151.441 DEFINITIONS.

Subdivision 1. **Scope.** As used in sections 151.43 to 151.471, the following terms have the meanings given in this section.

Subd. 2. **Dispenser.** "Dispenser" 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, but does not include a person who dispenses only products to be used in animals in accordance with United States Code, title 21, section 360b(a)(5).

Subd. 3. **Disposition.** "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.

Subd. 4. **Distribute or distribution.** "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 United States Code, title 21, section 353(b)(1), or the dispensing of a product approved under United States Code, title 21, section 360b(b).

Subd. 5. **Manufacturer.** "Manufacturer" means, with respect to a product:

(1) a person who holds an application approved under United States Code, title 21, section 355, or a license issued under United States Code, title 42, section 262, for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

(2) a co-licensed partner of the person described in clause (1) that obtains the product directly from a person described in this subdivision; or

(3) an affiliate of a person described in clause (1) or (2) that receives the product directly from a person described in this subdivision.

Subd. 6. **Medical convenience kit.** "Medical convenience kit" means 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.

Subd. 7. **Package.** "Package" means the smallest individual salable 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. For purposes of this subdivision, an "individual salable 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.

Subd. 8. **Prescription drug.** "Prescription drug" means a drug for human use subject to United States Code, title 21, section 353(b)(1).

Subd. 9. **Product.** "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, but does not include blood or blood components intended for transfusion; radioactive drugs or radioactive biological products as defined in Code of Federal Regulations, title 21, section 600.3(ee), that are regulated by the Nuclear Regulatory Commission or by a state pursuant

to an agreement with such commission under United States Code, title 42, section 2021; imaging drugs; an intravenous product described in subdivision 12, paragraph (b), clauses (14) to (16); any medical gas defined in United States Code, title 21, section 360ddd; homeopathic drugs marketed in accordance with applicable federal law; or a drug compounded in compliance with United States Code, title 21, section 353a or 353b.

Subd. 10. **Repackager.** "Repackager" means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or for distribution without a further transaction.

Subd. 11. **Third-party logistics provider.** "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.

Subd. 12. **Transaction.** (a) "Transaction" means the transfer of a product between persons in which a change of ownership occurs.

(b) The term "transaction" does not include:

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

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

(3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including:

(i) a public health emergency declaration pursuant to United States Code, title 42, section 247d;

(ii) a national security or peacetime emergency declared by the governor pursuant to section 12.31; or

(iii) a situation involving an action taken by the commissioner of health pursuant to section 144.4197, 144.4198, or 151.37, subdivisions 2, paragraph (b), and 10, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(4) the dispensing of a drug pursuant to a valid prescription issued by a licensed practitioner;

(5) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with United States Code, title 21, section 353(d);

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

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

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

(9) 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;

(10) the dispensing of a product approved under United States Code, title 21, section 360b(c);

(11) transfer of products 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 United States Code, title 42, section 2021;

(12) transfer of a combination product that is not subject to approval under United States Code, title 21, section 355, or licensure under United States Code, title 42, section 262, and that is:

(i) a product comprised of a device and one 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) two 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) two or more finished medical devices plus one or more drug or biological products that are packaged together in a medical convenience kit;

(13) the distribution of a medical convenience kit if:

(i) the medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a device manufacturer in accordance with United States Code, title 21, section 360(b)(2);

(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, United States Code, title 21, section 801, et seq.;

(iii) in the case of a medical convenience kit that includes a product, the person who manufactures the kit:

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

(B) 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:

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

(14) 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;

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

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

(17) the distribution of a medical gas as defined in United States Code, title 21, section 360ddd; or

(18) the distribution or sale of any licensed product under United States Code, title 42, section 262, that meets the definition of a device under United States Code, title 21, section 321(h).

Subd. 13. **Wholesale distribution.** "Wholesale distribution" means the distribution of a drug to a person other than a consumer or patient, or receipt of a drug by a person other than the consumer or patient, but does not include:

(1) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(2) the distribution of a drug or an offer to distribute a drug among hospitals or other health care entities that are under common control;

(3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including:

(i) a public health emergency declaration pursuant to United States Code, title 42, section 247d;

(ii) a national security or peacetime emergency declared by the governor pursuant to section 12.31; or

(iii) a situation involving an action taken by the commissioner of health pursuant to section 144.4197, 144.4198, or 151.37, subdivisions 2, paragraph (b), and 10, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(4) the dispensing of a drug pursuant to a valid prescription issued by a licensed practitioner;

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

(6) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(7) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(8) the distribution of a drug by the manufacturer of such drug;

(9) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(10) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(11) the distribution of a drug or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with United States Code, title 21, section 360eee-1(e);

(12) salable drug returns when conducted by a dispenser;

(13) 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 section as a medical convenience kit, if:

(i) the medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a device manufacturer in accordance with United States Code, title 21, section 360(b)(2);

(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, United States Code, title 21, section 801, et seq.;

(iii) in the case of a medical convenience kit that includes a product, the person that manufactures the kit:

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

(B) 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:

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

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

(C) a product intended for irrigation or reconstitution;

(D) an anesthetic;

(E) an anticoagulant;

(F) a vasopressor; or

(G) a sympathomimetic;

(14) the distribution of an intravenous drug 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;

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

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

(17) the distribution of medical gas, as defined in United States Code, title 21, section 360ddd;

(18) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(19) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in United States Code, title 21, section 360eee(16)(B), and registered under United States Code, title 21,

section 360, for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

Subd. 14. **Wholesale distributor.** "Wholesale distributor" means a person engaged in wholesale distribution but does not include a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager.

History: *1Sp2019 c 9 art 10 s 44; 2020 c 83 art 1 s 43*