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PART 1300—DEFINITIONS

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AUTHORITY: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

SOURCE: 62 FR 13941, Mar. 24, 1997, unless otherwise noted.

§ 1300.01 Definitions relating to controlled substances.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

(b) As used in parts 1301 through 1308, 1312, and 1317 of this chapter, the following terms shall have the meanings specified:

Act means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951).

Administration means the Drug Enforcement Administration.

Administrator means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

Anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes:

(1) 3β,17-dihydroxy-5a-androstane
(2) 3α,17β-dihydroxy-5a-androstane
(3) 5α-androstan-3,17-dione
(4) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene)
(5) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene)
(6) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene)
(7) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene)
(8) 1-androstenedione ([5α]-androst-1-en-3,17-dione)
(9) 4-androstenedione (androst-4-en-3,17-dione)
(10) 5-androstenedione (androst-5-en-3,17-dione)
(11) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)
(12) boldenone (17β-hydroxyandrost-1,4-diene-3-one)
(13) boldione (androsta-1,4-diene-3,17-dione)
(14) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)
(15) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one)
(16) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one)
(17) desoxymethyltestosterone (17α-methyl-5α-androst-2-en-17β-ol) (a.k.a. 'madol')
(18) Δ1-dihydrotestosterone (a.k.a.'1-testosterone') (17β-hydroxy-5α-androst-1-en-3-one)
(19) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one)
(20) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one)
(21) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene)
(22) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one)
(23) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one)
(24) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]-furazan)
(25) 13β-ethyl-17β-hydroxygon-4-en-3-one
(26) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one)
(27) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one)
(28) mestanolone (17α-methyl-17β-hydroxy-5-androstan-3-one)
(29) mesterolone (1α-methyl-17β-hydroxy-[5α]-androstan-3-one)
(30) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one)
(31) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene)
(32) Methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one)
(33) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one)

(34) 17α-methyl-3β,17β-dihydroxy-5a-androstane
(35) 17α-methyl-3α,17β-dihydroxy-5a-androstane
(36) 17α-methyl-3β,17β-dihydroxyandrost-4-ene
(37) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one)
(38) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one)
(39) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9,11-trien-3-one)
(40) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one)
(41) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one)
(42) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. '17-α-methyl-1-testosterone')
(43) nandrolone (17β-hydroxyestr-4-en-3-one)
(44) 19-nor-4-androstenediol (3β, 17β-dihydroxyestr-4-ene)
(45) 19-nor-4-androstenediol (3α, 17β-dihydroxyestr-4-ene)
(46) 19-nor-5-androstenediol (3β, 17β-dihydroxyestr-5-ene)
(47) 19-nor-5-androstenediol (3α, 17β-dihydroxyestr-5-ene)
(48) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione)
(49) 19-nor-4-androstenedione (estr-4-en-3,17-dione)
(50) 19-nor-5-androstenedione (estr-5-en-3,17-dione)
(51) norbolethone (13β, 17α-diethyl-17β-hydroxygon-4-en-3-one)
(52) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one)
(53) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one)
(54) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one)
(55) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]-androstan-3-one)
(56) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one)
(57) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-[5α]-androstan-3-one)
(58) Prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole)
(59) stanozolol (17α-methyl-17β-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole)
(60) stenbolone (17β-hydroxy-2-methyl-[5α]-androst-1-en-3-one)
(61) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone)
(62) testosterone (17β-hydroxyandrost-4-en-3-one)
(63) tetrahydrogestrinone (13β, 17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one)
(64) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one)
(65) Any salt, ester, or ether of a drug or substance described in this paragraph. Except such term does not include an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

Automated dispensing system means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

Basic class means, as to controlled substances listed in Schedules I and II:

(1) Each of the opiates, including its 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, listed in §1308.11(b) of this chapter;

(2) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.11(c) of this chapter;

(3) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.11(d) of this chapter;

(4) Each of the following substances, 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:

(i) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(ii) Apomorphine;

(iii) Codeine;

(iv) Etorphine hydrochloride;

(v) Ethylmorphine;

(vi) Hydrocodone;

(vii) Hydromorphone;

(viii) Metopon;

(ix) Morphine;

(x) Oxycodone;

(xi) Oxymorphone;

(xii) Thebaine;

(xiii) Mixed alkaloids of opium listed in §1308.12(b)(2) of this chapter;

(xiv) Cocaine; and

(xv) Ecgonine;

(5) Each of the opiates, including its 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, listed in §1308.12(c) of this chapter; and

(6) Methamphetamine, its salts, isomers, and salts of its isomers;

(7) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(8) Phenmetrazine and its salts;

(9) Methylphenidate;

(10) Each of the substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.12(e) of this chapter.

Central fill pharmacy means a pharmacy which is permitted by the state in which it is located to prepare controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed ''authorized'' to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

Collection means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The term *collector* means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized under this chapter to so receive a controlled substance for the purpose of destruction.

Commercial container means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

Competent national authority, for purposes of importation and exportation of controlled substances and listed chemicals, means an entity lawfully entitled to authorize the import and export of controlled substances, and to regulate or enforce national controls over listed chemicals, and included as such in the directory of ''Competent National Authorities Under the International Drug Control Treaties'' published by the United Nations Office on Drugs and Crime. For purposes of exports of narcotic drugs, the term also includes freely associated states authorized to receive such exports pursuant to 48 U.S.C. 1972.

Compounder means any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.

Controlled substance has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.).

Customs officer means either an Officer of the Customs as defined in 19 U.S.C. 1401(i) (that is, of the U.S. Customs and Border Protection), or any individual duly authorized to accept entries of merchandise, to collect duties, and to enforce the customs laws of any commonwealth, territory, or possession of the United States.

Customs territory of the United States means the several States, the District of Columbia, and Puerto Rico.

Detoxification treatment means the dispensing, for a period of time as specified below, of a narcotic drug or narcotic drugs in decreasing doses to an individual 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 of time. There are two types of detoxification treatment: Short-term detoxification treatment and long-term detoxification treatment.

(1) Short-term detoxification treatment is for a period not in excess of 30 days.

(2) Long-term detoxification treatment is for a period more than 30 days but not in excess of 180 days.

Dispenser means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

Export means, with respect to any article, any taking out or removal of such article from the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs laws, export control laws enforced by other agencies, or related laws of the United States).

Exporter includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in any schedule.

Freight forwarding facility means a separate facility operated by a distributing registrant through which sealed, packaged controlled substances in unmarked shipping containers (*i.e.*, the containers do not indicate that the contents include controlled substances) are, in the course of delivery to, or return from, customers, transferred in less than 24 hours. A distributing registrant who operates a freight forwarding facility may use the facility to transfer controlled substances from any location the distributing registrant operates that is registered with the Administration to manufacture, distribute, or import controlled substances, or, with respect to returns, registered to dispense controlled substances, provided that the notice required by §1301.12(b)(4) of Part 1301 of this chapter has been submitted and approved. For purposes of this definition, a distributing registrant is a person who is registered with the Administration as a manufacturer, distributor (excluding reverse distributor), and/or importer.

Hearing means:

(1) In part 1301 of this chapter, any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

(2) In part 1303 of this chapter, any hearing held regarding the determination of aggregate production quota or the issuance, adjustment, suspension, or denial of a procurement quota or an individual manufacturing quota.

(3) In part 1308 of this chapter, any hearing held for the issuance, amendment, or repeal of any rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

Import means, with respect to any article, any bringing in or introduction of such article into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

Importer includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.

Individual practitioner means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or

the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

Institutional practitioner means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

Interested person means any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

Inventory means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

Isomer means:

(1) The optical isomer, except as used in §1308.11(d) and §1308.12(b)(4) of this chapter. As used in §1308.11(d) of this chapter, the term ''isomer'' means any optical, positional, or geometric isomer. As used in §1308.12(b)(4) of this chapter, the term ''isomer'' means any optical or geometric isomer;

(2) As used in §1308.11(d) of this chapter, the term ''positional isomer'' means any substance possessing the same molecular formula and core structure and having the same functional group(s) and/or substituent(s) as those found in the respective Schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no existing chemical functionalities are destroyed relative to the respective Schedule I hallucinogen. Rearrangements of alkyl moieties within or between functional group(s) or substituent(s), or divisions or combinations of alkyl moieties, that do not create new chemical functionalities or destroy existing chemical functionalities, are allowed i.e., result in compounds which are positional isomers. For purposes of this definition, the ''core structure'' is the parent molecule that is the common basis for the class; for example, tryptamine, phenethylamine, or ergoline. Examples of rearrangements resulting in creation and/or destruction of chemical functionalities (and therefore resulting in compounds which are not positional isomers) include, but are not limited to: Ethoxy to *alpha*-hydroxyethyl, hydroxy and methyl to methoxy, or the repositioning of a phenolic or alcoholic hydroxy group to create a hydroxyamine. Examples of rearrangements resulting in compounds which would be positional isomers include: *Tert*-butyl to *sec*-butyl, methoxy and ethyl to isopropoxy, N,N-diethyl to N-methyl-N-propyl, or *alpha*-methylamino to N-methylamino.

Label means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

Labeling means all labels and other written, printed, or graphic matter:

(1) Upon any controlled substance or any of its commercial containers or wrappers, or

(2) Accompanying such controlled substance.

Long Term Care Facility (LTCF) means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

Maintenance treatment means the dispensing for a period in excess of twenty-one days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

Manufacture means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance.

Manufacturer means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

Mid-level practitioner means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the State in which they practice.

Name means the official name, common or usual name, chemical name, or brand name of a substance.

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:

(1) 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.

(2) Poppy straw and concentrate of poppy straw.

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

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

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

(6) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (1) through (5) of this definition.

Narcotic treatment program means a program engaged in maintenance and/or detoxification treatment with narcotic drugs.

Net disposal means, for a stated period, the quantity of a basic class of controlled substance distributed by the registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of controlled substance or a noncontrolled substance, plus the quantity of that basic class otherwise disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of controlled substance or a noncontrolled substance or in the manufacture of dosage forms of that basic class.

Person includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

Pharmacist means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

Port of entry means, unless distinguished as being a foreign port of entry, any place at which a customs officer is duly authorized to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs laws of the United States (whether or not such place is a port of entry as defined in title 19 of the United States Code or its associated implementing regulations). Examples of ports of entry include, but are not limited to, places designated as ports of entry or customs stations in title 19 of the *Code of Federal Regulations* or by the governing customs authority of that area. When shipments are transported under U.S. Customs and Border Protection's immediate transportation

procedures, the port of entry shall be the port of final destination.

Port of export means, unless distinguished as being a foreign port of export, any place under the control of a customs officer where goods are loaded on an aircraft, vessel or other conveyance for export outside of the United States. For goods loaded aboard an aircraft or vessel in the United States, that stops at several ports before departing the United States, the port of export is the first port where the goods were actually loaded. For goods offloaded from the original conveyance to another conveyance (even if the aircraft or vessel belongs to the same carrier) at any port subsequent to the port where the first on-loading occurred in the United States, the port where the goods were loaded onto the last conveyance before departing the United States is the port of export.

Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Proceeding means all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act (21 U.S.C. 811), commencing with the publication by the Administrator of the proposed rule, amended rule, or repeal in the FEDERAL REGISTER.

Purchaser means any registered person entitled to obtain and execute order forms pursuant to §§1305.04 and 1305.06.

Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Register and *registration* refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

Return information means supplemental information required to be reported to the Administration following an import or export transaction containing the particulars of the transaction and any other information as the Administration may specify.

Reverse distribute means to acquire controlled substances from another registrant or law enforcement for the purpose of:

(1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or

(2) Destruction.

Reverse distributor is a person registered with the Administration as a reverse distributor.

Supplier means any registered person entitled to fill order forms pursuant to §1305.06 of this chapter.

United States, when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States, which, in addition to the customs territory of the United States, include but are not limited to the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

[62 FR 13941, Mar. 24, 1997, as amended at 65 FR 44678, July 19, 2000; 68 FR 37409, June 24, 2003; 68 FR 41228, July 11, 2003; 70 FR 25465, May 13, 2005; 70 FR 74656, Dec. 16, 2005; 71 FR 60427, Oct. 13, 2006; 72 FR 67852, Dec. 3, 2007; 74 FR 63609, Dec. 4, 2009; 77 FR 4230, Jan. 27, 2012; 77 FR 44461, July 30, 2012; 79 FR 53559, Sept. 9, 2014; 81 FR 97018, Dec. 30, 2016]

§1300.02 Definitions relating to listed chemicals.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

(b) As used in parts 1309, 1310, and 1313 of this chapter, the following terms shall have the meaning specified:

Act means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances

Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951).

Administration means the Drug Enforcement Administration.

Administrator means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

At retail, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

Broker and *trader* mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by—

(1) Negotiating contracts;

(2) Serving as an agent or intermediary; or

(3) Fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

Chemical export means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the customs and related laws of the United States).

Chemical exporter is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

Chemical importer is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

Chemical mixture means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

Combination ephedrine product means a drug product containing ephedrine or its salts, optical isomers, or salts of optical isomers, and therapeutically significant quantities of another active medicinal ingredient.

Competent national authority, for purposes of importation and exportation of controlled substances and listed chemicals, means an entity lawfully entitled to authorize the import and export of controlled substances, and to regulate or enforce national controls over listed chemicals, and included as such in the directory of ''Competent National Authorities Under the International Drug Control Treaties'' published by the United Nations Office on Drugs and Crime.

Customs officer means either an Officer of the Customs as defined in 19 U.S.C. 1401(i) (that is, of the U.S. Customs and Border Protection), or any individual duly authorized to accept entries of merchandise, to collect duties, and to enforce the customs laws of any commonwealth, territory, or possession of the United States.

Customs territory of the United States means the several States, the District of Columbia, and Puerto Rico.

Drug product means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Federal Food, Drug, and Cosmetic Act for distribution in the United States.

Encapsulating machine means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

Established business relationship means the regulated person has imported or exported a listed chemical at least once within the past six months, or twice within the past twelve months from or to a foreign manufacturer, distributor, or end user of the chemical that has an established business with a fixed street address. A person or business that functions as a broker or intermediary is not a customer for purposes of this definition.

Established record as an importer means that the regulated person has imported a listed chemical at least once within the past six months, or

twice within the past twelve months from a foreign supplier.

Export means, with respect to any article, any taking out or removal of such article from the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs laws, export control laws enforced by other agencies, or related laws of the United States).

Hearing means any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

Import means, with respect to any article, any bringing in or introduction of such article into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

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.

Listed chemical means any List I chemical or List II chemical.

List I chemical means a chemical specifically designated by the Administrator in §1310.02(a) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

List II chemical means a chemical, other than a List I chemical, specifically designated by the Administrator in §1310.02(b) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

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).

Name means the official name, common or usual name, chemical name, or brand name of a substance.

Person includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

Port of entry, unless distinguished as being a foreign port of entry, means any place at which a customs officer is duly authorized to accept entries of merchandise, to collect duties, and to enforce the various provisions of the customs laws of the United States (whether or not such place is a port of entry as defined in title 19 of the United States Code or its associated implementing regulations). Examples of ports of entry include, but are not limited to, places designated as ports of entry or customs stations in title 19 of the *Code of Federal Regulations* or by the governing customs authority of that area. When shipments are transported under U.S. Customs and Border Protection immediate transportation procedures, the port of entry shall be the port of final destination.

Port of export means, unless distinguished as being a foreign port of export, any place under the control of a customs officer where goods are loaded on an aircraft, vessel or other conveyance for export outside of the United States. For goods loaded aboard an aircraft or vessel in the United States that stops at several ports before departing the United States, the port of export is the first port where the goods were loaded. For goods off-loaded from the original conveyance to another conveyance (even if the aircraft or vessel belongs to the same carrier) at any port subsequent to the port where the first on-loading occurred in the United States, the port where the goods were loaded onto the last conveyance before departing the United States is the port of export. For reporting purposes, in the case of an otherwise lawful export occurring by mail, the port of export is the place of mailing.

Readily retrievable means that certain records are kept by automatic data processing systems or other electronic

or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Register and *registration* refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

Regular customer means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported to the Administration subject to the criteria established in part 1313 of this chapter.

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 Administrator.

Regulated person means any individual, corporation, partnership, association, or other legal entity 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, tableting machine, or encapsulating machine.

Regulated seller means a retail distributor (including a pharmacy or a mobile retail vendor), except that the term does not include an employee or agent of the distributor.

Regulated transaction means:

(1) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, 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; in this context, agents or employees means individuals under the direct management and control of the 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 paragraph does not relieve a distributor, importer, or exporter from compliance with parts 1309, 1310, 1313, and 1315 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug other than a scheduled listed chemical product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to paragraph (1)(v) of this definition, unless—

(A) The Administrator has determined pursuant to the criteria in §1310.10 of this chapter 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

(B) 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;

(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 §1310.03(c) of this chapter; or

(vi) Any transaction in a chemical mixture designated in §§1310.12 and 1310.13 of this chapter that the Administrator has exempted from regulation.

(2) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such

term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

Retail distributor means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine or phenylpropanolamine 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. Also for the purposes of this paragraph, a ''grocery store'' is an entity within Standard Industrial Classification (SIC) code 5411, a ''general merchandise store'' is an entity within SIC codes 5300 through 5399 and 5499, and a ''drug store'' is an entity within SIC code 5912.

Return information means supplemental information required to be reported to the Administration following an import or export transaction containing the particulars of the transaction and any other information as the Administration may specify.

Scheduled listed chemical product means:

(1) A product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.

(2) Scheduled listed chemical product does not include any product that is a controlled substance under part 1308 of this chapter. In the absence of such scheduling by the Attorney General, a chemical specified in paragraph (1) of this definition may not be considered to be a controlled substance.

Tableting machine means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

United States, when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States, which, in addition to the customs territory of the United States, include but are not limited to the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Valid prescription means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

[75 FR 16304, Mar. 31, 2010, as amended at 77 FR 4233, Jan. 27, 2012; 81 FR 97019, Dec. 30, 2016]

§ 1300.03 Definitions relating to electronic orders for controlled substances and electronic prescriptions for controlled substances.

For the purposes of this chapter, the following terms shall have the meanings specified:

Application service provider means an entity that sells electronic prescription or pharmacy applications as a hosted service, where the entity controls access to the application and maintains the software and records on its servers.

Audit trail means a record showing who has accessed an information technology application and what operations the user performed during a given period.

Authentication means verifying the identity of the user as a prerequisite to allowing access to the information application.

Authentication protocol means a well specified message exchange process that verifies possession of a token to remotely authenticate a person to an application.

Biometric authentication means authentication based on measurement of the individual's physical features or repeatable actions where those features or actions are both distinctive to the individual and measurable.

Biometric subsystem means the hardware and software used to capture, store, and compare biometric data. The biometric subsystem may be part of a

larger application. The biometric subsystem is an automated system capable of:

(1) Capturing a biometric sample from an end user.

(2) Extracting and processing the biometric data from that sample.

(3) Storing the extracted information in a database.

(4) Comparing the biometric data with data contained in one or more reference databases.

(5) Determining how well the stored data matches the newly captured data and indicating whether an identification or verification of identity has been achieved.

Cache means to download and store information on a local server or hard drive.

Certificate policy means a named set of rules that sets forth the applicability of the specific digital certificate to a particular community or class of application with common security requirements.

Certificate revocation list (CRL) means a list of revoked, but unexpired certificates issued by a certification authority.

Certification authority (CA) means an organization that is responsible for verifying the identity of applicants, authorizing and issuing a digital certificate, maintaining a directory of public keys, and maintaining a Certificate Revocation List.

Certified information systems auditor (CISA) means an individual who has been certified by the Information Systems Audit and Control Association as qualified to audit information systems and who performs compliance audits as a regular ongoing business activity.

Credential means an object or data structure that authoritatively binds an identity (and optionally, additional attributes) to a token possessed and controlled by a person.

Credential service provider (CSP) means a trusted entity that issues or registers tokens and issues electronic credentials to individuals. The CSP may be an independent third party or may issue credentials for its own use.

CSOS means controlled substance ordering system.

Digital certificate means a data record that, at a minimum—

(1) Identifies the certification authority issuing it;

(2) Names or otherwise identifies the certificate holder;

(3) Contains a public key that corresponds to a private key under the sole control of the certificate holder;

(4) Identifies the operational period; and

(5) Contains a serial number and is digitally signed by the certification authority issuing it.

Digital signature means a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed.

Digitally sign means to affix a digital signature to a data file.

Electronic prescription means a prescription that is generated on an electronic application and transmitted as an electronic data file.

Electronic prescription application provider means an entity that develops or markets electronic prescription software either as a stand-alone application or as a module in an electronic health record application.

Electronic signature means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message.

False match rate means the rate at which an impostor's biometric is falsely accepted as being that of an authorized user. It is one of the statistics used to measure biometric performance when operating in the verification or authentication task. The false match rate is similar to the false accept (or acceptance) rate.

False non-match rate means the rate at which a genuine user's biometric is falsely rejected when the user's biometric data fail to match the enrolled data for the user. It is one of the statistics used to measure biometric performance when operating in the verification or authentication task. The false match rate is similar to the false reject (or rejection) rate, except

that it does not include the rate at which a biometric system fails to acquire a biometric sample from a genuine user.

FIPS means Federal Information Processing Standards. These Federal standards, as incorporated by reference in §1311.08 of this chapter, prescribe specific performance requirements, practices, formats, communications protocols, etc., for hardware, software, data, etc.

FIPS 140–2, as incorporated by reference in §1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled ''Security Requirements for Cryptographic Modules,'' a Federal standard for security requirements for cryptographic modules.

FIPS 180–2, as incorporated by reference in §1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled ''Secure Hash Standard,'' a Federal secure hash standard.

FIPS 180–3, as incorporated by reference in §1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled ''Secure Hash Standard (SHS),'' a Federal secure hash standard.

FIPS 186–2, as incorporated by reference in §1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled ''Digital Signature Standard,'' a Federal standard for applications used to generate and rely upon digital signatures.

FIPS 186–3, as incorporated by reference in §1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled ''Digital Signature Standard (DSS),'' a Federal standard for applications used to generate and rely upon digital signatures.

Hard token means a cryptographic key stored on a special hardware device (e.g., a PDA, cell phone, smart card, USB drive, one-time password device) rather than on a general purpose computer.

Identity proofing means the process by which a credential service provider or certification authority validates sufficient information to uniquely identify a person.

Installed electronic prescription application means software that is used to create electronic prescriptions and that is installed on a practitioner's computers and servers, where access and records are controlled by the practitioner.

Installed pharmacy application means software that is used to process prescription information and that is installed on a pharmacy's computers or servers and is controlled by the pharmacy.

Intermediary means any technology system that receives and transmits an electronic prescription between the practitioner and pharmacy.

Key pair means two mathematically related keys having the properties that:

(1) One key can be used to encrypt a message that can only be decrypted using the other key; and

(2) Even knowing one key, it is computationally infeasible to discover the other key.

NIST means the National Institute of Standards and Technology.

NIST SP 800–63–1, as incorporated by reference in §1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled ''Electronic Authentication Guideline,'' a Federal standard for electronic authentication.

NIST SP 800–76–1, as incorporated by reference in §1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled ''Biometric Data Specification for Personal Identity Verification,'' a Federal standard for biometric data specifications for personal identity verification.

Operating point means a point chosen on a receiver operating characteristic (ROC) curve for a specific algorithm at which the biometric system is set to function. It is defined by its corresponding coordinates—a false match rate and a false non-match rate. An ROC curve shows graphically the tradeoff between the principal two types of errors (false match rate and false non-match rate) of a biometric system by plotting the performance of a specific algorithm on a specific set of data.

Paper prescription means a prescription created on paper or computer generated to be printed or transmitted via

facsimile that meets the requirements of part 1306 of this chapter including a manual signature.

Password means a secret, typically a character string (letters, numbers, and other symbols), that a person memorizes and uses to authenticate his identity.

PDA means a Personal Digital Assistant, a handheld computer used to manage contacts, appointments, and tasks.

Pharmacy application provider means an entity that develops or markets software that manages the receipt and processing of electronic prescriptions.

Private key means the key of a key pair that is used to create a digital signature.

Public key means the key of a key pair that is used to verify a digital signature. The public key is made available to anyone who will receive digitally signed messages from the holder of the key pair.

Public Key Infrastructure (PKI) means a structure under which a certification authority verifies the identity of applicants; issues, renews, and revokes digital certificates; maintains a registry of public keys; and maintains an up-to-date certificate revocation list.

Readily retrievable means that certain records are kept by automatic data processing applications or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

SAS 70 Audit means a third-party audit of a technology provider that meets the American Institute of Certified Public Accountants (AICPA) Statement of Auditing Standards (SAS) 70 criteria.

Signing function means any keystroke or other action used to indicate that the practitioner has authorized for transmission and dispensing a controlled substance prescription. The signing function may occur simultaneously with or after the completion of the two-factor authentication protocol that meets the requirements of part 1311 of this chapter. The signing function may have different names (e.g., approve, sign, transmit), but it serves as the practitioner's final authorization that he intends to issue the prescription for a legitimate medical reason in the normal course of his professional practice.

SysTrust means a professional service performed by a qualified certified public accountant to evaluate one or more aspects of electronic systems.

Third-party audit means an independent review and examination of records and activities to assess the adequacy of system controls, to ensure compliance with established policies and operational procedures, and to recommend necessary changes in controls, policies, or procedures.

Token means something a person possesses and controls (typically a key or password) used to authenticate the person's identity.

Trusted agent means an entity authorized to act as a representative of a certification authority or credential service provider in confirming practitioner identification during the enrollment process.

Valid prescription means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

WebTrust means a professional service performed by a qualified certified public accountant to evaluate one or more aspects of Web sites.

[75 FR 16304, Mar. 31, 2010]

§ 1300.04 Definitions relating to the dispensing of controlled substances by means of the Internet.

(a) Any term not defined in this part or elsewhere in this chapter shall have the definition set forth in sections 102 and 309 of the Act (21 U.S.C. 802, 829).

(b) The term *covering practitioner* means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who:

(1) Has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through

the practice of telemedicine, within the previous 24 months; and

(2) Is temporarily unavailable to conduct the evaluation of the patient.

(c) 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.

(d) 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:

(1) 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 309 of the Act (21 U.S.C. 829) and §§ 1306.21 and 1306.22 of this chapter (for purposes of this definition, such a prescription shall be referred to as the ''original prescription'');

(2) 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 paragraph (d)(1) of this section (*i.e.*, the same controlled substance as described in paragraph (d)(1)); and

(3) The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

(e) The term *homepage* means the opening or main page or screen of the Web site of an online pharmacy that is viewable on the Internet.

(f) The term *in-person medical evaluation* means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals. Nothing in this paragraph shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(g) 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.

(h) The term *online pharmacy* 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. The term includes, but is not limited to, a pharmacy that has obtained a modification of its registration pursuant to §§ 1301.13 and 1301.19 of this chapter that currently authorizes it to dispense controlled substances by means of the Internet, regardless of whether the pharmacy is currently dispensing controlled substances by means of the Internet. The term does not include:

(1) Manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 303 of the Act (21 U.S.C. 823(a), (b), (d), or (e)) (§ 1301.13 of this chapter) who do not dispense controlled substances to an unregistered individual or entity;

(2) Nonpharmacy practitioners who are registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter) and whose activities are authorized by that registration;

(3) 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 303(f) of the Act (21 U.S.C. 823(f)) (§ 1301.13 of this chapter);

(4) 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;

(5) Any agent or employee of any hospital or facility referred to in paragraph (h)(3) or (h)(4) of this section, 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 paragraph (h)(4) of this section, only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such paragraph;

(6) Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(7) 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;

(8) A pharmacy registered under section 303(f) of the Act (21 U.S.C. 823(f)) (§1301.13 of this chapter) 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 (k) of this section; or

(ii) Filling new prescriptions for controlled substances in Schedule III, IV, or V, as defined in paragraph (d) of this section;

(9)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of filling prescriptions that were electronically prescribed in a manner authorized by this chapter and otherwise in compliance with the Act.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(9)(i) of this section, it would fall outside the definition of an online pharmacy; or

(10)(i) Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of the transmission of prescription information between a pharmacy and an automated dispensing system located in a long term care facility when the registration of the automated dispensing system is held by that pharmacy as described in §§1301.17 and 1301.27 and the pharmacy is otherwise complying with this chapter.

(ii) A registered pharmacy will be deemed to meet this exception if, in view of all of its activities other than those referred to in paragraph (h)(10)(i) of this section, it would fall outside the definition of an online pharmacy.

(i) Effective January 15, 2010, the term *practice of telemedicine* means 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 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), which practice falls within a category listed in the following paragraphs (i)(1) through (7):

(1) *Treatment in a hospital or clinic.* The practice of telemedicine is being conducted while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f) of the Act (21 U.S.C. 823(f)) by a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(2) *Treatment in the physical presence of a practitioner.* The practice of telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a practitioner

acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(3) *Indian Health Service or tribal organization.* The practice of telemedicine is being conducted by a practitioner 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; who is acting within the scope of the employment, contract, or compact; and who is designated as an Internet Eligible Controlled Substances Provider by the Secretary of Health and Human Services under section 311(g)(2) of the Act (21 U.S.C. 831(g)(2));

(4) *Public health emergency declared by the Secretary of Health and Human Services.* The practice of telemedicine is being conducted during a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d), and involves patients located in such areas, and such controlled substances, as the Secretary of Health and Human Services, with the concurrence of the Administrator, designates, provided that such designation shall not be subject to the procedures prescribed by the Administrative Procedure Act (5 U.S.C. 551–559 and 701–706);

(5) *Special registration.* The practice of telemedicine is being conducted by a practitioner who has obtained from the Administrator a special registration under section 311(h) of the Act (21 U.S.C. 831(h));

(6) *Department of Veterans Affairs medical emergency.* The practice of telemedicine is being conducted:

(i) In a medical emergency situation:

(A) That prevents the patient from being in the physical presence of a practitioner registered under section 303(f) of the Act (21 U.S.C. 823(f)) 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;

(B) That prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f) of the Act (21 U.S.C. 823(f));

(C) 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

(D) 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:

(A) Is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(B) Is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and

(C) Issues a controlled substance prescription in this emergency context that is limited to a maximum of a five-day supply which may not be extended or refilled; or

(7) *Other circumstances specified by regulation.* The practice of telemedicine is being conducted under any other circumstances that the Administrator and the Secretary of Health and Human Services have jointly, by regulation, determined to be consistent

with effective controls against diversion and otherwise consistent with the public health and safety.

(j) *Temporary definition of practice of telemedicine.* Prior to January 15, 2010, or as otherwise specified by regulation prior to that date, instead of the definition in paragraph (i), 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 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.

(k) The term *refilling prescriptions for controlled substances in Schedule III, IV, or V:*

(1) 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 309 of the Act (21 U.S.C. 829) and §§ 1306.21 and 1306.22 of this chapter, as appropriate; and

(2) Does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(l)(1) The term *valid prescription* means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by:

(i) A practitioner who has conducted at least one in-person medical evaluation of the patient; or

(ii) A covering practitioner.

(2) Nothing in this paragraph (l) shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

[74 FR 15619, Apr. 6, 2009]

§ 1300.05 Definitions relating to the disposal of controlled substances.

(a) Any term not defined in this part or elsewhere in this chapter shall have the definition set forth in section 102 of the Act (21 U.S.C. 802).

(b) As used in part 1317 of this chapter, the following terms shall have the meanings specified:

Employee means an employee as defined under the general common law of agency. Some of the factors relevant to the determination of employee status include: The hiring party's right to control the manner and means by which the product is accomplished; the skill required; the source of the instrumentalities and tools; the location of the work; the duration of the relationship between the parties; whether the hiring party has the right to assign additional projects to the hired party; the extent of the hired party's discretion over when and how long to work; the method of payment; the hired party's role in hiring and paying assistants; whether the work is part of the regular business of the hiring party; whether the hiring party is in business; the provision of employee benefits; and the tax treatment of the hired party. Other applicable factors may be considered and no one factor is dispositive. The following criteria will determine whether a person is an *employee* of a registrant for the purpose of disposal: The person is directly paid by the registrant; subject to direct oversight by the registrant; required, as a condition of employment, to follow the registrant's procedures and guidelines pertaining to the handling of controlled substances; subject to receive a performance rating or performance evaluation on a regular/routine basis from the registrant; subject to disciplinary action by the registrant; and required to render services at the registrant's registered location.

Law enforcement officer means a person who is described in paragraph (1), (2) or (3) of this definition:

(1) Meets all of the following criteria:

(i) Employee of either a law enforcement agency, or law enforcement component of a Federal agency;

(ii) Is under the direction and control of a Federal, State, tribal, or local government;

(iii) Acting in the course of his/her official duty; and

(iv) Duly sworn and given the authority by a Federal, State, tribal, or local government to carry firearms, execute and serve warrants, make arrests without warrant, and make seizures of property;

(2) Is a Veterans Health Administration (VHA) police officer authorized by the Department of Veterans Affairs to participate in collection activities conducted by the VHA; or

(3) Is a Department of Defense (DOD) police officer authorized by the DOD to participate in collection activities conducted by the DOD.

Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered ''non-retrievable'' when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

On-site means located on or at the physical premises of the registrant's registered location. A controlled substance is destroyed *on-site* when destruction occurs on the physical premises of the destroying registrant's registered location. A hospital/clinic has an *on-site* pharmacy when it has a pharmacy located on the physical premises of the registrant's registered location.

[79 FR 53560, Sept. 9, 2014]

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

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