

Kansas Administrative Regulations

State Board of Pharmacy

Article 14.—Wholesale Distributors

68-14-4. Minimum required information for registration.

(a) Each wholesale distributor, virtual wholesale distributor, third-party logistics provider, or outsourcing facility shall provide the board with the following minimum information as part of the registration requirements described in K.S.A. 65-1645, and amendments thereto, and as part of any renewal of any registration:

- (1) The name, commercial business address, and telephone number of the registrant;
- (2) each trade or business name used by the registrant;
- (3) the address, telephone number, and name of the contact person for each facility used by the registrant for the storage, handling, and distribution of prescription-only drugs or devices;
- (4) the type of ownership or operation, including partnership, corporation, or sole proprietorship;
- (5) the name of each owner, operator, facility manager, and designated representative of the registrant, including the following:
 - (A) If a person, the name, address, and date of birth of the person;
 - (B) if a partnership, the name, address, and date of birth of each partner and the name of the partnership;
 - (C) if a corporation, the name, title, address, and date of birth of each corporate officer and director, the corporate name, and the name of the state of incorporation; and
 - (D) if a sole proprietorship, the name, address, and date of birth of the sole proprietor and the name of the business entity;
- (6) a list of all states where the registrant is registered as a wholesale distributor, virtual wholesale distributor, third-party logistics provider, or outsourcing facility;
- (7) a copy of any current DEA registration;

(8) all disciplinary actions or sanctions by any state or federal agency against the registrant or any principal, owner, director, officer, facility manager, or designated representative thereof;

(9) if the facility is located outside of Kansas, a record of the following:

(A) A current registration in the state where the registrant is located;

(B) a satisfactory inspection conducted within the previous 36-month period by the registering entity of the state where the registrant is located. If no such inspection record is readily available, the record of a satisfactory inspection conducted at the expense of the registrant within the previous 36-month period by a third party recognized by the board to inspect may be accepted; and

(C) a designated resident agent in Kansas for service of process, the record of whom shall also be on file with the secretary of state; and

(10) if the registrant is an outsourcing facility, a record of the following:

(A) A current outsourcing facility registration from the food and drug administration (FDA); and

(B) a current inspection report from an FDA inspection conducted within the previous 24-month period 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. If no such inspection record is readily available, the record of a satisfactory inspection conducted at the expense of the registrant within the previous 36-month period by a third party recognized by the board to inspect may be accepted.

(b) Each registrant shall provide the board with a surety bond that meets the requirements of 21 U.S.C. 360eee-2.

(c) Each registrant shall provide and maintain, in readily retrievable form, a list of all manufacturers, wholesale distributors, third-party logistics providers, outsourcing facilities, and dispensers with which the registrant is transacting business.

(d) Each registrant shall submit revised information requested by subsection (a) within 30 days after any change in that information.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1643, K.S.A. 65-1645, K.S.A. 65-1655, K.S.A. 65-1655a, and K.S.A. 65-1655b; effective June 15, 1992; amended July 23, 1999; amended Jan. 3, 2020.)

***** Authenticated Kansas Administrative Regulation *****