

TITLE 21 - FOOD AND DRUGS
CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL
SUBCHAPTER I - CONTROL AND ENFORCEMENT
Part A - Introductory Provisions

§ 802. Definitions

As used in this subchapter:

- (1) The term “addict” means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.
- (2) The term “administer” refers to the direct application of a controlled substance to the body of a patient or research subject by—
 - (A) a practitioner (or, in his presence, by his authorized agent), or
 - (B) the patient or research subject at the direction and in the presence of the practitioner,
 whether such application be by injection, inhalation, ingestion, or any other means.
- (3) The term “agent” means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier’s or warehouseman’s business.
- (4) The term “Drug Enforcement Administration” means the Drug Enforcement Administration in the Department of Justice.
- (5) The term “control” means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.
- (6) The term “controlled substance” means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.
- (7) The term “counterfeit substance” means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.
- (8) The terms “deliver” or “delivery” mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.
- (9) The term “depressant or stimulant substance” means—
 - (A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or
 - (B) a drug which contains any quantity of
 - (i) amphetamine or any of its optical isomers;
 - (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or
 - (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or
 - (C) lysergic acid diethylamide; or
 - (D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term “dispenser” means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term “distribute” means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term “distributor” means a person who so delivers a controlled substance or a listed chemical.

(12) The term “drug” has the meaning given that term by section 321 (g)(1) of this title.

(13) The term “felony” means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term “isomer” means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term “isomer” means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term “isomer” means any optical or geometric isomer.

(15) The term “manufacture” means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term “manufacturer” means a person who manufactures a drug or other substance.

(16) The term “marihuana” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term “narcotic drug” means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term “opiate” means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term “opium poppy” means the plant of the species *Papaver somniferum* L., except the seed thereof.

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- (20) The term “poppy straw” means all parts, except the seeds, of the opium poppy, after mowing.
- (21) The term “practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.
- (22) The term “production” includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.
- (23) The term “immediate precursor” means a substance—
- (A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;
 - (B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and
 - (C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.
- (24) The term “Secretary”, unless the context otherwise indicates, means the Secretary of Health and Human Services.
- (25) The term “serious bodily injury” means bodily injury which involves—
- (A) a substantial risk of death;
 - (B) protracted and obvious disfigurement; or
 - (C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.
- (26) The term “State” means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.
- (27) The term “ultimate user” means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.
- (28) The term “United States”, when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.
- (29) The term “maintenance treatment” means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.
- (30) The term “detoxification treatment” means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.
- (31) The term “Convention on Psychotropic Substances” means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term “Single Convention on Narcotic Drugs” means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.
- (32) (A) Except as provided in subparagraph (C), the term “controlled substance analogue” means a substance—
- (i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;
 - (ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

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(Y) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term “list II chemical” means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

- (A) Acetic anhydride.
- (B) Acetone.
- (C) Benzyl chloride.
- (D) Ethyl ether.
- (E) Repealed. Pub. L. 101–647, title XXIII, § 2301(b), Nov. 29, 1990, 104 Stat. 4858.
- (F) Potassium permanganate.
- (G) 2-Butanone (or Methyl Ethyl Ketone).
- (H) Toluene.
- (I) Iodine.
- (J) Hydrochloric gas.

(36) The term “regular customer” means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term “regular importer” means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term “regulated person” means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term “regulated transaction” means—

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include—

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 830 of this title;

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], subject to clause (v), unless—

(I) the Attorney General has determined under section 814 of this title that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

- (II) the quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General;
- (v) any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under section 830 (b)(3) of this title; or
- (vi) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II of this chapter based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and
- (B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.
- (40) The term “chemical mixture” means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.
- (41) (A) The term “anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes—
- (i) androstenediol—
 - (I) 3b,17b-dihydroxy-5a-androstane; and
 - (II) 3a,17b-dihydroxy-5a-androstane;
 - (ii) androstanedione (5a-androstan-3,17-dione);
 - (iii) androstenediol—
 - (I) 1-androstenediol (3b,17b-dihydroxy-5a-androst-1-ene);
 - (II) 1-androstenediol (3a,17b-dihydroxy-5a-androst-1-ene);
 - (III) 4-androstenediol (3b,17b-dihydroxy-androst-4-ene); and
 - (IV) 5-androstenediol (3b,17b-dihydroxy-androst-5-ene);
 - (iv) androstenedione—
 - (I) 1-androstenedione ([5a]-androst-1-en-3,17-dione);
 - (II) 4-androstenedione (androst-4-en-3,17-dione); and
 - (III) 5-androstenedione (androst-5-en-3,17-dione);
 - (v) bolasterone (7a,17a-dimethyl-17b-hydroxyandrost-4-en-3-one);
 - (vi) boldenone (17b-hydroxyandrost-1,4,-diene-3-one);
 - (vii) calusterone (7b,17a-dimethyl-17b-hydroxyandrost-4-en-3-one);
 - (viii) clostebol (4-chloro-17b-hydroxyandrost-4-en-3-one);
 - (ix) dehydrochloromethyltestosterone (4-chloro-17b-hydroxy-17a-methyl-androst-1,4-dien-3-one);
 - (x) *1-dihydrotestosterone (a.k.a. “1-testosterone”) (17b-hydroxy-5a-androst-1-en-3-one);
 - (xi) 4-dihydrotestosterone (17b-hydroxy-androstan-3-one);
 - (xii) drostanolone (17b-hydroxy-2a-methyl-5a-androstan-3-one);
 - (xiii) ethylestrenol (17a-ethyl-17b-hydroxyestr-4-ene);
 - (xiv) fluoxymesterone (9-fluoro-17a-methyl-11b,17b-dihydroxyandrost-4-en-3-one);
 - (xv) formebolone (2-formyl-17a-methyl-11a,17b-dihydroxyandrost-1,4-dien-3-one);
 - (xvi) furazabol (17a-methyl-17b-hydroxyandrostano[2,3-c]-furazan);
 - (xvii) 13b-ethyl-17b-hydroxygon-4-en-3-one;
 - (xviii) 4-hydroxytestosterone (4,17b-dihydroxy-androst-4-en-3-one);

- (**xix**) 4-hydroxy-19-nortestosterone (4,17b-dihydroxy-estr-4-en-3-one);
- (**xx**) mestanolone (17a-methyl-17b-hydroxy-5a-androstan-3-one);
- (**xxi**) mesterolone (1a-methyl-17b-hydroxy-[5a]-androstan-3-one);
- (**xxii**) methandienone (17a-methyl-17b-hydroxyandrost-1,4-dien-3-one);
- (**xxiii**) methandriol (17a-methyl-3b,17b-dihydroxyandrost-5-ene);
- (**xxiv**) methenolone (1-methyl-17b-hydroxy-5a-androst-1-en-3-one);
- (**xxv**) 17a-methyl-3b, 17b-dihydroxy-5a-androstane;
- (**xxvi**) 17a-methyl-3a,17b-dihydroxy-5a-androstane;
- (**xxvii**) 17a-methyl-3b,17b-dihydroxyandrost-4-ene.
- (xxviii) 17a-methyl-4-hydroxynandrolone
(17a-methyl-4-hydroxy-17b-hydroxyestr-4-en-3-one);
- (**xxix**) methyl dienolone (17a-methyl-17b-hydroxyestra-4,9(10)-dien-3-one);
- (**xxx**) methyl trienolone (17a-methyl-17b-hydroxyestra-4,9,11-trien-3-one);
- (**xxxi**) methyl testosterone (17a-methyl-17b-hydroxyandrost-4-en-3-one);
- (**xxxii**) mibolerone (7a,17a-dimethyl-17b-hydroxyestr-4-en-3-one);
- (xxxiii) 17a-methyl-*1-dihydrotestosterone
(17b-hydroxy-17a-methyl-5a-androst-1-en-3-one) (a.k.a. “17-a-methyl-1-testosterone”);
- (**xxxiv**) nandrolone (17b-hydroxyestr-4-en-3-one);
- (**xxxv**) norandrostenediol—
- (**I**) 19-nor-4-androstenediol (3b, 17b-dihydroxyestr-4-ene);
- (**II**) 19-nor-4-androstenediol (3a, 17b-dihydroxyestr-4-ene);
- (**III**) 19-nor-5-androstenediol (3b, 17b-dihydroxyestr-5-ene); and
- (**IV**) 19-nor-5-androstenediol (3a, 17b-dihydroxyestr-5-ene);
- (**xxxvi**) norandrostenedione—
- (**I**) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and
- (**II**) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
- (xxxvii) norbolethone (13b,17a-diethyl-17b-hydroxygon-4-en-3-one);
- (xxxviii) norclostebol (4-chloro-17b-hydroxyestr-4-en-3-one);
- (**xxxix**) norethandrolone (17a-ethyl-17b-hydroxyestr-4-en-3-one);
- (**xl**) normethandrolone (17a-methyl-17b-hydroxyestr-4-en-3-one);
- (**xli**) oxandrolone (17a-methyl-17b-hydroxy-2-oxa-[5a]-androstan-3-one);
- (**xlii**) oxymesterone (17a-methyl-4,17b-dihydroxyandrost-4-en-3-one);
- (**xliii**) oxymetholone
(17a-methyl-2-hydroxymethylene-17b-hydroxy-[5a]-androstan-3-one);
- (**xliv**) stanozolol (17a-methyl-17b-hydroxy-[5a]-androst-2-eno[3,2-c]-pyrazole);
- (**xlv**) stenbolone (17b-hydroxy-2-methyl-[5a]-androst-1-en-3-one);
- (**xlvi**) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
- (**xlvii**) testosterone (17b-hydroxyandrost-4-en-3-one);
- (xlviii) tetrahydrogestrinone (13b,17a-diethyl-17b-hydroxygon-4,9,11-trien-3-one);
- (**xl ix**) trenbolone (17b-hydroxyestr-4,9,11-trien-3-one); and
- (**xl x**) ¹ any salt, ester, or ether of a drug or substance described in this paragraph.

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The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 811 of this title.

- (B)** (i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.
- (ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).
- (42)** The term “international transaction” means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.
- (43)** The terms “broker” and “trader” mean a person that assists in arranging an international transaction in a listed chemical by—
- (A) negotiating contracts;
- (B) serving as an agent or intermediary; or
- (C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.
- (44)** The term “felony drug offense” means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, anabolic steroids, or depressant or stimulant substances.
- (45)** (A) The term “scheduled listed chemical product” means, subject to subparagraph (B), a product that—
- (i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and
- (ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] as a nonprescription drug.
- Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.
- (B)** Such term does not include a product described in subparagraph (A) if the product contains a chemical specified in such subparagraph that the Attorney General has under section 811 (a) of this title added to any of the schedules under section 812 (c) of this title. In the absence of such scheduling by the Attorney General, a chemical specified in such subparagraph may not be considered to be a controlled substance.
- (46)** The term “regulated seller” means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor.
- (47)** The term “mobile retail vendor” means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).
- (48)** The term “at retail”, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.
- (49)** (A) The term “retail distributor” means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

- (i)** A grocery store is an entity within SIC code 5411.
- (ii)** A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.
- (iii)** A drug store is an entity within SIC code 5912.

(50) The term “Internet” means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(51) The term “deliver, distribute, or dispense by means of the Internet” refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(52) The term “online pharmacy”—

(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet; and

(B) does not include—

- (i)** manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 823 of this title who do not dispense controlled substances to an unregistered individual or entity;
- (ii)** nonpharmacy practitioners who are registered under section 823 (f) of this title and whose activities are authorized by that registration;
- (iii)** any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 823 (f) of this title;
- (iv)** a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act [25 U.S.C. 450 et seq.];
- (v)** any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;
- (vi)** mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;
- (vii)** a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;
- (viii)** a pharmacy registered under section 823 (f) of this title whose dispensing of controlled substances via the Internet consists solely of—
 - (I)** refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (55); or
 - (II)** filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (56); or
- (ix)** any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and safety to exempt from the definition of an “online pharmacy”.

(53) The term “homepage” means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term “practice of telemedicine” means, for purposes of this subchapter, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m (m) of title 42, which practice—

(A) is being conducted—

(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 823 (f) of this title; and

(ii) by a practitioner—

(I) acting in the usual course of professional practice;

(II) acting in accordance with applicable State law; and

(III) registered under section 823 (f) of this title in the State in which the patient is located, unless the practitioner—

(aa) is exempted from such registration in all States under section 822 (d) of this title; or

(bb) is—

(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(BB) registered under section 823 (f) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823 (f) of this title;

(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner—

(i) acting in the usual course of professional practice;

(ii) acting in accordance with applicable State law; and

(iii) registered under section 823 (f) of this title in the State in which the patient is located, unless the practitioner—

(I) is exempted from such registration in all States under section 822 (d) of this title; or

(II) is—

(aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(bb) registered under section 823 (f) of this title in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823 (f) of this title;

(C) is being conducted by a practitioner—

(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act [25 U.S.C. 450 et seq.];

(ii) acting within the scope of the employment, contract, or compact described in clause (i); and

(iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 831 (g)(2) of this title;

(D) **(i)** is being conducted during a public health emergency declared by the Secretary under section 247d of title 42; and

- (ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5;
 - (E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 831 (h) of this title;
 - (F) is being conducted—
 - (i) in a medical emergency situation—
 - (I) that prevents the patient from being in the physical presence of a practitioner registered under section 823 (f) of this title who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;
 - (II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 823 (f) of this title;
 - (III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and
 - (IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and
 - (ii) by a practitioner that—
 - (I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;
 - (II) is registered under section 823 (f) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823 (f) of this title; and
 - (III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or
 - (G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.
- (55) The term “refilling prescriptions for controlled substances in schedule III, IV, or V”—
- (A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 829 of this title, as appropriate; and
 - (B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.
- (56) The term “filling new prescriptions for controlled substances in schedule III, IV, or V” means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if—
- (A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 829 of this title (in this paragraph referred to as the “original prescription”);
 - (B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and
 - (C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

Footnotes

¹ So in original. Probably should be “(I)”.

(Pub. L. 91–513, title II, § 102, Oct. 27, 1970, 84 Stat. 1242; Pub. L. 93–281, § 2, May 14, 1974, 88 Stat. 124; Pub. L. 95–633, title I, § 102(b), Nov. 10, 1978, 92 Stat. 3772; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 96–132, § 16(a), Nov. 30, 1979, 93 Stat. 1049; Pub. L. 98–473, title II, § 507(a), (b), Oct. 12, 1984, 98 Stat. 2071; Pub. L. 98–509, title III, § 301(a), Oct. 19, 1984, 98 Stat. 2364; Pub. L. 99–514, § 2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 99–570, title I, §§ 1003(b), 1203, 1870, Oct. 27, 1986, 100 Stat. 3207–6, 3207–13, 3207–56; Pub. L. 99–646, § 83, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 100–690, title VI, § 6054, Nov. 18, 1988, 102 Stat. 4316; Pub. L. 101–647, title XIX, § 1902(b), title XXIII, § 2301, title XXXV, § 3599I, Nov. 29, 1990, 104 Stat. 4852, 4858, 4932; Pub. L. 103–200, §§ 2(a), 7–9 (a), Dec. 17, 1993, 107 Stat. 2333, 2340; Pub. L. 103–322, title IX, § 90105(d), title XXXIII, § 330024(a), (b), (d)(1), Sept. 13, 1994, 108 Stat. 1988, 2150; Pub. L. 104–237, title II, §§ 204(a), 209, title IV, § 401(a), (b), Oct. 3, 1996, 110 Stat. 3102, 3104, 3106, 3107; Pub. L. 104–294, title VI, §§ 604(b)(4), 607 (j), Oct. 11, 1996, 110 Stat. 3506, 3512; Pub. L. 105–115, title I, § 126(c)(3), Nov. 21, 1997, 111 Stat. 2328; Pub. L. 106–172, §§ 3(c), 5 (a), Feb. 18, 2000, 114 Stat. 9, 10; Pub. L. 106–310, div. B, title XXXVI, § 3622(a), Oct. 17, 2000, 114 Stat. 1231; Pub. L. 107–273, div. B, title IV, § 4002(c)(1), Nov. 2, 2002, 116 Stat. 1808; Pub. L. 108–358, § 2(a), Oct. 22, 2004, 118 Stat. 1661; Pub. L. 109–162, title XI, § 1180, Jan. 5, 2006, 119 Stat. 3126; Pub. L. 109–177, title VII, §§ 711(a)(1), (2)(A), 712 (a)(1), Mar. 9, 2006, 120 Stat. 256, 257, 263; Pub. L. 110–425, § 3(a), Oct. 15, 2008, 122 Stat. 4821.)

References in Text

Schedules I, II, III, IV, and V, referred to in pars. (6), (14), (32)(A), (52)(B)(viii), (55), and (56), are set out in section 812 (c) of this title.

This subchapter, referred to in introductory provisions and in pars. (34), (35), (39)(A)(iii), (vi), and (54), 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.

Subchapter II of this chapter, referred to in par. (39)(A)(iii), (vi), was in the original “title III”, meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in pars. (39)(A)(iv) and (45)(A)(ii), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

The Indian Self-Determination and Education Assistance Act, referred to in pars. (52)(B)(iv) and (54)(C)(i), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to subchapter II (§ 450 et seq.) of chapter 14 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 450 of Title 25 and Tables.

Amendments

2008—Pars. (50) to (56). Pub. L. 110–425 added pars. (50) to (56).

2006—Par. (39)(A)(iv). Pub. L. 109–177, § 712(a)(1)(A)(i), amended cl. (iv) generally. Prior to amendment, cl. (iv) related to transactions involving drugs containing ephedrine, pseudoephedrine, or phenylpropanolamine.

Par. (39)(A)(v), (vi). Pub. L. 109–177, § 712(a)(1)(A)(ii), (iii), added cl. (v) and redesignated former cl. (v) as (vi).

Par. (41)(A)(xvii). Pub. L. 109–162, § 1180(1), substituted “13b-ethyl-17b-hydroxygon-4-en-3-one;” for “13b-ethyl-17a-hydroxygon-4-en-3-one;”.

Par. (41)(A)(xliv). Pub. L. 109–162, § 1180(2), substituted “(17a-methyl-17b-hydroxy-[5a]-androst-2-eno[3,2-c]-pyrazole);” for “(17a-methyl-17a-hydroxy-[5a]-androst-2-eno[3,2-c]-pyrazole);”.

Par. (45). Pub. L. 109–177, §§ 711(a)(1)(B), 712 (a)(1)(B), added par. (45) and struck out former par. (45) which defined “ordinary over-the-counter pseudoephedrine or phenylpropanolamine product”.

Pars. (46) to (48). Pub. L. 109–177, §§ 711(a)(1)(B), added pars. (46) to (48). Former par. (46) redesignated (49).

NB: This unofficial compilation of the U.S. Code is current as of Jan. 4, 2012 (see <http://www.law.cornell.edu/uscode/uscprint.html>).

Par. (49). Pub. L. 109–177, § 711(a)(1)(A), (2)(A), redesignated par. (46) as (49), substituted “ephedrine, pseudoephedrine, or” for “pseudoephedrine or” in subpar. (A), redesignated subpar. (C) as (B), and struck out former subpar. (B) which read as follows: “For purposes of this paragraph, sale for personal use means the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use.”

2004—Par. (41). Pub. L. 108–358, § 2(a)(1), realigned margins, added subpar. (A), and struck out former subpar. (A) which defined “anabolic steroid”.

Par. (44). Pub. L. 108–358, § 2(a)(2), inserted “anabolic steroids,” after “marihuana,”.

2002—Pars. (43), (44). Pub. L. 107–273 repealed Pub. L. 104–294, §§ 604(b)(4), 607 (j)(2). See 1996 Amendment note below.

2000—Par. (32)(A). Pub. L. 106–172, § 5(a)(1), substituted “subparagraph (C)” for “subparagraph (B)” in introductory provisions.

Par. (32)(B), (C). Pub. L. 106–172, § 5(a)(2), (3), added subpar. (B) and redesignated former subpar. (B) as (C).

Par. (34)(X), (Y). Pub. L. 106–172, § 3(c), added subpar. (X) and redesignated former subpar. (X) as (Y).

Par. (39)(A)(iv)(II). Pub. L. 106–310 substituted “9 grams” for “24 grams” in two places and inserted before semicolon at end “and sold in package sizes of not more than 3 grams of pseudoephedrine base or 3 grams of phenylpropanolamine base”.

1997—Par. (9)(A). Pub. L. 105–115 redesignated cl. (i) as subpar. (A) and struck out cl. (ii) which read as follows: “any derivative of barbituric acid which has been designated by the Secretary as habit forming under section 352 (d) of this title; or”.

1996—Par. (26). Pub. L. 104–294, § 607(j)(1), amended par. (26) generally. Prior to amendment, par. (26) read as follows: “The term ‘State’ means any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.”

Par. (34)(P), (S), (U). Pub. L. 104–237, § 209(1), substituted “Isosafrole” for “Insosafrole” in subpar. (P), “N-Methylephedrine” for “N-Methylepherdrine” in subpar. (S), and “Hydriodic acid” for “Hydriotic acid” in subpar. (U).

Par. (35)(G). Pub. L. 104–237, § 209(2), amended subpar. (G) generally, inserting “(or Methyl Ethyl Ketone)” before period at end.

Par. (35)(I), (J). Pub. L. 104–237, § 204(a), added subpars. (I) and (J).

Par. (39)(A)(iv)(I)(aa). Pub. L. 104–237, § 401(a)(1), (b)(1), substituted “, pseudoephedrine or its salts, optical isomers, or salts of optical isomers, or phenylpropanolamine or its salts, optical isomers, or salts of optical isomers unless otherwise provided by regulation of the Attorney General issued pursuant to section 814 (e) of this title, except that any sale of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products by retail distributors shall not be a regulated transaction (except as provided in section 401(d) of the Comprehensive Methamphetamine Control Act of 1996);” for “as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient;”.

Par. (39)(A)(iv)(II). Pub. L. 104–237, § 401(a)(2), (b)(2), inserted “, pseudoephedrine, phenylpropanolamine,” after “ephedrine” and inserted before semicolon “, except that the threshold for any sale of products containing pseudoephedrine or phenylpropanolamine products by retail distributors or by distributors required to submit reports by section 830 (b)(3) of this title shall be 24 grams of pseudoephedrine or 24 grams of phenylpropanolamine in a single transaction”.

Pars. (43), (44). Pub. L. 104–294, §§ 604(b)(4), 607 (j)(2), which provided for amendment to section identical to Pub. L. 104–237, § 401(b)(3), below, were repealed by Pub. L. 107–273, § 4002(c)(1).

Pub. L. 104–237, § 401(b)(3), redesignated par. (43), relating to felony drug offense, as (44).

Pars. (45), (46). Pub. L. 104–237, § 401(b)(4), added pars. (45) and (46).

1994—Par. (34)(V), (W). Pub. L. 103–322, § 330024(b), realigned margins and capitalized first letter.

Par. (35). Pub. L. 103–322, § 330024(d)(1), made technical correction to directory language of Pub. L. 103–200, § 2(a)(4)(B). See 1993 Amendment note below.

Par. (39)(A)(iv)(II). Pub. L. 103–322, § 330024(a), substituted “; or” for period at end.

Par. (43). Pub. L. 103–322, § 90105(d), added par. (43) defining “felony drug offense”.

1993—Par. (33). Pub. L. 103–200, § 2(a)(1), substituted “any list I chemical or any list II chemical” for “any listed precursor chemical or listed essential chemical”.

NB: This unofficial compilation of the U.S. Code is current as of Jan. 4, 2012 (see <http://www.law.cornell.edu/uscode/uscprint.html>).

Par. (34). Pub. L. 103–200, § 2(a)(2), substituted “list I chemical” for “listed precursor chemical” and “important to the manufacture” for “critical to the creation” in introductory provisions.

Par. (34)(A), (F), (H). Pub. L. 103–200, § 2(a)(3), inserted “, its esters,” before “and”.

Par. (34)(O). Pub. L. 103–200, § 8(1), (2), redesignated subpar. (P) as (O) and struck out former subpar. (O) which read as follows: “D-lysergic acid.”

Par. (34)(P) to (S). Pub. L. 103–200, § 8(2), redesignated subpars. (Q) to (T) as (P) to (S), respectively. Former subpar. (P) redesignated (O).

Par. (34)(T). Pub. L. 103–200, § 8(2), redesignated subpar. (V) as (T). Former subpar. (T) redesignated (S).

Par. (34)(U). Pub. L. 103–200, § 8(1), (2), redesignated subpar. (X) as (U) and struck out former subpar. (U) which read as follows: “N-ethylephedrine.”

Par. (34)(V). Pub. L. 103–200, § 8(2), (4), added subpar. (V) and redesignated former subpar. (V) as (T).

Par. (34)(W). Pub. L. 103–200, § 8(1), (4), added subpar. (W) and struck out former subpar. (W) which read as follows: “N-ethylpseudoephedrine.”

Par. (34)(X). Pub. L. 103–200, § 8(2), (3), redesignated subpar. (Y) as (X) and substituted “through (U)” for “through (X)”.

Par. (34)(Y). Pub. L. 103–200, § 8(2), redesignated subpar. (Y) as (X).

Par. (35). Pub. L. 103–200, § 2(a)(4)(A), (C), substituted “list II chemical” for “listed essential chemical” and struck out “as a solvent, reagent, or catalyst” before “in manufacturing”.

Pub. L. 103–200, § 2(a)(4)(B), as amended by Pub. L. 103–322, § 330024(d)(1), inserted “(other than a list I chemical)” before “specified” the first time appearing.

Par. (37). Pub. L. 103–200, § 9(a), amended par. (37) generally. Prior to amendment, par. (37) read as follows: “The term ‘regular supplier’ means, with respect to a regulated person, a supplier with whom the regulated person has an established business relationship that is reported to the Attorney General.”

Par. (38). Pub. L. 103–200, § 2(a)(5), inserted before period at end “or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine”.

Par. (39)(A). Pub. L. 103–200, §§ 2(a)(6)(A), 7, in introductory provisions, substituted “importation, or exportation of, or an international transaction involving shipment of,” for “importation or exportation of” and inserted “a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical,” before “a threshold amount.”

Par. (39)(A)(iii). Pub. L. 103–200, § 2(a)(6)(B), inserted “or any category of transaction for a specific listed chemical or chemicals” after “transaction”.

Par. (39)(A)(iv). Pub. L. 103–200, § 2(a)(6)(C), amended cl. (iv) generally. Prior to amendment, cl. (iv) read as follows: “any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act; or”.

Par. (39)(A)(v). Pub. L. 103–200, § 2(a)(6)(D), inserted before semicolon at end “which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II of this chapter based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered”.

Par. (40). Pub. L. 103–200, § 2(a)(7), substituted “list I chemical or a list II chemical” for “listed precursor chemical or a listed essential chemical” in two places.

Pars. (42), (43). Pub. L. 103–200, § 2(a)(8), added pars. (42) and (43).

1990—Par. (32)(A). Pub. L. 101–647, § 3599I, substituted “the stimulant” for “the stimulent” in cl. (ii) and “a stimulant” for “a stimulent” in cl. (iii).

Par. (34)(M) to (Y). Pub. L. 101–647, § 2301(a), added subpars. (M) to (Y).

Par. (35)(E). Pub. L. 101–647, § 2301(b), struck out subpar. (E) “Hydriodic acid.”

Par. (41). Pub. L. 101–647, § 1902(b), added par. (41).

1988—Par. (8). Pub. L. 100–690, § 6054(1), inserted “or a listed chemical” after “a controlled substance”.

Par. (11). Pub. L. 100–690, § 6054(2), inserted “or a listed chemical” after “a controlled substance” in two places.

Pars. (33) to (40). Pub. L. 100–690, § 6054(3), added pars. (33) to (40).

NB: This unofficial compilation of the U.S. Code is current as of Jan. 4, 2012 (see <http://www.law.cornell.edu/uscode/uscprint.html>).

- 1986—Par. (6). Pub. L. 99–514 substituted “Internal Revenue Code of 1986” for “Internal Revenue Code of 1954”.
- Par. (14). Pub. L. 99–570, § 1870, and Pub. L. 99–646 amended par. (14) identically, substituting “any optical” for “the optical” in second and third sentences.
- Par. (25). Pub. L. 99–570, § 1003(b)(1), added par. (25). Former par. (25) redesignated (26).
- Pars. (26) to (31). Pub. L. 99–570, § 1003(b)(2), redesignated pars. (25) to (30) as (26) to (31), respectively.
- Par. (32). Pub. L. 99–570, § 1203, added par. (32).
- 1984—Pars. (14) to (16). Pub. L. 98–473, § 507(a), added par. (14) and redesignated former pars. (14) to (16) as (15) to (17), respectively.
- Par. (17). Pub. L. 98–473, § 507, redesignated former par. (16) as (17), and expanded and revised definition of “narcotic drug”, including within term poppy straw, cocaine, and ecgonine. Former par. (17) redesignated (18).
- Pars. (18) to (28). Pub. L. 98–473, § 507(a), redesignated former pars. (17) to (27) as (18) to (28), respectively.
- Par. (29). Pub. L. 98–509 which directed the substitution of “one hundred and eighty” for “twenty-one” in par. (28), was executed to par. (29) in view of the redesignation of par. (28) as par. (29) by Pub. L. 98–473.
- Pub. L. 98–473, § 507(a), redesignated former par. (28) as (29). Former par. (29) redesignated (30).
- Par. (30). Pub. L. 98–473, § 507(a), redesignated former par. (29) as (30).
- 1979—Par. (4). Pub. L. 96–132 substituted provisions defining “Drug Enforcement Administration” for provisions defining “Bureau of Narcotics and Dangerous Drugs”.
- 1978—Par. (29). Pub. L. 95–633 added par. (29).
- 1974—Pars. (27), (28). Pub. L. 93–281 added pars. (27) and (28).

Change of Name

“Secretary of Health and Human Services” substituted for “Secretary of Health, Education, and Welfare” in par. (24) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508 (b) of Title 20, Education.

Effective Date of 2008 Amendment

Pub. L. 110–425, § 3(j), Oct. 15, 2008, 122 Stat. 4832, provided that:

“(1) In general.—Except as provided in paragraph (2), the amendments made by this Act [enacting section 831 of this title and amending this section and sections 823, 827, 829, 841, 843, 882 and 960 of this title] shall take effect 180 days after the date of enactment of this Act [Oct. 15, 2008].

“(2) Definition of practice of telemedicine.—

“(A) In general.—Until the earlier of 3 months after the date on which regulations are promulgated to carry out section 311(h) of the Controlled Substances Act [21 U.S.C. 831 (h)], as amended by this Act, or 15 months after the date of enactment of this Act—

“(i) the definition of the term ‘practice of telemedicine’ in subparagraph (B) of this paragraph shall apply for purposes of the Controlled Substances Act [21 U.S.C. 801 et seq.]; and

“(ii) the definition of the term ‘practice of telemedicine’ in section 102(54) of the Controlled Substances Act [21 U.S.C. 802 (54)], as amended by this Act, shall not apply.

“(B) Temporary phase-in of telemedicine regulation.—During the period specified in subparagraph (A), the term ‘practice of telemedicine’ means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (as that term is defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m (m)), if the practitioner is using an interactive telecommunications system that satisfies the requirements of section 410.78(a)(3) of title 42, Code of Federal Regulations.

“(C) Rule of construction.—Nothing in this subsection may be construed to create a precedent that any specific course of conduct constitutes the ‘practice of telemedicine’ (as that term is defined in section 102(54) of the Controlled Substances Act, as amended by this Act) after the end of the period specified in subparagraph (A).”

Effective Date of 2004 Amendment

Pub. L. 108–358, § 2(d), Oct. 22, 2004, 118 Stat. 1664, provided that: “The amendments made by this section [amending this section, section 811 of this title, and provisions set out as a note under this section] shall take effect 90 days after the date of enactment of this Act [Oct. 22, 2004].”

Effective Date of 2002 Amendment

Pub. L. 107–273, div. B, title IV, § 4002(c)(1), Nov. 2, 2002, 116 Stat. 1808, provided that the amendment made by section 4002 (c)(1) is effective Oct. 11, 1996.

Effective Date of 2000 Amendment

Pub. L. 106–310, div. B, title XXXVI, § 3622(b), Oct. 17, 2000, 114 Stat. 1231, provided that: “The amendments made by subsection (a) [amending this section] shall take effect 1 year after the date of the enactment of this Act [Oct. 17, 2000].”

Effective Date of 1997 Amendment

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of this title.

Effective Date of 1996 Amendments

Amendment by section 604(b)(4) of Pub. L. 104–294 effective Sept. 13, 1994, see section 604(d) of Pub. L. 104–294, set out as a note under section 13 of Title 18, Crimes and Criminal Procedure.

Section 401(g) of Pub. L. 104–237 provided that: “Notwithstanding any other provision of this Act [see section 1(a) of Pub. L. 104–237, set out as a Short Title of 1996 Amendments note under section 801 of this title], this section [amending this section and section 814 of this title and enacting provisions set out as a note below] shall not apply to the sale of any pseudoephedrine or phenylpropanolamine product prior to 12 months after the date of enactment of this Act [Oct. 3, 1996], except that, on application of a manufacturer of a particular pseudoephedrine or phenylpropanolamine drug product, the Attorney General may, in her sole discretion, extend such effective date up to an additional six months. Notwithstanding any other provision of law, the decision of the Attorney General on such an application shall not be subject to judicial review.”

Effective Date of 1994 Amendment

Section 330024(f) of Pub. L. 103–322 provided that: “The amendments made by this section [amending this section and sections 824, 960, and 971 of this title] shall take effect as of the date that is 120 days after the date of enactment of the Domestic Chemical Diversion Control Act of 1993 [Dec. 17, 1993].”

Effective Date of 1993 Amendment

Section 11 of Pub. L. 103–200 provided that: “This Act [enacting section 814 of this title, amending this section and sections 821 to 824, 830, 843, 880, 957, 958, 960, and 971 of this title, and enacting provisions set out as a note under section 801 of this title] and the amendments made by this Act shall take effect on the date that is 120 days after the date of enactment of this Act [Dec. 17, 1993].”

Effective Date of 1990 Amendment

Section 1902(d) of Pub. L. 101–647 provided that: “This section [amending this section and section 812 of this title and enacting provisions set out as a note under section 829 of this title] and the amendment made by this section shall take effect 90 days after the date of enactment of this Act [Nov. 29, 1990].”

Effective Date of 1988 Amendment

Section 6061 of title VI of Pub. L. 100–690 provided that: “Except as otherwise provided in this subtitle, this subtitle [subtitle A (§§ 6051–6061) of title VI of Pub. L. 100–690, enacting section 971 of this title, amending this section and sections 830, 841 to 843, 872, 876, 881, 960, and 961 of this title, and enacting provisions set out as notes under this section and section 971 of this title] shall take effect 120 days after the enactment of this Act [Nov. 18, 1988].”

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.

Regulations

Pub. L. 110–425, § 3(k)(1), Oct. 15, 2008, 122 Stat. 4833, provided that: “The Attorney General may promulgate and enforce any rules, regulations, and procedures which may be necessary and appropriate for the efficient execution of functions under this Act [see Short Title of 2008 Amendment note set out under section 801 of this title] or the amendments made by this Act, and, with the concurrence of the Secretary of Health and Human Services where this Act or the amendments made by this Act so provide, promulgate any interim rules necessary for the implementation of this Act or the amendments made by this Act, prior to its effective date [see Effective Date of 2008 Amendment note above].”

Section 301(b) of Pub. L. 98–509 provided that: “The Secretary of Health and Human Services shall, within ninety days of the date of the enactment of this Act [Oct. 19, 1984], promulgate regulations for the administration of section 102(28) of the Controlled Substances Act [21 U.S.C. 802 (29)] as amended by subsection (a) and shall include in the first report submitted under section 505 (b) [503(b)] of the Public Health Service Act [former 42 U.S.C. 290aa–2 (b)] after the expiration of such ninety days the findings of the Secretary with respect to the effect of the amendment made by subsection (a).”

Construction of 2008 Amendment

Pub. L. 110–425, § 4, Oct. 15, 2008, 122 Stat. 4834, provided that: “Nothing in this Act [see Short Title of 2008 Amendment note set out under section 801 of this title] or the amendments made by this Act shall be construed as authorizing, prohibiting, or limiting the use of electronic prescriptions for controlled substances.”

Preservation of State Authority To Regulate Scheduled Listed Chemicals

Pub. L. 109–177, title VII, § 711(g), Mar. 9, 2006, 120 Stat. 263, provided that: “This section [amending this section and sections 830, 841, 842, and 844 of this title and enacting provisions set out as notes under sections 830 and 844 of this title] and the amendments made by this section may not be construed as having any legal effect on section 708 of the Controlled Substances Act [21 U.S.C. 903] as applied to the regulation of scheduled listed chemicals (as defined in section 102(45) of such Act [21 U.S.C. 802 (45)]).”

Report on Diversion of Ordinary, Over-the-Counter Pseudoephedrine and Phenylpropanolamine Products

Pub. L. 106–310, div. B, title XXXVI, § 3642, Oct. 17, 2000, 114 Stat. 1237, provided that:

“(a) Study.—The Attorney General shall conduct a study of the use of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products in the clandestine production of illicit drugs. Sources of data for the study shall include the following:

“(1) Information from Federal, State, and local clandestine laboratory seizures and related investigations identifying the source, type, or brand of drug products being utilized and how they were obtained for the illicit production of methamphetamine and amphetamine.

“(2) Information submitted voluntarily from the pharmaceutical and retail industries involved in the manufacture, distribution, and sale of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine, including information on changes in the pattern, volume, or both, of sales of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products.

“(b) Report.—

“(1) Requirement.—Not later than 1 year after the date of the enactment of this Act [Oct. 17, 2000], the Attorney General shall submit to Congress a report on the study conducted under subsection (a).

“(2) Elements.—The report shall include—

“(A) the findings of the Attorney General as a result of the study; and

“(B) such recommendations on the need to establish additional measures to prevent diversion of ordinary, over-the-counter pseudoephedrine and phenylpropanolamine (such as a threshold on ordinary, over-the-counter pseudoephedrine and phenylpropanolamine products) as the Attorney General considers appropriate.

“(3) Matters considered.—In preparing the report, the Attorney General shall consider the comments and recommendations including the comments on the Attorney General’s proposed findings and recommendations, of State and local law enforcement and regulatory officials and of representatives of the industry described in subsection (a)(2).

“(c) Regulation of Retail Sales.—

“(1) In general.—Notwithstanding section 401(d) of the Comprehensive Methamphetamine Control Act of 1996 [Pub. L. 104–237] (21 U.S.C. 802 note) and subject to paragraph (2), the Attorney General shall establish by

NB: This unofficial compilation of the U.S. Code is current as of Jan. 4, 2012 (see <http://www.law.cornell.edu/uscode/uscprint.html>).

regulation a single-transaction limit of not less than 24 grams of ordinary, over-the-counter pseudoephedrine or phenylpropanolamine (as the case may be) for retail distributors, if the Attorney General finds, in the report under subsection (b), that—

“(A) there is a significant number of instances (as set forth in paragraph (3)(A) of such section 401 (d) for purposes of such section) where ordinary, over-the-counter pseudoephedrine products, phenylpropanolamine products, or both such products that were purchased from retail distributors were widely used in the clandestine production of illicit drugs; and

“(B) the best practical method of preventing such use is the establishment of single-transaction limits for retail distributors of either or both of such products.

“(2) Due process.—The Attorney General shall establish the single-transaction limit under paragraph (1) only after notice, comment, and an informal hearing.”

Regulation of Retail Sales of Certain Precursor Chemicals; Effect on Thresholds; Combination Ephedrine Products

Pub. L. 104–237, title IV, § 401(d)–(f), Oct. 3, 1996, 110 Stat. 3108, which authorized the Attorney General to establish a single-transaction limit of 24 grams for pseudoephedrine, phenylpropanolamine, and combination ephedrine products for retail distributors, was repealed by Pub. L. 109–177, title VII, § 712(b), Mar. 9, 2006, 120 Stat. 264.

Exemption for Substances in Paragraph (41)

Pub. L. 101–647, title XIX, § 1903, Nov. 29, 1990, 104 Stat. 4853, as amended by Pub. L. 108–358, § 2(c), Oct. 22, 2004, 118 Stat. 1663, provided that:

“(a) Drugs for Treatment of Rare Diseases.—If the Attorney General finds that a drug listed in paragraph (41) of section 102 of the Controlled Substances Act (as added by section 2 [1902] of this Act) is—

“(1) approved by the Food and Drug Administration as an accepted treatment for a rare disease or condition, as defined in section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb); and

“(2) does not have a significant potential for abuse, the Attorney General may exempt such drug from any production regulations otherwise issued under the Controlled Substances Act as may be necessary to ensure adequate supplies of such drug for medical purposes.

“(b) Date of Issuance of Regulations.—The Attorney General shall issue regulations implementing this section not later than 45 days after the date of enactment of this Act [Nov. 29, 1990], except that the regulations required under section 3 (a) [former 1903(a)] shall be issued not later than 180 days after the date of enactment of this Act.”