Guidance for Facility Renewal Applicants

Approved by Kansas State Board of Pharmacy: April 27, 2023

Last Updated: May 21, 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, 65-1627l, 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 application from the resident state or NABP
 - ii. Wholesale Distributors Satisfactory inspection conducted within the last 36 months from the date of application from the resident state, NABP, or FDA
 - iii. Manufacturers Satisfactory inspection conducted within the last 36 months from the date of 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 <u>not</u> 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 Kanas during the probationary period.
 - v. Renew the registration and be denied for failure to meet the renewal requirements.