

2020 Kansas Statutes

65-1655b. Information required of applicant for registration as outsourcing facility; factors for reviewing qualifications of applicants; denial of application if not in public interest; inspection by the board; rules and regulations. (a) The board shall require an applicant for registration as an outsourcing facility under K.S.A. 65-1643, and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

- (1) The name, full business address and telephone number of the applicant;
- (2) all trade or business names used by the applicant;
- (3) the type of ownership or operation of the applicant;
- (4) the name of the owner or operator, or both, of the applicant, including:
 - (A) If a person, the name of the person;
 - (B) if a partnership, the name of each partner, and the name of the partnership;
 - (C) if a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation;
 - (D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
- (5) a copy of the valid FDA registration as an outsourcing facility as required by 21 U.S.C. § 353b;
- (6) the name and license number of the pharmacist who is designated as the pharmacist-in-charge of the outsourcing facility;
- (7) a copy of a current inspection report resulting from an FDA inspection that indicates compliance with the requirements of the federal food, drug and cosmetic act, including guidance documents and current good manufacturing practices established by the FDA, or if no FDA inspection has been conducted within the prior two-year period, the outsourcing facility must undergo an inspection pursuant to subsection (e); and
- (8) such other information as the board deems appropriate.

Changes in any information in this subsection shall be submitted to the board as required by the board.

(b) In reviewing the qualifications for applicants for initial registration or renewal of registration as an outsourcing facility, the board shall consider the following factors:

- (1) Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;
- (2) any felony convictions of the applicant under federal or state laws;
- (3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
- (4) the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
- (5) suspension or revocation by any federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
- (6) compliance with registration requirements under previously granted registrations, if any;
- (7) compliance with requirements to maintain or make available to the board or to federal, state or local law enforcement officials those records required by the federal food, drug and cosmetic act, and rules and regulations adopted pursuant thereto; and
- (8) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(c) After consideration of the qualifications for applicants for registration as an outsourcing facility, the board may deny an initial application for registration or application for renewal of a registration if the board determines that the granting of such registration would not be in the public interest. The authority of the board under this subsection to deny a registration to operate as an outsourcing facility shall be in addition to the authority of the board under K.S.A. 65-1627(e) or 65-1645(e), and amendments thereto.

(d) The board by rules and regulations shall require that personnel employed by

persons registered as an outsourcing facility have appropriate education or experience, or both, to assume responsibility for positions related to compliance with state registration requirements.

(e) Each outsourcing facility must undergo an inspection by the board or a third party recognized by the board for the purpose of inspecting operations prior to initial registration and periodically thereafter in accordance with a schedule to be determined by the board, but not less than once every three years. The board shall adopt rules and regulations to establish standards and requirements for the issuance and maintenance of an outsourcing facility registration, including inspections of facilities domiciled in the state.

(f) The board by rules and regulations shall establish standards and requirements for the issuance and maintenance of an outsourcing facility registration, including, but not limited to, requirements regarding the following:

- (1) An application and renewal fee;
- (2) a surety bond;
- (3) registration and periodic inspections;
- (4) certification of a designated representative;
- (5) designation of a registered agent;
- (6) storage of drugs and devices;
- (7) handling, transportation and shipment of drugs and devices;
- (8) security;
- (9) examination of drugs and devices and treatment of those found to be unacceptable as defined by the board;
- (10) due diligence regarding other trading partners;
- (11) creation and maintenance of records, including transaction records; and
- (12) procedures for operation.

(g) Notwithstanding any other provision, no outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also registered as a pharmacy in this state and meets all other applicable requirements of federal and state law.

(h) This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

History: L. 2017, ch. 34, § 14; Apr. 20.