

Secretary of State Office of Professional Regulation

PHARMACY Renewal Instructions for Wholesale Pharmacy

Includes full service wholesalers, virtual distributors and other related drug supply chain entities and trading partners.

To renew, you must submit the following:

 Submit an online renewal application and pay the non-refundable application fee. Renewal applications are found within the online licensing system at: <u>https://secure.professionals.vermont.gov/prweb/PRServlet/app/default/ybVBleIGIHMIPa8qpM9BaiNEZfD</u> <u>PENuF*/!STANDARD</u>

All required documentation must be uploaded within the online services system. The office will not accept paper copies of documentation pertaining to renewal requirements.

2. The Vermont Board of Pharmacy has made updated to the Drug Outlet license categories. You will be asked for additional information and documentation during the renewal.

Be prepared to answer questions about the following and supply any related information/documentation, which includes but is not limited to:

- Is the entity a Contract/Actual Manufacturer, Virtual Manufacturer, a Full-Service Wholesaler or a Virtual Distributor?
- Has the entity shipped or arranged for shipment of drugs into Vermont within the past 2 years?
- Has the entity 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 than 3 years old).

Acceptable inspections: FDA, NABP's Drug Distributor Accreditation (formerly known as VAWD) or State Board Inspection. If the state does not inspect the drug outlet type, submit a statement from the State's Board of Pharmacy.

4. **Report changes in contact person**: If applicable, upload the Statement of Contact Person form and the signed and notarized Affirmation form.

NOTE: Any change of address or other contact information, by an applicant or licensee, <u>must</u> be forwarded to this office no later than thirty (30) days after change occurs.

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.