

315.340 Permit for operation of in-state outsourcing facility doing business in Kentucky -- Requirements -- Administrative regulations.

- (1) (a) A person shall not operate an outsourcing facility within this Commonwealth, physically or by means of the Internet, facsimile, phone, mail, or any other means, without first obtaining a permit from the board.
- (b) An application for a permit to operate an outsourcing facility shall be made to the board upon forms provided by the board and shall contain such information as the board requires, which may include affirmative evidence of the ability to comply with the requirements of this chapter and the administrative regulations promulgated by the board.
- (c) Each application shall be accompanied by a nonrefundable permit fee to be set by administrative regulation promulgated by the board, not to exceed five hundred dollars (\$500).
- (2) (a) As a prerequisite to obtaining or renewing a permit from the board, the outsourcing facility shall:
 1. Register as an outsourcing facility with the United States Secretary of Health and Human Services in accordance with 21 U.S.C. sec. 353b; and
 2. Submit a copy of a current inspection report resulting from an inspection conducted by the United States Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.
- (b)
 1. The inspection report required pursuant to paragraph (a)2. of this subsection shall be deemed current for the purposes of this section if the inspection was conducted no more than:
 - a. One (1) year prior to the date of submission of an application for a permit to the board; or
 - b. Two (2) years prior to the date of submission of an application for renewal of a permit to the board.
 2. If the outsourcing facility has not been inspected by the United States Food and Drug Administration within the period required under subparagraph 1. of this paragraph, the board may:
 - a. Accept an inspection report or other documentation from another entity that is satisfactory to the board; or
 - b. Cause an inspection to be conducted by its duly authorized agent and charge an inspection fee in an amount sufficient to cover the costs of the inspection.
- (3) (a) Upon receipt of an application for a permit to operate an outsourcing facility accompanied by the permit fee prescribed by administrative regulation, the board shall:
 1. Issue a permit if the outsourcing facility meets the requirements of this chapter and the administrative regulations promulgated by the board; or

2. Refuse to issue or renew any permit to operate if the outsourcing facility fails to meet the requirements of this chapter and the administrative regulations promulgated by the board.
 - (b) The board shall act upon an application for a permit to operate within thirty (30) days after the receipt of the application. The board may issue a temporary permit to operate in any instance where it considers additional time necessary for investigation and consideration before taking final action upon the application. The temporary permit shall be valid for a period of thirty (30) days, unless extended.
- (4) A separate permit to operate shall be required for each outsourcing facility.
- (5)
 - (a) Each permit to operate an outsourcing facility, unless suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by the renewal fee as established by administrative regulations promulgated by the board. The renewal fee shall not exceed five hundred dollars (\$500).
 - (b) An additional nonrefundable fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal penalty for failure to renew by June 30 of each year.
- (6) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable, except that a buyer may operate the outsourcing facility under the permit of the seller pending a decision by the board on an application, which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.
- (7) The board may promulgate administrative regulations to ensure:
 - (a) That proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular outsourcing facility; and
 - (b) Health and sanitation standards for areas within outsourcing facilities that adhere to Current Good Manufacturing Practices published by the United States Food and Drug Administration.
- (8) Each outsourcing facility shall comply with KRS 218A.202.
- (9) Each outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.
- (10) A pharmacist may temporarily operate an outsourcing facility in an area not designated on the permit as authorized in KRS 315.500.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 2, effective June 29, 2017.