

Secretary of State Office of Professional Regulation

PHARMACY Renewal Instructions for Non-Resident (Out of State) Pharmacies

In order to renew you will need to:

- Submit an online renewal application and pay the non-refundable application fee. Renewal
 applications are found within the online licensing system at:
 https://secure.professionals.vermont.gov/prweb/PRServlet/app/default/ybVBleIGIHMIPa8qpM9BaiNEZfDPENuF*/!STANDARD
- 2. Be prepared to answer questions about the following and supply any related information/documentation, which include but are not limited to:
 - Has the pharmacy dispensed or shipped prescriptions into Vermont within the past 2 years?
 - Does the pharmacy prepare nonsterile compounds, compounded sterile products, or products for home infusion?
 - Has the pharmacy conducted a recall of compounded products (sterile and nonsterile) or
 - products for home infusion within the past two years?
 - Does the pharmacy dispense compounded products or home infusion products prepared by another pharmacy?
 - FDA questions
 - Has the pharmacy been inspected by the FDA within the past 5 years?
 - · Was your entity issued a Form 483?
 - · Was your entity issued an Untitled letter?
 - Was your entity issued a Warning Letter?
 - Was your entity subject to a seizure by the FDA?
 - Was your entity subject to an injunction by the FDA?
 - Has your firm received a request for a Regulatory Meeting with the FDA?
- 3. Submit Inspection: All entities must submit proof (i.e., full inspection report) that they have successfully passed and maintained an acceptable current inspection (not more 3 years old).
 Acceptable inspections: FDA, NABP VPP, VIPPS Certificate or State Board Inspection. NOTE: inspections for pharmacies that perform compounding or home infusion must evaluate the pharmacy's facility and compounding operations for compliance with USP General Chapters <795> for nonsterile compounding and <797> for sterile compounding/home infusion.
- 4. **Report changes in pharmacist manager**: If applicable, upload the Statement of Pharmacist in Charge form and the signed and notarized Affirmation form.

Important Notes for Renewal

If your first license was issued within 90 days of the first renewal expiration date, your license is valid until the next renewal date. Please check the expiration date printed on your license.

Three (3) courtesy renewal reminders are sent to the email on file starting approximately 6 weeks prior to the renewal expiration date. It is your responsibility to ensure your email address is up to date. You may update your email by logging in to Online Licensing and updating your profile. Please check your spam folder and add our office to your safe senders list.