

Guidance for Facility Renewal Applicants

Approved by Kansas State Board of Pharmacy: July 11, 2024

Last Updated: May 22, 2024

- I. Purpose
 - a. The purpose of this guidance is to provide clarification regarding the options available to nonresident pharmacies, wholesale distributors, and manufacturers considering renewing their registration in Kansas.
- II. Statutory Authority
 - a. See K.S.A. 65-1627, 65-1627I, 65-1643, 65-1645, 65-1655, and 65-1657.
- III. Guidance
 - a. Kansas law requires the following inspections be provided at the time of renewal:
 - i. Nonresident Pharmacies – Satisfactory inspection conducted within the last 18 months from the date of renewal application from the resident state or NABP
 - ii. Wholesale Distributors – Satisfactory inspection conducted within the last 36 months from the date of renewal application from the resident state, NABP, or FDA
 - iii. Manufacturers – Satisfactory inspection conducted within the last 36 months from the date of renewal application from the resident state, NABP, or FDA
 - b. If the facility does not have an inspection that meets the requirements of paragraph (a), the facility may do one of the following:
 - i. Do not renew and allow the registration to expire for non-renewal on June 30.
 1. This is not considered disciplinary action.
 2. Expired registrations may not conduct business in Kansas.
 3. If a facility wishes to conduct future business in Kansas, a late renewal is allowed until December 31 or a new application is required after December 31.
 - ii. Withdraw a pending application for renewal and allow the registration to expire for non-renewal on June 30.
 1. See notes under subparagraph (b)(i) which also apply here.
 2. The Board does not issue refunds.
 - iii. Request an inspection that meets the requirements of paragraph (a) and provide it to the Board by June 30.
 - iv. Renew the registration and enter into a Consent Agreement with the Board entering into a non-disciplinary probation status until a satisfactory inspection can be conducted by the Board.
 1. Inspections are anticipated to be completed within 6 months.
 2. Actual costs of the Board's inspection will be charged to the facility and require payment after the inspection but before ending the probationary period.
 3. An estimate of the inspection costs will be provided to the facility at the time of entering the Consent Agreement.
 4. This is not considered disciplinary action and will not be reportable to NABP or NPDB.
 5. Registration status will show as "Active – Renewal Pending Review" and the facility is authorized to continue doing business in Kansas during the probationary period.
 - v. Renew the registration and be denied for failure to meet the renewal requirements.