

Surety Bond Requirements for Wholesale Distributors

What are the requirements for surety bonds?

The surety bond must meet the requirements of 21 U.S.C. 360eee-2, which says:

(3)The furnishing of a bond or other equivalent means of security, as follows:

(A)(i)For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of \$100,000 or other equivalent means of security acceptable to the State.

(ii)For purposes of clause (i), the State or other applicable authority may accept a surety bond in the amount of \$25,000 if the annual gross receipts of the previous tax year for the wholesaler is \$10,000,000 or less.

(B)If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State shall be waived.

If I have a surety bond in another state, will it meet the requirements in Kansas?

If a wholesale distributor can provide evidence that it possesses the required bond in another state, the requirement for a bond will be waived.

Is there an exemption for veterinary wholesale distributors?

Yes. Veterinary wholesale distributors are exempt from the surety bond requirement in Kansas.

Is there an exemption for non-prescription drug/device distributors?

Yes. At their meeting on June 4, 2020, the Board decided to exempt non-prescription drug/device distributors from the surety bond requirement in Kansas.

Is there an exemption for manufacturers, distributors, or repackagers of active pharmaceutical ingredients (API), or for medical gas distributors?

Yes. Any manufacturer, distributor, or repackager of API are exempt from the surety bond requirement in Kansas. Medical gas distributors are also exempt from this requirement.

Can I use one surety bond for all my registration locations?

Each registered facility will need its own surety bond.

Can I use a letter of credit in lieu of a surety bond?

Effective June 4, 2020, the Board will accept a letter of credit that meets the same requirements as the surety bond.

Does the Board have a standard or sample surety bond form?

Yes, the Board has created the S-340 \$25,000 Surety Bond Form and the S-345 \$100,000 Surety Bond Form. Neither of these forms are required but may be used by wholesale distributors to meet the surety bond requirements.

Pharmacist-in-Charge Requirements

Can the PIC also be the designated representative for the facility?

Yes, the designated representative and the PIC may be the same person. If the PIC is already licensed in Kansas for the non-resident pharmacy, no further action is required for that licensee. The background check process is already complete. Please let us know if you have additional questions.

Does the PIC need be licensed in Kansas?

Yes, all outsourcing facilities must designate a Kansas-licensed PIC for the facility. The PIC does not need to be the same pharmacist that is designated as the PIC for the home state registration.

Does the PIC need to do anything if he/she is already licensed in Kansas?

If the PIC is already licensed in Kansas, all he/she must do is sign the application and provide the license information.

Can a pharmacist be PIC at more than one location?

A pharmacist can only be a full-time PIC at one location. Full-time is defined as a location that has pharmacist services 30 hours or more per week. However, a pharmacist may be a PIC at the same location where the facility has multiple registrations. For example, a pharmacist may be PIC at a non-resident pharmacy that is also applying for registration as an outsourcing facility.

Waivers

How do I apply for a waiver?

Requests for waiver of the inspection or Kansas-licensed PIC requirements should be made in conjunction with an initial or renewal application. Requests should include detailed documentation of steps toward completion of these requirements, such as proof of pending NABP applications, scheduled exam dates, emails documenting an upcoming inspection, etc.

Do I need a waiver before I submit my application or renewal?

No. Requests for waiver should be made in conjunction with an initial or renewal application.

Will the Board grant a waiver if I request one early?

No. The Board will review requests on a case-by-case basis in conjunction with the application or renewal submission.

Business Partners

Do veterinary wholesale distributors need to provide a list of end-user customers?

No. Veterinary wholesale distributors should provide a list of suppliers they purchase from and facilities that they ship to that are going to further distribute the product.

Miscellaneous

When does the facility need to be in compliance?

The facility must be in compliance and have submitted an initial or renewal application to the Board no later than June 30, 2020 in the correct registration category. Temporary waivers may be available on a case-by-case basis for inspection and PIC licensure requirements.

Do we need to maintain other existing registrations in Kansas?

That depends on the services provided and the type of business transacted by the facility. If you have questions, please email the inspector assigned to your state or county – contact information is available on our [website](#). Facilities may maintain additional registrations as they deem appropriate or as necessary to meet other state requirements. If the facility needs to remain registered in another category (i.e., pharmacy, non-resident pharmacy, wholesale distributor, etc.), the facility will need to renew that registration prior to June 30, 2020.

How should virtual manufacturers and virtual distributors be registered?

The Board is currently working to update statutes and regulations to be consistent with virtual facility operations. For the time being, virtual manufacturers and virtual distributors should register (or remain registered) in Kansas as a wholesale distributor (5-XXXXXX). The Board will work with individual facilities to determine any requirements for wholesale distributor applications or renewals that would not apply in the virtual setting. For example, virtual facilities may provide the Board with a copy of the manufacturer’s FDA inspection, in lieu of an inspection of their virtual facility. Virtual facilities may also be exempt from the surety bond requirements.