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.

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.

Virtual Manufacturers and Non-Resident Manufacturers

How should virtual manufacturers, or non-resident manufacturers be registered?

Effective May 2021, the Board has updated requirements for non-resident manufacturers shipping to Kansas and virtual facility operations. During the 2021 renewal period (May 17 – June 30, 2021), virtual manufacturers and non-resident manufacturers will be required to do the following to remain registered in Kansas:

- Complete and submit a BR-04 Manufacturer application along with the renewal fee. Submissions must be received or post-marked no later than June 30, 2021.
- Non-resident facilities must attach a copy of the most recent inspection report conducted at the current physical location within the past three years by the state of residence, NABP, or FDA.
- Virtual facilities must attach a list of all products manufactured, as well as the name, address, and phone number of all FDA-registered contract manufacturers; and attach the most recent report of an FDA inspection of manufacturing activities for each manufacturer contracted with the virtual facility to provide any product that is shipped into Kansas.

Upon receipt, the Board will issue a new prefix (4-XXXXX) for the facility registration. Applications must be received before June 30, 2021. Expired registrations are not authorized to do business in Kansas.

If a virtual manufacturer does not have an FDA registration number but lists the labeler code, is the BA-04 form required?

Yes. The FDA registration number fields should be left blank. The facility is still required to complete the BA-04 because it owns the NDA, ANDA, or UDI.

What facilities qualify as virtual manufacturers in Kansas?

A Virtual Manufacturer is an entity that engages in the manufacture of drug or device products for which it:

- Owns the NDA or ANDA number, if a prescription drug;
- Owns the UDI number, as available, for a prescription device;
- Contracts with a contract manufacturing organization for the physical manufacture of the drug or device product;
- Is not involved in the physical manufacture of the drug or device product; and
- At no time takes physical possession of, or stores, the drug or device product.

A "Virtual Manufacturer" may include entities that are identified as a broker, own-label distributor, sponsor manufacturer, private-label manufacturer, or contract manufacturer.

What if we are a manufacturer and a distributor?

If the facility is only shipping products into Kansas that are manufactured at that specific facility into Kansas, register as a manufacturer.

If the facility is shipping products into Kansas manufactured at other facilities/locations, register as a distributor or a third party logistics provider (depending on whether or not the facility takes ownership).

If the facility is shipping products manufactured at that specific location into Kansas and products manufactured at other facilities into Kansas, register as both a manufacturer and a distributor/3PL.

What type of supplemental information should a virtual manufacturer provide?

1. A list of drug or device products it distributes;
2. A list of the NDA or ANDA numbers associated with each drug it distributes;
3. A list of the UDI numbers, as available, associated with each device it distributes;
4. The name and facility address of the contract manufacturer for each drug or device product it distributes;
5. Verification of current FDA registration for each contract manufacturing facility listed;
6. If the contract manufacturer distributes into Kansas, the wholesale distributor permit number for the contract manufacturer;
7. If the contract manufacturer does not distribute into Kansas, the name and Kansas wholesale distributor registration number for the entity that physically distributes the product into this State;

Miscellaneous

When does the facility need to be in compliance?

Facilities were required to 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.

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.