



**Secretary of State
Office of Professional Regulation**

**PHARMACY
Application Instructions for Non-Resident Manufacturer**

The FDA has revised its definition of Wholesale Drug Outlets to no longer include “manufacturers”. Therefore, the Vermont Board of Pharmacy is updating their drug outlet licenses to create a non-resident manufacturer license that will include actual/contract manufacturers, virtual manufacturers and re-packagers/re-labelers. Please review the policy adopted by the Board on January 23, 2019: “*Board Policy on Licensure of Virtual Drug Manufacturers, Contract Manufacturers, Virtual Manufacturers, Brokers/Intermediaries/Facilitators, and Re-packagers/Re-labelers*” that explains its expectation that all entities involved in the drug supply chain that results in prescription drugs entering Vermont shall be licensed.

<https://cms.sec.state.vt.us:8443/share/s/F1Q7fcSRTn2lBrgTtb-PfA>

A new application is required when a pharmacy changes ownership or relocates.

1. Submit online application and application fee. (nonrefundable processing fees) All signatures required on the application must be those of an Owner, a Partner or Corporate Officer.
2. Submit FDA Establishment Identifier Number to provide evidence that applicant entity is duly registered with the FDA (Virtual Manufacturers – if applicable.)
3. Submit Flow chart showing ownership. If an actual flow chart is not available, a description of the ownership or hierarchy of the organization is acceptable.
4. Upload statement of Contact Person using the form provided in the online application.
5. Submit Affirmation Forms. Affirmations must be completed by the sole proprietor, all members, all partners, or corporate officers and directors, and the contact person(s) for the facility used by the applicant for storage, handling, and distribution of drugs, stating that they have not been convicted of, and are not under indictment for, any felony or misdemeanor arising from the violation of any drug or pharmacy related law. Questions must be answered, and your signature must be notarized.
6. Submit Inspection. Copy of most recent Inspection Report form from the state in which the entity is located.
 - Note: All entities must submit proof with initial and renewal applications that they have successfully passed an inspection (not more than three years old) performed by the Pharmacy Board in the state in which they reside or an inspection from another similar body approved by the Board.
 - For virtual manufacturers, if your state does not inspect this type of facility, please submit a statement from the state licensing agency to that effect. This letter must be on official letterhead.
7. Provide information about FDA inspections, and actions issued, to your entity within the past 5 years. Documents submitted should be un-redacted and marked confidential.
8. Provide DEA registration information, if controlled substances will be shipped into Vermont. You will need to contact the Vermont Prescription Monitoring System (VPMS) through the Vermont Department of Health to register. You may call 802-652-4147 or e-mail AHS.VDHPMS@Vermont.gov to get further instruction.
9. Please upload a list of trading partners using the form provided within the online application.
10. Submit Verification of Licensure and Good Standing. Verification of licensure standing directly from the licensing authority in the state where the wholesaler or manufacturer is located that will be shipping drugs to Vermont. No

form is provided. Contact your state's Board of Pharmacy or applicable licensing authority and request that a verification of good standing be sent to Vermont. Note: Online verification is acceptable provided the state in which the facility is located reports whether disciplinary action(s) has been taken against the applicant.

11. Convictions/Denials/Disciplinary Actions. Must submit a complete list of disciplinary actions taken against the applicant, including actions taken against its parent, its subsidiaries, or any other person or organization with a controlling interest (including those owning 5% or more) in this drug outlet. If the answer is "yes" on the application form, provide certified copies of the charges, if filed, and of the Final Disposition Order. In addition, a signed and sworn statement from the CEO, COO, president or equivalent management level corporate officer showing how the company has responded to the prior violation such that the Vermont Board of Pharmacy can be assured that a repeat or similar violation will not occur in Vermont. Please also ask the state in which the action was taken to provide to the Board verification of current licensure standing. An Investigative Team will review this information to determine whether further investigation or action is needed before a final decision is made regarding your application.
12. Proof of registration (Certificate of Authority, LLC Articles and/or Tradename Registration) with the Vermont Secretary of State's Corporations Division. Please attach copies of your certificate(s) and articles.