

(D) any actions taken by the manufacturer to prevent diversion of the drug product; and

(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) as applied to the drug product.

(3) Status pending application for reinstatement

A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless—

(A) the Attorney General has evidence that, applying the factors described in subsection (b) to the drug product, the drug product is being diverted; and

(B) the Attorney General so notifies the applicant.

(4) Amendment and modification

A regulation reinstating an exemption under paragraph (1) may be modified or revoked with respect to a particular drug product upon a finding that—

(A) applying the factors described in subsection (b) to the drug product, the drug product is being diverted; or

(B) there is a significant change in the data that led to the issuance of the regulation.

(Pub. L. 91-513, title II, §204, as added Pub. L. 103-200, §2(b)(1), Dec. 17, 1993, 107 Stat. 2334; amended Pub. L. 104-237, title IV, §401(c), Oct. 3, 1996, 110 Stat. 3108; Pub. L. 109-177, title VII, §712(a)(2), Mar. 9, 2006, 120 Stat. 263.)

Editorial Notes

AMENDMENTS

2006—Subsec. (e). Pub. L. 109-177 struck out subsec. (e). Text read as follows: “Pursuant to subsection (d)(1) of this section, the Attorney General shall by regulation reinstate the exemption with respect to a particular ephedrine, pseudoephedrine, or phenylpropanolamine drug product if the Attorney General determines that the drug product is manufactured and distributed in a manner that prevents diversion. In making this determination the Attorney General shall consider the factors listed in subsection (d)(2) of this section. Any regulation issued pursuant to this subsection may be amended or revoked based on the factors listed in subsection (d)(4) of this section.”

1996—Subsec. (e). Pub. L. 104-237 added subsec. (e).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104-237 not applicable to sale of any pseudoephedrine or phenylpropanolamine product prior to 12 months after Oct. 3, 1996, except that, on application of manufacturer of particular drug product, Attorney General may exercise sole and judicially

unreviewable discretion to extend such effective date up to additional 6 months, see section 401(g) of Pub. L. 104-237, set out as a note under section 802 of this title.

EFFECTIVE DATE

Section effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as an Effective Date of 1993 Amendment note under section 802 of this title.

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

§ 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

(Pub. L. 91-513, title II, §301, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 103-200, §3(a), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 108-447, div. B, title VI, §633(b), Dec. 8, 2004, 118 Stat. 2922.)

Editorial Notes

AMENDMENTS

2004—Pub. L. 108-447 substituted “listed chemicals” for “the registration and control of regulated persons and of regulated transactions”.

1993—Pub. L. 103-200 inserted before period at end “and to the registration and control of regulated persons and of regulated transactions”.

Statutory Notes and Related Subsidiaries

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

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.

§ 822. Persons required to register

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(3)(A) Except as provided in subparagraph (C), the registration of any registrant under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals terminates if and when such registrant—

- (i) dies;
- (ii) ceases legal existence;
- (iii) discontinues business or professional practice; or
- (iv) surrenders such registration.

(B) In the case of such a registrant who ceases legal existence or discontinues business or professional practice, such registrant shall promptly notify the Attorney General in writing of such fact.

(C) No registration under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals, and no authority conferred thereby, may be assigned or otherwise transferred except upon such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a registration is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to such registration until the Attorney General receives such written consent.

(D) In the case of a registrant under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring such business or professional practice to another entity), such registrant shall return to the Attorney General for cancellation—

- (i) the registrant's certificate of registration;
- (ii) any unexecuted order forms in the registrant's possession; and
- (iii) any other documentation that the Attorney General may require.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

- (1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.
- (2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.
- (3) An ultimate user who possesses such substance for a purpose specified in section 802(25)¹ of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

(1) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(2) Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(3) Notwithstanding paragraph (1), a registrant that is dispensing pursuant to section 823(g)¹ of this title narcotic drugs to individuals for maintenance treatment or detoxification treatment shall not be required to have a separate registration to incorporate one or more mobile medication units into the registrant's practice to dispense such narcotics at locations other than the registrant's principal place of business or professional practice described in paragraph (1), so long as the registrant meets such standards for operation of a mobile medication unit as the Attorney General may establish.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(g) Delivery of controlled substances by ultimate users for disposal

(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this subchapter may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this subchapter to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose

¹ See References in Text note below.

of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(5)(A) In the case of a person receiving hospice care, an employee of a qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the person receiving hospice care, for the purpose of disposal of the controlled substance so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law and—

- (i) the disposal occurs after the death of a person receiving hospice care;
- (ii) the controlled substance is expired; or
- (iii)(I) the employee is—
 - (aa) the physician of the person receiving hospice care; and
 - (bb) registered under section 823(g) of this title; and

(II) the hospice patient no longer requires the controlled substance because the plan of care of the hospice patient has been modified.

(B) For the purposes of this paragraph:

(i) The terms “hospice care” and “hospice program” have the meanings given to those terms in section 1395x(dd) of title 42.

(ii) The term “employee of a qualified hospice program” means a physician, physician assistant, nurse, or other person who—

(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;

(II)(aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and

(bb) is acting within the scope of such employment in accordance with applicable State law; and

(III) has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion.

(iii) The term “qualified hospice program” means a hospice program that—

(I) has written policies and procedures for assisting in the disposal of the controlled substances of a person receiving hospice care after the person's death;

(II) at the time when the controlled substances are first ordered—

(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;

(bb) discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties

are educated regarding the safe disposal of controlled substances; and

(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and

(III) at the time following the disposal of the controlled substances—

(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and

(bb) the time, date, and manner in which that disposal occurred.

(Pub. L. 91-513, title II, §302, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 98-473, title II, §510, Oct. 12, 1984, 98 Stat. 2072; Pub. L. 103-200, §3(b), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 111-273, §3(a), Oct. 12, 2010, 124 Stat. 2859; Pub. L. 113-143, §2, Aug. 1, 2014, 128 Stat. 1750; Pub. L. 115-271, title III, §3222(a), Oct. 24, 2018, 132 Stat. 3948; Pub. L. 117-53, §2, Nov. 10, 2021, 135 Stat. 411; Pub. L. 117-215, title I, §103(b)(1)(B), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117-328, div. FF, title I, §1252(a), Dec. 29, 2022, 136 Stat. 5681.)

Editorial Notes

REFERENCES IN TEXT

This subchapter, referred to in subsecs. (a)(3), (b), (c), and (g)(1), 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.

Section 802(25) of this title, referred to in subsec. (c)(3), was redesignated section 802(26) of this title by Pub. L. 98-473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071, and was further redesignated section 802(27) of this title by Pub. L. 99-570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207-6.

Section 823(g) of this title, referred to in subsec. (e)(3), was redesignated section 823(h) of this title by Pub. L. 117-215, title I, §103(a)(1), Dec. 2, 2022, 136 Stat. 2261.

AMENDMENTS

2022—Subsec. (e)(3). Pub. L. 117-328, §1252(a), added par. (3).

Subsec. (g)(5)(A)(iii)(I)(bb). Pub. L. 117-215 substituted “823(g)” for “823(f)”.

2021—Subsec. (a)(3). Pub. L. 117-53 added par. (3).

2018—Subsec. (g)(5). Pub. L. 115-271 added par. (5).

2014—Subsec. (e). Pub. L. 113-143 designated existing provisions as par. (1) and added par. (2).

2010—Subsec. (g). Pub. L. 111-273 added subsec. (g).

1993—Subsec. (a)(1). Pub. L. 103-200, §3(b)(1), inserted “or list I chemical” after “controlled substance” in two places.

Subsec. (b). Pub. L. 103-200, §3(b)(2), inserted “or list I chemicals” after “controlled substances” and “or chemicals” after “such substances”.

Subsec. (c). Pub. L. 103-200, §3(b)(3), inserted “or list I chemical” after “controlled substance” wherever appearing.

Subsec. (e). Pub. L. 103-200, §3(b)(4), inserted “or list I chemicals” after “controlled substances”.

1984—Subsec. (a). Pub. L. 98-473 designated existing provisions as par. (1), struck out provisions relating to dispensing controlled substances, and added par. (2).

Statutory Notes and Related Subsidiaries

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

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.

RULE OF CONSTRUCTION RELATING TO STATE AND LOCAL LAW

Pub. L. 115-271, title III, §3222(c), Oct. 24, 2018, 132 Stat. 3949, provided that: “Nothing in this section [amending this section and enacting provisions set out as a note below] or the amendments made by this section shall be construed to prevent a State or local government from imposing additional controls or restrictions relating to the regulation of the disposal of controlled substances in hospice care or hospice programs.”

GUIDANCE

Pub. L. 115-271, title III, §3222(b), Oct. 24, 2018, 132 Stat. 3949, provided that: “The Attorney General may issue guidance to hospice programs (as defined in paragraph (5) of section 302(g) of the Controlled Substances Act [21 U.S.C. 822(g)], as added by subsection (a)) to assist the programs in satisfying the requirements under such paragraph (5).”

FINDINGS

Pub. L. 111-273, §2, Oct. 12, 2010, 124 Stat. 2858, provided that: “Congress finds the following:

“(1) The nonmedical use of prescription drugs is a growing problem in the United States, particularly among teenagers.

“(2) According to the Department of Justice’s 2009 National Prescription Drug Threat Assessment—

“(A) the number of deaths and treatment admissions for controlled prescription drugs (CPDs) has increased significantly in recent years;

“(B) unintentional overdose deaths involving prescription opioids, for example, increased 114 percent from 2001 to 2005, and the number of treatment admissions for prescription opioids increased 74 percent from 2002 to 2006; and

“(C) violent crime and property crime associated with abuse and diversion of CPDs has increased in all regions of the United States over the past 5 years.

“(3) According to the Office of National Drug Control Policy’s 2008 Report ‘Prescription for Danger’, prescription drug abuse is especially on the rise for teens—

“(A) one-third of all new abusers of prescription drugs in 2006 were 12- to 17-year-olds;

“(B) teens abuse prescription drugs more than any illicit drug except marijuana—more than cocaine, heroin, and methamphetamine combined; and

“(C) responsible adults are in a unique position to reduce teen access to prescription drugs because the drugs often are found in the home.

“(4)(A) Many State and local law enforcement agencies have established drug disposal programs (often called ‘take-back’ programs) to facilitate the collection and destruction of unused, unwanted, or expired medications. These programs help get outdated or unused medications off household shelves and out of the reach of children and teenagers.

“(B) However, take-back programs often cannot dispose of the most dangerous pharmaceutical drugs—controlled substance medications—because Federal law does not permit take-back programs to accept controlled substances unless they get specific permission from the Drug Enforcement Administration and arrange for full-time law enforcement officers to receive the controlled substances directly from the member of the public who seeks to dispose of them.

“(C) Individuals seeking to reduce the amount of unwanted controlled substances in their household

consequently have few disposal options beyond discarding or flushing the substances, which may not be appropriate means of disposing of the substances. Drug take-back programs are also a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water.

“(D) Long-term care facilities face a distinct set of obstacles to the safe disposal of controlled substances due to the increased volume of controlled substances they handle.

“(5) This Act [see Short Title of 2010 Amendment note set out under section 801 of this title] gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act [21 U.S.C. 801 et seq.], that will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

“(6) The goal of this Act is to encourage the Attorney General to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner. This will also serve to reduce instances of diversion and introduction of some potentially harmful substances into the environment.”

PROVISIONAL REGISTRATION

Pub. L. 91-513, title II, §703, Oct. 27, 1970, 84 Stat. 1283, as amended by Pub. L. 99-514, §2, Oct. 22, 1986, 100 Stat. 2095, provided that:

“(a)(1) Any person who—

“(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302 [this section], and

“(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1986 [formerly I.R.C. 1954, section 4722 of Title 26],

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 [section 823 of this title] for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

“(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 [section 360 of this title] or under such section 4722 [section 4722 of Title 26] (as the case may be) shall be his registration number for purposes of section 303 of this title [section 823 of this title].

“(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

“(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

“(1) the date on which such person has registered with the Attorney General under section 303 [section 823 of this title] or has had his registration denied under such section, or

“(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be, whichever occurs first.”

§ 822a. Prescription drug take back expansion

(a) Definition of covered entity

In this section, the term “covered entity” means—

(1) a State, local, or tribal law enforcement agency;