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