

315.404 Returns or exchanges of prescription drugs.

- (1) (a) A wholesale distributor may receive prescription drug returns or exchanges from a pharmacy, pharmacy warehouse, or other person authorized to distribute a prescription drug to an end user under the terms and conditions of an agreement between the parties.
 - (b) Returns of expired, damaged, recalled, or otherwise nonsalable prescription drugs shall be distributed by the receiving wholesale distributor only to the original manufacturer, a third-party returns processor, or a reverse distributor licensed as a wholesale distributor.
 - (c) Returns or exchanges of prescription drugs that may or may not be salable, including any redistribution by a receiving wholesaler, shall not be subject to the requirements of KRS 315.406 if they are exempt from the pedigree requirements of the federal regulations for the federal Prescription Drug Marketing Act of 1987 as amended by the Prescription Drug Amendments of 1992 and any amendments thereto.
- (2) A manufacturer or wholesale distributor shall supply prescription drugs only to a person or entity licensed to possess or distribute prescription drugs to an end user.
 - (3) Prescription drugs supplied by a manufacturer or wholesale distributor shall be delivered only to the business address of the licensee or the address listed on the license, to the address of a health-care entity authorized by the licensee, or to an authorized person or agent of the licensee at the premises of the manufacturer or wholesale distributor if the identity and authority of the authorized agent is established.
 - (4) A licensed wholesale distributor, pharmacy, or other person authorized by law to furnish prescription drugs to an end user shall be accountable for their returns process and shall ensure that all aspects of their operations are secure and do not permit the entry of adulterated or counterfeit prescription drugs.

Effective: July 15, 2008

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