

WEST VIRGINIA CODE: §60A-8-5

§60A-8-5. Definitions.

As used in this article:

(a) "Wholesale distribution" and "wholesale distributions" mean distribution of prescription drugs, including directly or through the use of a third-party logistics provider or any other situation in which title, ownership or control over the prescription drug remains with one person or entity but the prescription drug is brought into this state by another person or entity on his, her or its behalf, to persons other than a consumer or patient, but does not include:

(1) Intracompany sales, being defined as any transaction, transfer or delivery into or within this state between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) 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 the United States Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control. For purposes of this article, "common 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, voting rights, by contract, or otherwise;

(5) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for "emergency medical reasons" for purposes of this article includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any twelve consecutive month period;

(6) The sale, purchase or trade of a drug, an offer to sell, purchase, or trade a drug or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors'

representatives, if the distribution is permitted under federal law [21 U. S. C. 353(d)];

(8) Drug returns by a pharmacy or chain drug warehouse to wholesale drug distributor or the drug's manufacturer; or

(9) The sale, purchase or trade of blood and blood components intended for transfusion.

(b) "Wholesale drug distributor" or "wholesale distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers, repackers, own-label distributors, jobbers, private-label distributors, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses, independent wholesale drug traders, prescription drug repackagers, physicians, dentists, veterinarians, birth control and other clinics, individuals, hospitals, nursing homes and/or their providers, health maintenance organizations and other health care providers, and retail and hospital pharmacies that conduct wholesale distributions, including, but not limited to, any pharmacy distributor as defined in this section. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs.

(c) "Pharmacy distributor" means any pharmacy licensed in this state or hospital pharmacy which is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this state or to any other person or entity, including, but not limited to, a wholesale drug distributor as defined in subdivision (b) of this section engaged in the delivery or distribution of prescription drugs and who is involved in the actual, constructive or attempted transfer of a drug in this state to other than the ultimate consumer except as otherwise provided for by law.

(d) "Manufacturer" means any person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling of a prescription drug, whether within or outside this state.

(e) "West Virginia Board of Pharmacy", "Board of Pharmacy" or "board" means the agency of this state authorized to license wholesale drug distribution except where otherwise provided.

(f) "Prescription drug" means any human drug required by federal law or regulation to be dispensed only by prescription, including finished dosage forms and active ingredients subject to section 503(b) of the federal food, drug and cosmetic act.

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

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

(i) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(j) "Person" means any individual, partnership, association, limited liability company, corporation or other entity.

(k) "Key person" means the person designated by the applicant or license holder from any of the following:

- (1) An officer, director, trustee, partner, principal or proprietor of a person that has applied for or holds a license issued under this article or an affiliate or holding company that has control of a person that has applied for or holds a license under this article.
- (2) A person that holds a combined direct, indirect or attributed debt or equity interest of more than five percent in a person that has applied for or holds a license under this article;
- (3) A person that holds a combined direct, indirect or attributed equity interest of more than five percent in a person that has a controlling interest in a person that has applied for or holds license under this article;
- (4) A managerial employee of a person that has applied for or holds a license under this article or a managerial employee of an affiliate or holding company that has control of a person that has applied for or holds a license under this article, who performs the function of principal executive officer, principal operating officer, principal accounting officer or an equivalent officer;
- (5) A managerial employee of a person that has applied for or holds a license under this article or a managerial employee of an affiliate or holding company that has control of a person that has applied for or holds a license under this article who will perform or performs the function of an operations manager or will exercise or exercises management, supervisory or policy-making authority over the distribution of prescription drugs.

(l) "Third-party logistics provider" means a person who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party logistics provider must be licensed as a wholesale distributor under this article and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.