospital or clinic with an onsite pharmacy;

(6) an eligible long-term care facility; or

(7) any other entity authorized by the Drug Enforcement Administration to dispose of prescription medications.

(b) Program authorized

The Attorney General, in coordination with the Administrator of the Drug Enforcement Administration, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, shall coordinate with covered entities in expanding or making available disposal sites for unwanted prescription medications.

(Pub. L. 114–198, title II, § 203, July 22, 2016, 130 Stat. 717.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Controlled Substances Act which comprises this subchapter.

Statutory Notes and Related Subsidiaries

ACCESS TO INCREASED DRUG DISPOSAL

Pub. L. 115–271, title III, subtitle B, ch. 6, Oct. 24, 2018, 132 Stat. 3950, provided that:

''SEC. 3251. SHORT TITLE.

''This chapter may be cited as the 'Access to Increased Drug Disposal Act of 2018'.

''SEC. 3252. DEFINITIONS.

''In this chapter—

''(1) the term 'Attorney General' means the Attorney General, acting through the Assistant Attorney General for the Office of Justice Programs;

''(2) the term 'authorized collector' means a narcotic treatment program, a hospital or clinic with an on-site pharmacy, a retail pharmacy, or a reverse distributor, that is authorized as a collector under section 1317.40 of title 21, Code of Federal Regulations (or any successor regulation);

''(3) the term 'covered grant' means a grant awarded under section 3003 [probably means section 3253; no section 3003 of Pub. L. 115–271 has been enacted]; and

''(4) the term 'eligible collector' means a person who is eligible to be an authorized collector.

''SEC. 3253. AUTHORITY TO MAKE GRANTS.

''The Attorney General shall award grants to States to enable the States to increase the participation of eligible collectors as authorized collectors.

''SEC. 3254. APPLICATION.

''A State desiring a covered grant shall submit to the Attorney General an application that, at a minimum—

''(1) identifies the single State agency that oversees pharmaceutical care and will be responsible for complying with the requirements of the grant;

''(2) details a plan to increase participation rates of eligible collectors as authorized collectors; and

''(3) describes how the State will select eligible collectors to be served under the grant.

''SEC. 3255. USE OF GRANT FUNDS.

''A State that receives a covered grant, and any subrecipient of the grant, may use the grant amounts only for the costs of installation, maintenance, training, purchasing, and disposal of controlled substances associated with the participation of eligible collectors as authorized collectors.

''SEC. 3256. ELIGIBILITY FOR GRANT.

''The Attorney General shall award a covered grant to 5 States, not less than 3 of which shall be States in the lowest quartile of States based on the participation rate of eligible collectors as authorized collectors, as determined by the Attorney General.

''SEC. 3257. DURATION OF GRANTS.

''The Attorney General shall determine the period of years for which a covered grant is made to a State.

''SEC. 3258. ACCOUNTABILITY AND OVERSIGHT.

''A State that receives a covered grant shall submit to the Attorney General a report, at such time and in such manner as the Attorney General may reasonably require, that—

''(1) lists the ultimate recipients of the grant amounts;

''(2) describes the activities undertaken by the State using the grant amounts; and

''(3) contains performance measures relating to the effectiveness of the grant, including changes in the participation rate of eligible collectors as authorized collectors.

''SEC. 3259. DURATION OF PROGRAM.

''The Attorney General may award covered grants for each of the first 5 fiscal years beginning after the date of enactment of this Act [Oct. 24, 2018].

''SEC. 3260. AUTHORIZATION OF APPROPRIATIONS.

''There is authorized to be appropriated to the Attorney General such sums as may be necessary to carry out this chapter.''

§ 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

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 May 1, 1971. 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 controlled 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) Distributors of controlled substances in schedule I or II

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 control 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) Manufacturers of marijuana for research purposes

(1)(A) As it relates to applications to manufacture marijuana for research purposes, when the Attorney General places a notice in the Federal Register to increase the number of entities registered under this chapter to manufacture marijuana to supply appropriately registered researchers in the United States, the Attorney General shall, not later than 60 days after the date on which the Attorney General receives a completed application—

(i) approve the application; or

(ii) request supplemental information.

(B) For purposes of subparagraph (A), an application shall be deemed complete when the applicant has submitted documentation showing each of the following:

(i) The requirements designated in the notice in the Federal Register are satisfied.

(ii) The requirements under this chapter are satisfied.

(iii) The applicant will limit the transfer and sale of any marijuana manufactured under this subsection—

(I) to researchers who are registered under this chapter to conduct research with controlled substances in schedule I; and

(II) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under 355(i)[1] of this title.

(iv) The applicant will transfer or sell any marijuana manufactured under this subsection only with prior, written consent for the transfer or sale by the Attorney General.

(v) The applicant has completed the application and review process under subsection (a) for the bulk manufacture of controlled substances in schedule I.

(vi) The applicant has established and begun operation of a process for storage and handling of controlled substances in schedule I, including for inventory control and monitoring security in accordance with section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act.

(vii) The applicant is licensed by each State in which the applicant will conduct operations under this subsection, to manufacture marijuana, if that State requires such a license.

(C) Not later than 30 days after the date on which the Attorney General receives supplemental information requested under subparagraph (A)(ii) with respect to an application, the Attorney General shall approve or deny the application.

(2) If an application described in this subsection is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.

(d) Limits of authorized activities

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 826 of this title.

(e) Manufacturers of controlled substances in schedule III, IV, or V

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.

(f) Distributors of controlled substances in schedule III, IV, or V

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 pub-

[1] So in original. Probably should be preceded by ''section''.

lic 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.

(g) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

(1) 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:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) 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.

(2)(A) 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 824(a) of this title.

(B)(i) The Attorney General shall register a practitioner to conduct research with marijuana (including any derivative, extract, preparation, and compound thereof) if—

(I) the applicant's research protocol has been reviewed and allowed—

(aa) by the Secretary of Health and Human Services under section 355(i) of this title;

(bb) by the National Institutes of Health or another Federal agency that funds scientific research; or

(cc) pursuant to sections 1301.18 and 1301.32 of title 21, Code of Federal Regulations, or any successors thereto; and

(II) the applicant has demonstrated to the Attorney General that there are effective procedures in place to adequately safeguard against diversion of the controlled substance for legitimate medical or scientific use pursuant to section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act, including demonstrating that the security measures are adequate for storing the quantity of marijuana the applicant would be authorized to possess.

(ii) The Attorney General may deny an application for registration under this subparagraph only if the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the Attorney General shall consider the factors listed in—

(I) subparagraphs (B) through (E) of paragraph (1); and

(II) subparagraph (A) of paragraph (1), if the applicable State requires practitioners conducting research to register with a board or authority described in such subparagraph (A).

(iii)(I) Not later than 60 days after the date on which the Attorney General receives a complete application for registration under this subparagraph, the Attorney General shall—

(aa) approve the application; or

(bb) request supplemental information.

(II) For purposes of subclause (I), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under clause (i) are satisfied.

(iv) Not later than 30 days after the date on which the Attorney General receives supplemental information as described in clause (iii)(I)(bb) in connection with an application described in this subparagraph, the Attorney General shall approve or deny the application.

(v) If an application described in this subparagraph is denied, the Attorney General shall provide a written explanation of the basis of denial to the applicant.

(vi)(I) If the Attorney General grants an application for registration under clause (i), the registrant may amend or supplement the research protocol without notification to, or review by, the Drug Enforcement Administration if the registrant does not change—

(aa) the quantity or type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound thereof);

(bb) the source of such marijuana or cannabidiol; or

(cc) the conditions under which such marijuana or cannabidiol is stored, tracked, or administered.

(II)(aa) If a registrant under clause (i) seeks to change the type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound thereof), the source of such marijuana or cannabidiol, or the conditions under which such marijuana or cannabidiol is stored, tracked, or administered, the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

(bb) A registrant may proceed with an amended or supplemental research protocol described in item (aa) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (aa).

(cc) The Attorney General may only object to an amended or supplemental research protocol under this subclause if additional security measures are needed to safeguard against diversion or abuse.

(dd) If a registrant under clause (i) seeks to address additional security measures identified by the Attorney General under item (cc), the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

(ee) A registrant may proceed with an amended or supplemental research protocol described in item (dd) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (dd).

(III)(aa) If a registrant under clause (i) seeks to change the quantity of marijuana needed for research and the change in quantity does not impact the factors described in item (bb) or (cc) of subclause (I) of this clause, the registrant shall notify the Attorney General via registered mail or using an electronic means permitted by the Attorney General.

(bb) A notification under item (aa) shall include—

(AA) the Drug Enforcement Administration registration number of the registrant;

(BB) the quantity of marijuana or cannabidiol already obtained;

(CC) the quantity of additional marijuana or cannabidiol needed to complete the research; and

(DD) an attestation that the change in quantity does not impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered.

(cc) The Attorney General shall ensure that—

(AA) any registered mail return receipt with respect to a notification under item (aa) is submitted for delivery to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General; and

(BB) notice of receipt of a notification using an electronic means permitted under item (aa) is provided to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General.

(dd)(AA) On and after the date described in subitem (BB), a registrant that submits a notification in accordance with item (aa) may proceed with the research as if the change in quantity has been approved on such date, unless the Attorney General notifies the registrant of an objection described in item (ee).

(BB) The date described in this subitem is the date on which a registrant submitting a notification under item (aa) receives the registered mail return receipt with respect to the notification or the date on which the registrant receives notice that the notification using an electronic means permitted under item (aa) was received by the Attorney General, as the case may be.

(ee) A notification submitted under item (aa) shall be deemed to be approved unless the Attorney General, not later than 10 days after receiving the notification, explicitly objects based on a finding that the change in quantity—

(AA) does impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered; or

(BB) necessitates that the registrant implement additional security measures to safeguard against diversion or abuse.

(IV) Nothing in this clause shall limit the authority of the Secretary of Health and Human Services over requirements related to research protocols, including changes in—

(aa) the method of administration of marijuana or cannabidiol;

(bb) the dosing of marijuana or cannabidiol; and

(cc) the number of individuals or patients involved in research.

(3) 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 subchapter.

(h) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications

Practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) 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)—

(1) 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;

(2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(3) 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.

(i) Applicants for distribution of list I chemicals

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 802(39)(A) of this title. 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.

(j) Registration to manufacture certain controlled substances for use only in a clinical trial

(1) For purposes of registration to manufacture a controlled substance under subsection (e) 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 824(c) of this title, 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 applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

(k) Emergency medical services that administer controlled substances

(1) Registration

For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (g).

(2) Option for single registration

In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) Hospital-based agency

If a hospital-based emergency medical services agency is registered under subsection (g), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) Administration outside physical presence of medical director or authorizing medical professional

Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) Delivery

A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) Storage

A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) No treatment as distribution

The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 828 of this title.

(8) Restocking of emergency medical services vehicles at a hospital

Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 828 of this title, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 827 of this title.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) Maintenance of records

(A) In general

A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 827 of this title of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 827(c)(1)(B) of this title.

(B) Requirements

Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) Other requirements

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) Regulations

The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) Rule of construction

Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this subchapter to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) Definitions

In this section:

(A) The term ''authorizing medical professional'' means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this chapter;
(ii) who is acting within the scope of the registration; and
(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term ''designated location'' means a location designated by an emergency medical services agency under paragraph (5).

(C) The term ''emergency medical services'' means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term ''emergency medical services agency'' means an organization providing emergency medical services, including such an organization that—
(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;
(ii) provides emergency medical services by ground, air, or otherwise; and
(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term ''emergency medical services professional'' means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term ''emergency medical services vehicle'' means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term ''hospital-based'' means, with respect to an agency, owned or operated by a hospital.

(H) The term ''medical director'' means a physician who is registered under subsection (g) and provides medical oversight for an emergency medical services agency.

(I) The term ''medical oversight'' means supervision of the provision of medical care by an emergency medical services agency.

(J) The term ''registered emergency medical services agency'' means—
(i) an emergency medical services agency that is registered pursuant to this subsection; or
(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (g).

(K) The term ''registered location'' means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (g), which shall be where the agency receives controlled substances from distributors.

(L) The term ''specific State authority'' means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term ''standing order'' means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term ''verbal order'' means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(*l*)[2] "Factors as may be relevant to and consistent with the public health and safety" defined

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 801 of this title.

(*l*)[2] Required training for prescribers

(1) Training required

As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

(A) If the practitioner is a physician (as defined under section 1395x(r) of title 42) and the practitioner 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 a board certification from 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 patients with opioid or other substance use disorders, or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at

[2] So in original. Two subsecs. (*l*) have been enacted.

risk of developing opioid or other substance use disorders, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (ACCME) or the Commission for Continuing Education Provider Recognition (CCEPR);

(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME or the CCEPR;

(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

(IV) any organization approved by the Assistant Secretary for Mental Health and Substance Use, the ACCME, or the CCEPR.

(v) The physician graduated in good standing from an accredited school of allopathic medicine, osteopathic medicine, dental surgery, or dental medicine in the United States during the 5-year period immediately preceding the date on which the physician first registers or renews under this section and has successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency or dental surgery or dental medicine curriculum that included not less than 8 hours of training on—

(I) treating and managing patients with opioid or other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder; or

(II) the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid and other substance use disorders.

(B) If the practitioner is not a physician (as defined under section 1395x(r) of title 42), the practitioner is legally authorized by the State to dispense controlled substances under schedule II, III, IV, or V and is dispensing such substances within such State in accordance with all applicable State laws, and the practitioner meets one or more of the following conditions:

(i) The practitioner has completed not fewer than 8 hours of training with respect to the treatment and management of patients with opioid or other substance use disorders (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 Associates, or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Use or the Accreditation Council for Continuing Medical Education.

(ii) The practitioner has graduated in good standing from an accredited physician assistant school or accredited school of advanced practice nursing in the United States during the 5-year period immediately preceding the date on which the practitioner first registers or renews under this section and has successfully completed a comprehensive physician assistant or advanced practice nursing curriculum that included not fewer than 8 hours of training on treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

(2) One-time training

(A) In general

The Attorney General shall not require any qualified practitioner to complete the training described in clause (iv) or (v) of paragraph (1)(A) or clause (i) or (ii) of paragraph (1)(B) more than once.

(B) Notification

Not later than 90 days after December 29, 2022, the Attorney General shall provide to qualified practitioners a single written, electronic notification of the training described in clauses (iv) and (v) of paragraph (1)(A) or clauses (i) and (ii) of paragraph (1)(B).

(3) Rule of construction

Nothing in this subsection shall be construed—

(A) to preclude the use, by a qualified practitioner, of training received pursuant to this subsection to satisfy registration requirements of a State or for some other lawful purpose; or

(B) to preempt any additional requirements by a State related to the dispensing of controlled substances under schedule II, III, IV, or V.

(4) Definitions

In this section:

(A) First applicable registration

The term ''first applicable registration'' means the first registration or renewal of registration by a qualified practitioner under this section that occurs on or after the date that is 180 days after December 29, 2022.

(B) Qualified practitioner

In this subsection, the term ''qualified practitioner'' means a practitioner who—

(i) is licensed under State law to prescribe controlled substances; and

(ii) is not solely a veterinarian.

(Pub. L. 91–513, title II, § 303, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 93–281, § 3, May 14, 1974, 88 Stat. 124; Pub. L. 95–633, title I, § 109, Nov. 10, 1978, 92 Stat. 3773; Pub. L. 98–473, title II, § 511, Oct. 12, 1984, 98 Stat. 2073; Pub. L. 103–200, § 3(c), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 106–310, div. B, title XXXV, § 3502(a), Oct. 17, 2000, 114 Stat. 1222; Pub. L. 107–273, div. B, title II, § 2501, Nov. 2, 2002, 116 Stat. 1803; Pub. L. 109–56, § 1(a), (b), Aug. 2, 2005, 119 Stat. 591; Pub. L. 109–177, title VII, § 712(a)(3), Mar. 9, 2006, 120 Stat. 263; Pub. L. 109–469, title XI, § 1102, Dec. 29, 2006, 120 Stat. 3540; Pub. L. 110–425, § 3(b), Oct. 15, 2008, 122 Stat. 4824; Pub. L. 114–89, § 3, Nov. 25, 2015, 129 Stat. 701; Pub. L. 114–145, § 2(a)(1), Apr. 19, 2016, 130 Stat. 354; Pub. L. 114–198, title III, § 303(a)(1), (b), July 22, 2016, 130 Stat. 720, 723; Pub. L. 115–83, § 2, Nov. 17, 2017, 131 Stat. 1267; Pub. L. 115–271, title III, §§ 3201(a)–(d), 3202(a), Oct. 24, 2018, 132 Stat. 3943, 3944; Pub. L. 117–215, title I, §§ 101, 102(a), 103(a), Dec. 2, 2022, 136 Stat. 2258, 2260, 2261; Pub. L. 117–328, div. FF, title I, §§ 1262(a), 1263(a), Dec. 29, 2022, 136 Stat. 5681, 5683.)

Editorial Notes

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsecs. (a) to (g)(2), (k)(1), (4), and (*l*)(1), (3)(B), are set out in section 812(c) of this title.

This chapter, referred to in subsecs. (c)(1)(A), (B) and (k)(13)(A)(i), was in the original ''this Act'', meaning Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

Section 105 of the Medical Marijuana and Cannabidiol Research Expansion Act, referred to in subsecs. (c)(1)(B)(vi) and (g)(2)(B)(i)(II), is section 105 of Pub. L. 117–215, which is set out as a note below.

This subchapter, referred to in subsecs. (g)(3) and (k)(12)(A), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2022—Subsecs. (c) to (e). Pub. L. 117–215, § 103(a)(1), (2), added subsec. (c) and redesignated former subsecs. (c) and (d) as (d) and (e), respectively. Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 117–215, § 103(a)(1), redesignated subsec. (e) as (f). Former subsec. (f) redesignated (g).

Pub. L. 117–215, § 101, designated introductory provisions through first sentence of concluding provisions as par. (1), redesignated former pars. (1) to (5) as subpars. (A) to (E), respectively, of par. (1), designated second to fourth sentences of concluding provisions as subpar. (A) of par. (2), added subpar. (B) of par. (2), and designated last sentence of concluding provisions as par. (3).

Subsec. (f)(2)(B)(vi). Pub. L. 117–215, § 102(a), added cl. (vi).

Subsec. (g). Pub. L. 117–215, § 103(a)(1), redesignated subsec. (f) as (g). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 117–328, § 1262(a), which directed amendment of subsec. (g) by substituting ''Practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment'' for ''(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment'', redesignating subpars. (A) to (C) of former par. (1) as pars. (1) to (3), respectively, redesignating cls. (i) and (ii) of par. (2) as subpars. (A) and (B), respectively, and striking former par. (2) which related to waiver of registration requirements, was executed to subsec. (h) to reflect the probable intent of Congress and the redesignation of subsec. (g) as (h) by Pub. L. 117–215, § 103(a)(1). See Amendment note below.

Pub. L. 117–215, § 103(a)(1), redesignated subsec. (g) as (h). Former subsec. (h) redesignated (i).

Subsec. (h)(2). Pub. L. 117–215, § 103(a)(3), substituted ''subsection (g)'' for ''subsection (f)'' wherever appearing.

Subsec. (i). Pub. L. 117–215, § 103(a)(1), redesignated subsec. (h) as (i). Former subsec. (i) redesignated (j).

Subsec. (j). Pub. L. 117–215, § 103(a)(1), redesignated subsec. (i) as (j). Former subsec. (j) redesignated (k).

Subsec. (j)(1). Pub. L. 117–215, § 103(a)(4), substituted ''subsection (e)'' for ''subsection (d)''.

Subsec. (k). Pub. L. 117–215, § 103(a)(1), (5), redesignated subsec. (j) as (k) and substituted ''subsection (g)'' for ''subsection (f)'' wherever appearing. Former subsec. (k) redesignated (*l*).

Subsec. (*l*). Pub. L. 117–328, § 1263(a), added subsec. (*l*) relating to required training for prescribers.

Pub. L. 117–215, § 103(a)(1), redesignated subsec. (k) as (*l*).

2018—Subsec. (g)(2)(B)(iii)(II). Pub. L. 115–271, § 3201(a), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: ''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.''

Subsec. (g)(2)(G)(ii)(VIII). Pub. L. 115–271, § 3202(a), added subcl. (VIII).

Subsec. (g)(2)(G)(iii)(II). Pub. L. 115–271, § 3201(b), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: ''during the period beginning on July 22, 2016, and ending on October 1, 2021, a qualifying other practitioner, as defined in clause (iv).''

Subsec. (g)(2)(G)(iii)(III). Pub. L. 115–271, § 3201(b)(1), (c), added subcl. (III).

Subsec. (g)(2)(G)(iv). Pub. L. 115–271, § 3201(d), substituted ''nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant'' for ''nurse practitioner or physician assistant'' wherever appearing.

2017—Subsecs. (j), (k). Pub. L. 115–83 added subsec. (j) and redesignated former subsec. (j) as (k).

2016—Subsec. (g)(2)(B). Pub. L. 114–198, § 303(a)(1)(A), added cls. (i) to (iii) and struck out former cls. (i) to (iii) which read as follows:

''(i) The practitioner is a qualifying physician (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 refer the patients for appropriate counseling and other appropriate ancillary services.

''(iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, 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. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number.''

Subsec. (g)(2)(D)(ii). Pub. L. 114–198, § 303(a)(1)(B)(i), substituted ''Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B)'' for ''Upon receiving a notification under subparagraph (B)''.

Subsec. (g)(2)(D)(iii). Pub. L. 114–198, §303(a)(1)(B)(ii), inserted ''and shall forward such determination to the Attorney General'' after ''a waiver under subparagraph (B)'' and substituted ''assign the practitioner'' for ''assign the physician''.

Subsec. (g)(2)(G)(ii)(I). Pub. L. 114–198, §303(a)(1)(C)(i), amended subcl. (I) generally. Prior to amendment, subcl. (I) read as follows: ''The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.''

Subsec. (g)(2)(G)(ii)(II). Pub. L. 114–198, §303(a)(1)(C)(ii), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: ''The physician holds an addiction certification from the American Society of Addiction Medicine.''

Subsec. (g)(2)(G)(ii)(III). Pub. L. 114–198, §303(a)(1)(C)(iii), struck out ''subspecialty'' before ''board certification''.

Subsec. (g)(2)(G)(ii)(IV). Pub. L. 114–198, §303(a)(1)(C)(iv), amended subcl. (IV) generally. Prior to amendment, subcl. (IV) read as follows: ''The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight 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.''

Subsec. (g)(2)(G)(iii), (iv). Pub. L. 114–198, §303(a)(1)(C)(v), added cls. (iii) and (iv).

Subsec. (g)(2)(H)(i)(III). Pub. L. 114–198, §303(a)(1)(D)(i), added subcl. (III).

Subsec. (g)(2)(H)(ii). Pub. L. 114–198, §303(a)(1)(D)(ii), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: ''Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.''

Subsec. (g)(2)(I), (J). Pub. L. 114–198, §303(b), added subpar. (I) and struck out former subpars. (I) and (J) which limited a State's ability to preclude a practitioner from dispensing or prescribing certain approved drugs and provided the effective date of the paragraph and authorized the Secretary and the Attorney General to make certain determinations.

Subsec. (j). Pub. L. 114–145 added subsec. (j).

2015—Subsec. (i). Pub. L. 114–89 added subsec. (i).

2008—Subsec. (f). Pub. L. 110–425, in introductory provisions, inserted ''and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet'' after ''schedule II, III, IV, or V'' and substituted ''or such modification of registration if the Attorney General determines that the issuance of such registration or modification'' for ''if he determines that the issuance of such registration''.

2006—Subsec. (g)(2)(B)(iii). Pub. L. 109–469, §1102(1), substituted ''unless, 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. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The'' for ''except that the''.

Subsec. (g)(2)(J)(i). Pub. L. 109–469, §1102(2)(A), substituted ''thereafter.'' for ''thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).''

Subsec. (g)(2)(J)(ii). Pub. L. 109–469, §1102(2)(B), substituted ''December 29, 2006'' for ''October 17, 2000'' in introductory provisions.

Subsec. (g)(2)(J)(iii). Pub. L. 109–469, §1102(2)(C), substituted ''subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective'' for ''this paragraph should not remain in effect, this paragraph ceases to be in effect''.

Subsec. (h). Pub. L. 109–177 substituted ''clause (iv) or (v) of section 802(39)(A) of this title'' for ''section 802(39)(A)(iv) of this title'' in introductory provisions.

2005—Subsec. (g)(2)(B)(iii). Pub. L. 109–56, §1(b), substituted ''The total'' for ''In any case in which the practitioner is not in a group practice, the total''.

Subsec. (g)(2)(B)(iv). Pub. L. 109–56, §1(a), struck out cl. (iv) which read as follows: ''In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.''

2002—Subsec. (g)(2)(I). Pub. L. 107–273, §2501(1), which directed the substitution of ''on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs,'' for ''on October 17, 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs,'', was executed by making the substitution for the phrase which in the original began with ''on the date of the enactment of the Drug Addiction Treatment Act of 2000,'' rather than the editorial translation ''on October 17, 2000,'' to reflect the probable intent of Congress.

Subsec. (g)(2)(J)(i). Pub. L. 107–273, §2501(2), which directed the substitution of ''the date referred to in subparagraph (I),'' for ''October 17, 2000,'' was executed by making the substitution for text which in the original read ''the date of the enactment of the Drug Addiction Treatment Act of 2000,'' rather than the editorial translation ''October 17, 2000,'' to reflect the probable intent of Congress.

2000—Subsec. (g). Pub. L. 106–310 designated existing provisions as par. (1), substituted ''Except as provided in paragraph (2), practitioners who dispense'' for ''Practitioners who dispense'', redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1) and redesignated former subpars. (A) and (B) of former par. (2) as cls. (i) and (ii), respectively, of subpar. (B) of par. (1), and added par. (2).

1993—Subsec. (h). Pub. L. 103–200 added subsec. (h).

1984—Subsec. (f). Pub. L. 98–473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978—Subsec. (f). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1974—Subsec. (g). Pub. L. 93–281 added subsec. (g).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section

3(j) of Pub. L. 110–425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–56, §1(c), Aug. 2, 2005, 119 Stat. 591, provided that: ''This section [amending this section] shall take effect on the date of enactment of this Act [Aug. 2, 2005].''

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as a note under section 801 of this title.

REGULATIONS

Pub. L. 117–215, title I, §102(b), Dec. 2, 2022, 136 Stat. 2261, provided that: ''Not later than 1 year after the date of enactment of this Act [Dec. 2, 2022], the Attorney General shall promulgate regulations to carry out the amendment made by this section [amending this section].''

UPDATE REGULATIONS

Pub. L. 117–328, div. FF, title I, §1252(b), Dec. 29, 2022, 136 Stat. 5681, provided that: ''Not later than 18 months after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services shall revise section 8.12(e)(1) of title 42, Code of Federal Regulations (or successor regulations), to eliminate the requirement that an opioid treatment program only admit an individual for treatment under the program if the individual has been addicted to opioids for at least 1 year before being so admitted for treatment.''

Pub. L. 114–198, title III, §303(c), July 22, 2016, 130 Stat. 723, provided that: ''Not later than 18 months after the date of enactment of this Act [July 22, 2016], the Attorney General and the Secretary of Health and Human Services, as appropriate, shall update regulations regarding practitioners described in subsection (a)(3)(B)(vii) (as amended by this section) [probably means subsec. (a)(3)(B)(vii) ''of this section'', set out as a note below] to include nurse practitioners and physician assistants to ensure the quality of patient care and prevent diversion.''

ADEQUATE AND UNINTERRUPTED SUPPLY

Pub. L. 117–215, title I, §104, Dec. 2, 2022, 136 Stat. 2263, provided that:

''(a) IN GENERAL.—On an annual basis, the Attorney General, in consultation with the Secretary of Health and Human Services, shall assess whether there is an adequate and uninterrupted supply of marijuana, including of specific strains, for research purposes.

''(b) REPORT TO CONGRESS.—If the Attorney General, in consultation with the Secretary of Health and Human Services, determines there is an inadequate or interrupted supply of marijuana, including of specific strains for research purposes, the Attorney General shall report to Congress within 60 days of the determination on at least—

''(1) the factors contributing to the inadequate or interrupted supply of marijuana;

''(2) expected impacts of the inadequate or interrupted supply on ongoing research protocols; and

''(3) specific steps the Attorney General will take to restore an adequate and uninterrupted supply of marijuana, including of specific strains, for research purposes.''

[For definition of ''marijuana'' as used in section 104 of Pub. L. 117–215, set out above, see section 2(a) of Pub. L. 117–215, set out as a note under section 801 of this title.]

SECURITY REQUIREMENTS

Pub. L. 117–215, title I, §105, Dec. 2, 2022, 136 Stat. 2264, provided that:

''(a) IN GENERAL.—An individual or entity engaged in researching marijuana or its components shall store it in a securely locked, substantially constructed cabinet.

''(b) REQUIREMENTS FOR OTHER MEASURES.—Any other security measures required by the Attorney General to safeguard against diversion shall be consistent with those required for practitioners conducting research on other controlled substances in schedules I and II in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) that have a similar risk of diversion and abuse.''

[For definitions of ''marijuana'', ''controlled substances'', and ''practitioners'' as used in section 105 of Pub. L. 117–215, set out above, see section 2(a) of Pub. L. 117–215, set out as a note under section 801 of this title.]

DEVELOPMENT OF FOOD AND DRUG ADMINISTRATION-APPROVED DRUGS USING CANNABIDIOL AND MARIJUANA

Pub. L. 117–215, title II, Dec. 2, 2022, 136 Stat. 2264, provided that:

''SEC. 201. MEDICAL RESEARCH ON CANNABIDIOL.

''Notwithstanding any provision of the Controlled Substances Act (21 U.S.C. 801 et seq.), the Safe and Drug-Free Schools and Communities Act (20 U.S.C. 7101 et seq.), chapter 81 of title 41, United States Code, or any other Federal law, an appropriately registered covered institution of higher education, practitioner, or manufacturer may manufacture, distribute, dispense, or possess marijuana or cannabidiol if the marijuana or cannabidiol is manufactured, distributed, dispensed, or possessed, respectively, for purposes of medical research for drug development or subsequent commercial production in accordance with section 202.

''SEC. 202. REGISTRATION FOR THE COMMERCIAL PRODUCTION AND DISTRIBUTION OF FOOD AND DRUG ADMINISTRATION-APPROVED DRUGS.

''The Attorney General shall register an applicant to manufacture or distribute cannabidiol or marijuana for the purpose of commercial production of a drug containing or derived from marijuana that is approved by the Secretary of Health and Human Services under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), in accordance with the applicable requirements under subsection (a) or (b) of section 303 of the Controlled Substances Act (21 U.S.C. 823).''

[For definitions of terms used in title II of Pub. L. 117–215, set out above, see section 2(a) of Pub. L. 117–215, set out as a note under section 801 of this title.]

TREATMENT FOR CHILDREN

Pub. L. 115–271, title III, §3202(b), Oct. 24, 2018, 132 Stat. 3945, provided that: ''The Secretary of Health and Human Services shall consider ways to ensure that an adequate number of qualified practitioners, as defined in [former] subparagraph (G)(ii) of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) [former 21 U.S.C. 823(h)(2)], who have a specialty in pediatrics or the treatment of children or adolescents, are granted a waiver under such section 303(g)(2) to treat children and adolescents with substance use disorders.''

GRANTS TO ENHANCE ACCESS TO SUBSTANCE USE DISORDER TREATMENT

Pub. L. 115–271, title III, §3203, Oct. 24, 2018, 132 Stat. 3945, provided that:

''(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a grant program under which the Secretary may make grants to accredited

schools of allopathic medicine or osteopathic medicine and teaching hospitals located in the United States to support the development of curricula that meet the requirements under [former] subclause (VIII) of section 303(g)(2)(G)(ii) of the Controlled Substances Act [former 21 U.S.C. 823(h)(2)(G)(ii)], as added by section 3202(a) of this Act.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, for grants under subsection (a), $4,000,000 for each of fiscal years 2019 through 2023.''

REPORTS TO CONGRESS

Pub. L. 114–198, title III, §303(a)(3), July 22, 2016, 130 Stat. 722, provided that:

''(A) IN GENERAL.—Not later than 3 years after the date of enactment of this Act [July 22, 2016] and not later than 3 years thereafter, the Secretary of Health and Human Services, in consultation with the Drug Enforcement Administration and experts in opioid use disorder research and treatment, shall—

''(i) perform a thorough review of the provision of opioid use disorder treatment services in the United States, including services provided in opioid treatment programs and other specialty and nonspecialty settings; and

''(ii) submit a report to the Congress on the findings and conclusions of such review.

''(B) CONTENTS.—Each report under subparagraph (A) shall include an assessment of—

''(i) compliance with the requirements of [former] section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) [former 21 U.S.C. 823(h)(2)], as amended by this section;

''(ii) the measures taken by the Secretary of Health and Human Services to ensure such compliance;

''(iii) whether there is further need to increase or decrease the number of patients a practitioner, pursuant to a waiver under [former] section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) [former 21 U.S.C. 823(h)(2)], is permitted to treat;

''(iv) the extent to which, and proportions with which, the full range of Food and Drug Administration-approved treatments for opioid use disorder are used in routine health care settings and specialty substance use disorder treatment settings;

''(v) access to, and use of, counseling and recovery support services, including the percentage of patients receiving such services;

''(vi) changes in State or local policies and legislation relating to opioid use disorder treatment;

''(vii) the use of prescription drug monitoring programs by practitioners who are permitted to dispense narcotic drugs to individuals pursuant to a waiver described in clause (iii);

''(viii) the findings resulting from inspections by the Drug Enforcement Administration of practitioners described in clause (vii); and

''(ix) the effectiveness of cross-agency collaboration between [the] Department of Health and Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment.''

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II;

(2) has been convicted of a felony under this subchapter or subchapter II or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

A registration pursuant to section 823(h)(1)[1] of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(h)(1)[1] of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

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[1] See References in Text note below.