

vention 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.)

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.

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 sub-recipient 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) 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.

(d) 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.

(e) 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 public interest, the following factors shall be considered:

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

(2) compliance with applicable State and local law;

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

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

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

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

The Attorney General shall register practitioners (including pharmacies, as distinguished