title unless the Secretary exercises the authority provided in section 353(b)(3) of this title to remove such medical gas from the requirements of section 353(b)(1) of this title, the gas is approved for use without a prescription pursuant to an application under section 355 or 360b of this title, or the use in question is authorized pursuant to another provision of this chapter relating to use of medical products in emergencies.

(2) Oxygen

(A) No prescription required for certain uses

Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

(i) For use in the event of depressurization or other environmental oxygen deficiency.

(ii) For oxygen deficiency or for use in emergency resuscitation, when administered by properly trained personnel.

(B) Labeling

For oxygen provided pursuant to subparagraph (A), the requirements of section 353(b)(4) of this title shall be deemed to have been met if its labeling bears a warning that the oxygen can be used for emergency use only and for all other medical applications a prescription is required.

(June 25, 1938, ch. 675, § 576, as added Pub. L. 112–144, title XI, § 1111, July 9, 2012, 126 Stat. 1109; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(S), Dec. 13, 2016, 130 Stat. 1155.)

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–255, § 3101(a)(2)(S)(i), inserted ''who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce'' after ''any person'' in introductory provisions.

Subsec. (a)(3)(A)(i)(VIII). Pub. L. 114–255, § 3101(a)(2)(S)(ii)(I)(aa), inserted ''for a new drug'' after ''any period of exclusivity''.

Subsec. (a)(3)(A)(ii). Pub. L. 114–255, § 3101(a)(2)(S)(ii)(I)(bb), inserted ''the'' before ''final use'' in introductory provisions.

Subsec. (a)(3)(B)(i). Pub. L. 114–255, § 3101(a)(2)(S)(ii)(II)(aa), inserted ''for a new drug'' after ''any period of exclusivity''.

Subsec. (a)(3)(B)(ii). Pub. L. 114–255, § 3101(a)(2)(S)(ii)(II)(bb), inserted comma after ''drug product''.

§ 360ddd–2. Inapplicability of drug fees to designated medical gases

A designated medical gas, alone or in combination with another designated gas or gases (as medically appropriate) deemed under section 360ddd–1 of this title to have in effect an approved application shall not be assessed fees under section 379h(a) or 379j–12(a) of this title on the basis of such deemed approval.

(June 25, 1938, ch. 675, § 577, as added Pub. L. 112–144, title XI, § 1111, July 9, 2012, 126 Stat. 1111; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(T), Dec. 13, 2016, 130 Stat. 1155.)

AMENDMENTS

2016—Pub. L. 114–255 inserted ''or 379j–12(a)'' after ''section 379h(a)''.

PART H—PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN

§ 360eee. Definitions

In this part:

(1) Affiliate

The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has the power to control, both of the business entities.

(2) Authorized

The term ''authorized'' means—

(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 360 of this title;

(B) in the case of a wholesale distributor, having a valid license under State law or section 360eee–2 of this title, in accordance with section 360eee–1(a)(6) of this title, and complying with the licensure reporting requirements under section 353(e) of this title;

(C) in the case of a third-party logistics provider, having a valid license under State law or section 360eee–3(a)(1) of this title, in accordance with section 360eee–1(a)(7) of this title, and complying with the licensure reporting requirements under section 360eee–3(b) of this title; and

(D) in the case of a dispenser, having a valid license under State law.

(3) Dispenser

The term ''dispenser''—

(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

(B) does not include a person who dispenses only products to be used in animals in accordance with section 360b(a)(5) of this title.

(4) Disposition

The term ''disposition'', with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

(5) Distribute or distribution

The term ''distribute'' or ''distribution'' means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product

pursuant to a prescription executed in accordance with section 353(b)(1) of this title or the dispensing of a product approved under section 360b(b) of this title.

(6) Exclusive distributor

The term ''exclusive distributor'' means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

(7) Homogeneous case

The term ''homogeneous case'' means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

(8) Illegitimate product

The term ''illegitimate product'' means a product for which credible evidence shows that the product—

(A) is counterfeit, diverted, or stolen;

(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(C) is the subject of a fraudulent transaction; or

(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

(9) Licensed

The term ''licensed'' means—

(A) in the case of a wholesale distributor, having a valid license in accordance with section 353(e) of this title or section 360eee–1(a)(6) of this title, as applicable;

(B) in the case of a third-party logistics provider, having a valid license in accordance with section 360eee–3(a) of this title or section 360eee–1(a)(7) of this title, as applicable; and

(C) in the case of a dispenser, having a valid license under State law.

(10) Manufacturer

The term ''manufacturer'' means, with respect to a product—

(A) a person that holds an application approved under section 355 of this title or a license issued under section 262 of title 42 for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

(B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or

(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

(11) Package

(A) In general

The term ''package'' means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

(B) Individual saleable unit

For purposes of this paragraph, an ''individual saleable unit'' is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

(12) Prescription drug

The term ''prescription drug'' means a drug for human use subject to section 353(b)(1) of this title.

(13) Product

The term ''product'' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 360eee–1 of this title, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 2021 of title 42, imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 360ddd of this title), homeopathic drugs marketed in accordance with applicable guidance under this chapter, or a drug compounded in compliance with section 353a or 353b of this title.

(14) Product identifier

The term ''product identifier'' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

(15) Quarantine

The term ''quarantine'' means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

(16) Repackager

The term ''repackager'' means a person who owns or operates an establishment that repacks and relabels a product or package for—

(A) further sale; or

(B) distribution without a further transaction.

(17) Return

The term ''return'' means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

(18) Returns processor or reverse logistics provider

The term ''returns processor'' or ''reverse logistics provider'' means a person who owns or

operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(19) Specific patient need

The term ''specific patient need'' refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(20) Standardized numerical identifier

The term ''standardized numerical identifier'' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

(21) Suspect product

The term ''suspect product'' means a product for which there is reason to believe that such product—

(A) is potentially counterfeit, diverted, or stolen;

(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(C) is potentially the subject of a fraudulent transaction; or

(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(22) Third-party logistics provider

The term ''third-party logistics provider'' means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(23) Trading partner

The term ''trading partner'' means—

(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(B) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(24) Transaction

(A) In general

The term ''transaction'' means the transfer of product between persons in which a change of ownership occurs.

(B) Exemptions

The term ''transaction'' does not include—

(i) intracompany distribution of any product between members of an affiliate or within a manufacturer;

(ii) the distribution of a product among hospitals or other health care entities that are under common control;

(iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 247d of title 42, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(iv) the dispensing of a product pursuant to a prescription executed in accordance with section 353(b)(1) of this title;

(v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 353(d) of this title;

(vi) the distribution of blood or blood components intended for transfusion;

(vii) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

(viii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of title 26 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(ix) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

(x) the dispensing of a product approved under section 360b(c) of this title;

(xi) products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 2021 of title 42;

(xii) a combination product that is not subject to approval under section 355 of this title or licensure under section 262 of title 42, and that is—

(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(II) 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

(III) 2 or more finished medical devices plus one or more drug or biological prod-

ucts that are packaged together in what is referred to as a ''medical convenience kit'' as described in clause (xiii);

(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a ''medical convenience kit'') if—

(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 360(b)(2) of this title;

(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.];

(III) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(IV) in the case of a medical convenience kit that includes a product, the product is—

(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

(bb) a product intended to maintain the equilibrium of water and minerals in the body;

(cc) a product intended for irrigation or reconstitution;

(dd) an anesthetic;

(ee) an anticoagulant;

(ff) a vasopressor; or

(gg) a sympathomimetic;

(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(xvi) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(xvii) the distribution of a medical gas (as defined in section 360ddd of this title); or

(xviii) the distribution or sale of any licensed product under section 262 of title 42 that meets the definition of a device under section 321(h) of this title.

(25) Transaction history

The term ''transaction history'' means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(26) Transaction information

The term ''transaction information'' means—

(A) the proprietary or established name or names of the product;

(B) the strength and dosage form of the product;

(C) the National Drug Code number of the product;

(D) the container size;

(E) the number of containers;

(F) the lot number of the product;

(G) the date of the transaction;

(H) the date of the shipment, if more than 24 hours after the date of the transaction;

(I) the business name and address of the person from whom ownership is being transferred; and

(J) the business name and address of the person to whom ownership is being transferred.

(27) Transaction statement

The ''transaction statement'' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—

(A) is authorized as required under the Drug Supply Chain Security Act;

(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 360eee–1 of this title;

(D) did not knowingly ship a suspect or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 360eee–1 of this title;

(F) did not knowingly provide false transaction information; and

(G) did not knowingly alter the transaction history.

(28) Verification or verify

The term ''verification'' or ''verify'' means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 360eee–1 of this title.

(29) Wholesale distributor

The term ''wholesale distributor'' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 353(e)(4) of this title).

(June 25, 1938, ch. 675, §581, as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 599.)

REFERENCES IN TEXT

The Comprehensive Drug Abuse Prevention and Control Act of 1970, referred to in par. (24)(B)(xiii)(II), is Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236, which is classified principally to chapter 13 (§ 801 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

The Drug Supply Chain Security Act, referred to in par. (27)(A), (B), is Pub. L. 113–54, title II, Nov. 27, 2013, 127 Stat. 599. For complete classification of this Act to the Code, see Short Title note set out under section 301 of this title and Tables.

§ 360eee–1. Requirements

(a) In general

(1) Other activities

Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements set forth in this section with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving product. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in this section, but shall not be required to duplicate requirements.

(2) Initial standards

(A) In general

The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders, issue a draft guidance document that establishes standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for compliance with this subsection and subsections (b), (c), (d), and (e). In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data. The standards established under this paragraph shall take into consideration the standards established under section 355e of this title and shall comply with a form and format developed by a widely recognized international standards development organization.

(B) Public input

Prior to issuing the draft guidance under subparagraph (A), the Secretary shall gather comments and information from stakeholders and maintain such comments and information in a public docket for at least 60 days prior to issuing such guidance.

(C) Publication

The Secretary shall publish the standards established under subparagraph (A) not later than 1 year after November 27, 2013.

(3) Waivers, exceptions, and exemptions

(A) In general

Not later than 2 years after November 27, 2013, the Secretary shall, by guidance—

(i) establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in this section, which the Secretary may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 247d of title 42;

(ii) establish a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section; and

(iii) establish a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of this section.

(B) Content

The guidance issued under subparagraph (A) shall include a process for the biennial review and renewal of such waivers, exceptions, and exemptions, as applicable.

(C) Process

In issuing the guidance under this paragraph, the Secretary shall provide an effective date that is not later than 180 days prior to the date on which manufacturers are required to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce consistent with this section.

(4) Self-executing requirements

Except where otherwise specified, the requirements of this section may be enforced without further regulations or guidance from the Secretary.

(5) Grandfathering product

(A) Product identifier

Not later than 2 years after November 27, 2013, the Secretary shall finalize guidance specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section shall be exempted from the requirements of this section.

(B) Tracing

For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015—

(i) authorized trading partners shall be exempt from providing transaction information as required under subsections