

**315.036 Permit to be acquired by manufacturer -- Fee -- Records required -- Report -- Exception.**

- (1) Except as provided in subsection (4) of this section, each manufacturer 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 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 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, compounds reasonable quantities of drugs pursuant to or in anticipation of a valid prescription drug order.

**Effective:** July 15, 2008

**History:** Amended 2008 Ky. Acts ch. 124, sec. 2, effective July 15, 2008. -- Amended 1996 Ky. Acts ch. 257, sec. 6, effective July 15, 1996. -- Created 1982 Ky. Acts ch. 191, sec. 5, effective July 15, 1982.