

**CHAPTER 124****(SB 118)**

AN ACT relating to drugs.

*Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

➔Section 1. KRS 214.034 is amended to read as follows:

Except as otherwise provided in KRS 214.036:

- (1) All parents, guardians, and other persons having care, custody, or control of any child shall have the child immunized against diphtheria, tetanus, poliomyelitis, pertussis, measles, rubella, mumps, hepatitis B, and haemophilis influenzae disease in accordance with testing and immunization schedules established by regulations of the Cabinet for Health and Family Services. Additional immunizations may be required by the Cabinet for Health and Family Services through the promulgation of an administrative regulation pursuant to KRS Chapter 13A if recommended by the United States Public Health Service or the American Academy of Pediatrics. All parents, guardians, and other persons having care, custody, or control of any child shall also have any child found to be infected with tuberculosis examined and treated according to administrative regulations of the Cabinet for Health and Family Services promulgated under KRS Chapter 13A. The persons shall also have booster immunizations administered to the child in accordance with the regulations of the Cabinet for Health and Family Services.
- (2) A local health department may, with the approval of the Department of Public Health, require all first-time enrollees in a public or private school within the health department's jurisdiction to be tested for tuberculosis prior to entering school. Following the first year of school, upon an epidemiological determination made by the state or local health officer in accordance with administrative regulations promulgated by the Cabinet for Health and Family Services, all parents, guardians, and other persons having care, custody, or control of any child shall have the child tested for tuberculosis, and shall have any child found to be infected with tuberculosis examined and treated according to administrative regulations of the Cabinet for Health and Family Services. Nothing in this section shall be construed to require the testing for tuberculosis of any child whose parent or guardian is opposed to such testing, and who objects by a written sworn statement to the testing for tuberculosis of the child on religious grounds. However, in a suspected case of tuberculosis, a local health department may require testing of this child.
- (3) All public or private primary or secondary schools, and preschool programs shall require a current immunization certificate for any child enrolled as a regular attendee, as provided by administrative regulation of the Cabinet for Health and Family Services, promulgated under KRS Chapter 13A, to be on file within two (2) weeks of the child's attendance.
- (4) All public or private primary schools shall require a current immunization certificate for hepatitis B for any child enrolled as a regular attendee in the sixth grade, as provided by administrative regulation of the Cabinet for Health and Family Services, promulgated under KRS Chapter 13A, to be on file within two (2) weeks of the child's attendance. ~~This provision shall sunset following the 2008-2009 school year unless otherwise authorized by the General Assembly.~~
- (5) For each child cared for in a day-care center, certified family child-care home, or any other licensed facility which cares for children, a current immunization certificate, as provided by administrative regulation of the Cabinet for Health and Family Services, promulgated under KRS Chapter 13A, shall be on file in the center, home, or facility within thirty (30) days of entrance into the program or admission to the facility.
- (6) Any forms relating to exemption from immunization requirements shall be available at public or private primary or secondary schools, preschool programs, day-care centers, certified family child-care homes, or other licensed facilities which care for children.

➔Section 2. KRS 315.036 is amended to read as follows:

- (1) Except as provided in subsection (4) of this section, each manufacturer ~~or wholesaler~~ of drugs shall be required to register with and obtain a permit from the board. Such permit shall be issued in accordance with policy and procedure prescribed by regulations of the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation of the board, not to exceed two hundred fifty dollars (\$250) annually or increase more than twenty-five dollars (\$25) per year.

- (2) ~~Manufacturers and wholesalers~~ shall be required to maintain accurate records of all drugs manufactured, received and sold, as established by administrative regulation of the board. Such records shall be made available to agents of the board for inspection at reasonable times. The board may require by regulation that ~~manufacturers and wholesalers~~ periodically report to the board all drugs manufactured, received, and sold.
- (3) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.
- (4) The provisions of subsection (1) of this section do not apply to a pharmacist who, in the normal course of professional practice ~~+~~
- ~~(a) compounds reasonable quantities of drugs pursuant to or in anticipation of a valid prescription drug order;~~
- ~~(b) Distributes limited quantities of prescription drugs to practitioners or pharmacies for the purpose of alleviating temporary shortages or responding to emergencies;~~
- ~~(c) Distributes prescription drugs to practitioners or pharmacies for the purpose of supplying or replenishing reasonable quantities utilized by practitioners or pharmacies in the normal course of professional practice, if:~~
- ~~1. A record of the transfer is maintained by both the transferring pharmacy and the receiving practitioner or pharmacy for a period of no less than five (5) years;~~
  - ~~2. The transfer is documented by purchase order or invoice and no prescription drug order shall be used to obtain supplies of drugs under this subsection;~~
  - ~~3. The total number of units transferred during a twelve (12) month period shall not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period; and~~
  - ~~4. All distributions are in accordance with all applicable federal and state laws and administrative regulations; or~~
- ~~(d) Transfers prescription drug inventory from one pharmacy to another pharmacy to effect a permanent pharmacy closure.~~

➔ SECTION 3. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

*As used in Sections 3 to 9 of this Act:*

- (1) *"Authorized distributor of record" means a wholesale distributor that:*
- (a) Has established an ongoing relationship with a manufacturer to distribute the manufacturer's prescription drug. An ongoing relationship exists between a wholesale distributor and a manufacturer if the wholesale distributor, including any affiliated group of the wholesale distributor as defined in Section 1504 of the Internal Revenue Code, has a written agreement for distribution in effect; and*
  - (b) Is listed on the manufacturer's current list of authorized distributors of record;*
- (2) *"Co-licensed partner" means two (2) or more entities that have the right to engage in the manufacturing or marketing or both of a prescription drug consistent with the Federal Drug Administration's implementation of the federal Prescription Drug Marketing Act;*
- (3) *"Co-licensed product" means a prescription drug manufactured by two (2) or more co-licensed partners;*
- (4) *"Counterfeit prescription drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed the drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, the other drug manufacturer, processor, packer, or distributor;*
- (5) *"Drop shipment" means the sale of a prescription drug to a wholesale distributor by the drug's manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the*

*manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor, and:*

- (a) *The wholesale distributor takes title to but not physical possession of the drug;*
  - (b) *The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer a prescription drug; and*
  - (c) *The pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer a prescription drug receives delivery directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the manufacturer's exclusive distributor, or an authorized distributor of record;*
- (6) *"Emergency medical reasons" includes but is not limited to:*
- (a) *Transfers of a prescription drug between health-care entities or between a health-care entity and a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruptions of the regular distribution schedules;*
  - (b) *Sales of drugs for use in the treatment of acutely ill or injured persons to nearby emergency medical services providers, firefighting organizations, or licensed health-care practitioners in the same marketing or service area;*
  - (c) *The provision of emergency supplies of drugs to nearby nursing homes, home health agencies, or hospice organizations for emergency use when necessary drugs cannot be obtained; or*
  - (d) *Transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;*
- (7) *"End user" means a patient or consumer that uses a prescription drug as prescribed by an authorized health-care professional;*
- (8) *"FDA" means the United States Food and Drug Administration and any successor agency;*
- (9) *"Manufacturer" means the same as defined in KRS 315.010;*
- (10) *"Manufacturer's exclusive distributor" means a distributor who:*
- (a) *Contracts with a manufacturer to provide or coordinate the warehousing, distributing, or other similar services on behalf of a manufacturer;*
  - (b) *Takes title of the prescription drug but does not have responsibility to direct the sale of the manufacturer's prescription drug;*
  - (c) *Is licensed under Section 4 of this Act; and*
  - (d) *Is an authorized distributor of record;*
- (11) *"Normal distribution channel" means a chain of custody for a prescription drug from a manufacturer, a manufacturer's co-licensed partner, a manufacturer's third-party logistics provider, or a manufacturer's exclusive distributor that goes directly, by drop shipment, or by intracompany transfer to:*
- (a) *A pharmacy or other designated person authorized by law to distribute a prescription drug to an end user;*
  - (b) *A pharmacy warehouse that performs intracompany sales or transfers of prescription drugs to a group of pharmacies under common ownership and control to a patient, pursuant to a prescription for a patient, or to a person authorized by law to administer a prescription drug for use by a patient;*
  - (c) *An authorized distributor of record:*
    - 1. *Then to a pharmacy or other designated person authorized by law to distribute a prescription drug to an end user;*
    - 2. *Then to a pharmacy warehouse as specified in paragraph (b) of this subsection; or*

3. *Then to another authorized distributor of record to a licensed health-care facility or pharmacy, or a practitioner authorized by law to distribute a prescription drug to an end user; or*
- (d) *A nonprofit organization under state contract to distribute prescription drugs to pharmacies pursuant to the state's emergency response plan and the subsequent distribution of those prescription drugs to pharmacies;*
- (12) *"Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug;*
- (13) *"Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs to a group of pharmacies under common ownership and control;*
- (14) *"Prescription drug" means the same as defined in KRS 315.010;*
- (15) *"Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, or other entities by receiving, taking inventory, and managing the disposition of outdated or nonsalable drugs;*
- (16) *"Third-party logistics provider" means an entity that contracts with a manufacturer to provide or coordinate the warehousing, distribution, or other similar services on behalf of a manufacturer, but does not take title to the drug or have responsibility to direct the sale of the manufacturer's drug. A third-party logistics provider who is a licensed wholesale distributor under Section 4 of this Act and is a manufacturer's authorized distributor of record shall be considered as part of the normal distribution channel;*
- (17) *"Wholesale distribution" means the distribution of a prescription drug to persons other than an end user, but does not include:*
- (a) *Intracompany sales or transfers;*
  - (b) *The sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons;*
  - (c) *The distribution of prescription drug samples by a manufacturer or authorized distributor;*
  - (d) *Drug returns or transfers to the original manufacturer, original wholesale distributor, or transfers to a reverse distributor or third-party returns processor;*
  - (e) *The sale, purchase, or trade of a drug pursuant to a prescription;*
  - (f) *The delivery of a prescription drug by a common carrier;*
  - (g) *The purchase or acquisition by a health-care entity or pharmacy that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization, or health-care entities or pharmacies that are members of the group organization;*
  - (h) *The sale, purchase, distribution, trade, or transfer of a drug by a charitable health-care entity to a nonprofit affiliate of the organization as otherwise permitted by law;*
  - (i) *The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy with another pharmacy or pharmacies; or*
  - (j) *The distribution of a prescription drug to a health-care practitioner or to another pharmacy if the total number of units transferred during a twelve (12) month period does not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period; and*
- (18) *"Wholesale distributor" means an entity engaged in the wholesale distribution of prescription drugs, including but not limited to manufacturers, manufacturers' exclusive distributors, authorized distributors of record, drug wholesalers or distributors, third-party logistics providers, third-party returns processors, reverse distributors, and pharmacy warehouses and retail pharmacies that engage in the wholesale distribution of a prescription drug.*

➔SECTION 4. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *A wholesale distributor shall be licensed by the board under this section prior to engaging in the wholesale distribution of prescription drugs in the Commonwealth. Each license application shall be accompanied by a reasonable fee prescribed by administrative regulation not to exceed two hundred fifty dollars (\$250) annually or increase more than twenty-five dollars (\$25) per year.*
- (2) *A wholesale distributor shall be required to maintain accurate records of all drugs handled in accordance with Sections 3 to 9 of this Act, and records shall be made available to agents of the board for inspection upon request.*
- (3) *Licensing requirements that exceed the requirements of federal law shall not apply to a manufacturer distributing its own FDA-approved drugs or co-licensed products, unless there is reasonable cause to believe that the manufacturer presents a special risk of distributing counterfeit prescription drugs in the Commonwealth.*
- (4) *Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provision of KRS 315.131.*
- (5) *The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to specify the criteria for licensure in conformity with the guidelines for state licensure of a wholesale prescription drug distributor issued by the FDA.*
- (6) *Pursuant to KRS 61.878, information provided by an applicant under this section and any related administrative regulation shall not be disclosed to any person or entity other than the board.*

➔SECTION 5. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (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 Section 6 of this Act 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.*

➔SECTION 6. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1)
  - (a) *As of the date specified by an administrative regulation promulgated by the board pursuant to KRS Chapter 13A, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug.*
  - (b) *A retail pharmacy or a pharmacy warehouse shall comply with paragraph (a) of this subsection only if it engages in wholesale distribution of prescription drugs.*
- (2) *The board shall specify the requirements for the contents and maintenance of a pedigree that are consistent with the federal requirements.*

- (3) *The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to implement the provisions of this section no later than one hundred eighty (180) days after the effective date of this Act.*

➔SECTION 7. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *The board shall not require the use of an electronic track and trace system to initiate, provide, receive, or maintain a pedigree by a person or entity licensed to possess, distribute, dispense, or administer prescription drugs for use by an end user until the FDA develops and implements standards for identification, validation, authentication, and tracking and tracing of prescription drugs pursuant to 21 U.S.C. sec. 355e. The electronic track and trace system requirements by the board shall meet the FDA's standards for all prescription drugs covered by the FDA standards.*
- (2) *Upon implementation of FDA standards for an electronic track and trace system, the requirements relating to a pedigree in Section 6 of this Act shall be superseded by the FDA standards and shall not apply to any prescription drugs specified in the FDA standards.*
- (3) *Prior to promulgation of any administrative regulation under KRS Chapter 13A that requires the use of an electronic track and trace system, the board shall consult with manufacturers, wholesale distributors, and pharmacies regarding implementation of the electronic track and trace system requirements and publish a report on its Web site about implementation issues, including but not limited to universal availability, technical and operational feasibility, and reliability for manufacturers, wholesale distributors, and pharmacies.*

➔SECTION 8. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *The board shall issue an order to the appropriate person or entity, including but not limited to wholesale distributors or retailers, to immediately cease distribution of prescription drugs within the Commonwealth if there are reasonable grounds to believe:*
- (a) 1. *The distribution of the prescription drug is in violation of Section 6 of this Act;*  
 2. *The prescription drug is accompanied by a falsified pedigree in violation of Section 6 of this Act; or*  
 3. *The prescription drug is a counterfeit prescription drug; and*
- (b) *Other procedures to intercede would result in an unreasonable delay.*
- (2) *A person in receipt of an order to cease distribution shall be notified in writing of the right to an administrative hearing to be conducted in accordance with KRS Chapter 13B no later than ten (10) days, excluding weekends and holidays, after the date of the order. If, after a hearing is conducted, the hearing officer determines that there are inadequate grounds to support the order, the order shall be vacated.*

➔SECTION 9. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

- (1) *A person engaged in the wholesale distribution of prescription drugs who unknowingly violates any provision of Sections 3 to 8 of this Act may be fined not more than five thousand dollars (\$5,000).*
- (2) *A person engaged in the wholesale distribution of prescription drugs who acts with gross negligence and violates any provision of Sections 3 to 8 of this Act may be fined not more than fifteen thousand dollars (\$15,000).*
- (3) *A person engaged in the wholesale distribution of prescription drugs who knowingly violates any provision of Sections 3 to 8 of this Act may be fined not more than one hundred thousand dollars (\$100,000).*

**Signed by Governor April 15, 2008.**