2023 Kansas Statutes

65-1643d. Registration as manufacturer or virtual manufacturer; information required in application; criteria for grant or denial; state board of pharmacy rules and regulations; inspections; registration of manufacturer or virtual manufacturer licensed or registered in another state. (a) The board shall require an applicant for registration as a manufacturer or virtual manufacturer 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) all addresses, telephone numbers and the names of contact individuals for all facilities used by the applicant for the storage, handling and distribution of prescription drugs or devices;

(4) the type of ownership or operation of the applicant;

(5) the name of the owner or operator of the applicant, including:

(A) If an individual, the name of the individual;

(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 of the corporation and the name of the state of incorporation; or

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) any other information as the board deems appropriate.

Changes in any information in this subsection shall be submitted to the board in a form and manner prescribed by the board.

(b) In reviewing the qualifications for applicants for initial registration or renewal of registration as a manufacturer or virtual manufacturer, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state or local laws relating to drug samples, manufacture of drugs or devices, 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) discipline, censure, warning, suspension or revocation by 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 the 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 deemed by the board to be relevant to and consistent with the public health and safety.

(c) After consideration of the qualifications for applicants for registration as a manufacturer or virtual manufacturer, 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 as a manufacturer or virtual manufacturer shall be in addition to the authority of the board under K.S.A. 65-1627(f) and 65-1645(e), and amendments thereto.

(d) The board by rules and regulations shall require that personnel employed by persons registered as a manufacturer or virtual manufacturer have appropriate education or experience to assume responsibility for positions related to compliance with state registration requirements.

(e) The board by rules and regulations may implement this section to conform to any requirements of the federal drug supply chain security act, 21 U.S.C. § 351 et seq., in effect on July 1, 2021.
(f) Each facility that manufactures drugs or devices shall undergo an inspection by the board or a third party recognized by the board 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 not later than July 1, 2022, to establish standards and requirements for the issuance and maintenance of a manufacturer and virtual manufacturer registration, including inspections.
(g) The board may register a manufacturer or virtual manufacturer that is licensed or registered under the laws of another state if:
(1) The requirements of that state are deemed by the board to be substantially equivalent to the requirements of this state; or
(2) the applicant is inspected by a third party recognized and approved by the board.
(h) The board by rule and regulation shall establish standards and requirements for the issuance and maintenance of a manufacturer and virtual manufacturer 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;
(12) procedures for operation; and
(13) procedures for compliance with the requirements of the federal drug supply chain security act, 21 U.S.C. § 351 et seq.
(i) This section shall be a part of and supplemental to the pharmacy act of the state of Kansas.
History: L. 2021, ch. 106, § 4; June 3.