

315.402 Licensure of wholesale distributors of prescription drugs -- Record retention -- Administrative regulations -- Confidentiality.

- (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 KRS 315.400 to 315.412, 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 provisions 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.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 124, sec. 4, effective July 15, 2008.