

Kansas Administrative Regulations

State Board of Pharmacy

Article 14.—Wholesale Distributors

68-14-2. Definitions.

As used in this article of the board's regulations and the pharmacy practice act, each of the following terms shall have the meaning specified in this regulation:

(a) "Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.

(b) "Blood component" means that part of blood separated by physical or mechanical means.

(c) "Common ownership and control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or by other means.

(d) "Drug sample" means a unit of a prescription-only drug that is not intended to be sold, is intended to promote the sale of the drug, and is distributed on a gratuitous basis.

(e) "Device" has the meaning specified in K.S.A. 65-656, and amendments thereto.

(f) "Emergency medical reasons" shall include transfers of prescription-only drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of these transfers shall not exceed five percent of the total prescription-only drug sales revenue of either the transferor or transferee pharmacy during any period of 12 consecutive months.

(g) "Excursion" means a deviation from the range of temperatures specified by the manufacturer for storage or transport of a prescription-only drug or device based on stability data.

(h) "Intracompany sales" and "intracompany distribution" mean any transaction or transfer between any division, subsidiary, parent, affiliated, or related company under the common ownership and control of a corporate entity.

(i) "Primary owner" means any person owning or controlling more than 50 percent of the wholesaler's business.

(j) "Room temperature" means a temperature that is maintained thermostatically and meets the following requirements:

(1) Encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F);

(2) results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and

(3) allows for excursions between 15° and 30°C (59° to 86°F) experienced in facilities, such that the allowable calculated mean kinetic temperature remains in the allowed range.

(k) "Virtual wholesale distribution" means arranging for the distribution of a drug or device, which may include taking actual possession of the drug or device and shall include contracting with another entity for the distribution, purchase, and sale of the drug or device.

(l) "Virtual wholesale distributor" means a business entity that arranges for the distribution of a drug or device, with or without taking actual possession of the drug or device, and contracts with others for the distribution, purchase, and sale.

(m) "Wholesale distribution" means distribution of prescription-only drugs or devices to persons other than a consumer or patient and shall include virtual wholesale distribution and virtual wholesale distributors, but this term shall not include either of the following:

(1) The distribution of drug samples by manufacturers' representatives or representatives of the authorized distributor of record, in accordance with 21 U.S.C. 353; or

(2) the sale, purchase, or trade of blood and blood components intended for transfusion.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1626, as amended by L. 2019, ch. 52, sec. 7, K.S.A. 65-1643, K.S.A. 65-1655, K.S.A. 65-1655a, and K.S.A. 65-1655b; effective June 15, 1992; amended July 23, 1999; amended Jan. 3, 2020.)

***** Authenticated Kansas Administrative Regulation *****