

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;

- (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