

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

- (1) (a) Each out-of-state outsourcing facility that does business physically or by means of the Internet, facsimile, phone, mail, or any other means, inside this Commonwealth, shall hold a current outsourcing facility permit issued by the board.
- (b) An application for a permit to operate an out-of-state outsourcing facility shall be made to the board upon forms provided by it and shall contain such information as the board requires, which may include affirmative evidence of ability to comply with reasonable standards and regulations as may be prescribed by the board.
- (c) Each application shall be accompanied by a permit fee to be set by administrative regulation promulgated by the board. The fee shall not exceed:
 1. Two hundred fifty dollars (\$250); or
 2. The current in-state outsourcing facility permit.
- (2) (a) As a prerequisite to obtaining or renewing a permit from the board, the out-of-state 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 out-of-state outsourcing facility has not been inspected by the United States Food and Drug Administration within the required 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 may 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 out-of-state outsourcing facility, accompanied by the permit fee required by

subsection (1) of this section, the board shall:

1. Issue a permit if the out-of-state outsourcing facility meets the requirements of this chapter and the administrative regulations promulgated by the board; or
 2. Refuse to renew any permit to operate unless the out-of-state outsourcing facility meets 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 thereof. 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 out-of-state outsourcing facility.
- (5) Each out-of-state outsourcing facility granted an out-of-state outsourcing facility permit by the board shall disclose to the board the location, names, and titles of all its principal corporate officers and all its pharmacists who are dispensing prescription drugs to entities within the Commonwealth. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office, corporate officer, or pharmacist.
- (6) (a) An out-of-state outsourcing facility granted an out-of-state outsourcing facility permit shall comply with all requests for information within three (3) business days of a written request by the board or its agents.
- (b) An out-of-state outsourcing facility shall maintain at all times a valid unexpired permit, license, or registration to conduct the outsourcing facility in compliance with the laws of the jurisdiction in which it is a resident.
- (c) As a prerequisite to seeking a permit from the board, the out-of-state outsourcing facility shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. Thereafter, the out-of-state outsourcing facility granted a permit shall submit to the board a copy of any subsequent inspection report of the outsourcing facility conducted by the regulatory or licensing body of the jurisdiction in which it is located.
- (7) Each out-of-state outsourcing facility granted an out-of-state outsourcing facility permit by the board shall maintain records of any controlled substances or dangerous drugs.
- (8) Each out-of-state outsourcing facility shall, during its regular hours of operation, but not less than five (5) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state outsourcing facility for the purpose of facilitating communication. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to an entity within the Commonwealth.
- (9) An out-of-state outsourcing facility shall comply with KRS 218A.202.

- (10) An out-of-state outsourcing facility doing business within the Commonwealth of Kentucky shall use the address on file with the board as the return address on the labels of any package shipped into or within the Commonwealth. The return address shall be placed on the package in a clear and prominent manner.
- (11)
 - (a) A permit to operate an out-of-state 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 nonrefundable renewal fee established by subsection (1) of this section.
 - (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.
- (12) 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 out-of-state 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.
- (13) The board may promulgate administrative regulations to ensure that proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular out-of-state outsourcing facility.
- (14) Each out-of-state outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations, to include all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.

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