State of Vermont
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Board Policy on Licensure of Virtual Drug Manufacturers, Contract Manufacturers, Virtual Distributors, Brokers/Intermediaries/Facilitators, and Repackagers/Relabelers

For the purposes of administering 26 V.S.A. §§ 2021, 2022(7), & 2061(a)&(b) in conformity with the intent of the General Assembly, the Vermont Board of Pharmacy finds that the following are "entities that are engaged in the dispensing, delivery, or distribution of prescription drugs." Each must, therefore, become licensed with the Board if engaged in the transmission of prescription drugs into the State of Vermont:

1. **Virtual Manufacturers** – companies which own title [the FDA New Drug Application (NDA) or Abbreviated New Drug Application (ANDA)] for a prescription drug and which contract with others for the actual manufacturing and/or distribution of the drug;

2. **Virtual Distributors** – companies which arrange for the distribution of a prescription drug and which may or may not take actual possession of the drug or but contracts with others for the distribution, purchase, and sale;

3. **Contract manufacturers, relabelers, and/or repackagers**; and

4. **Brokers/Facilitators/Intermediaries** – parties that mediate between a buyer and a seller, or act in any way to bring buyers and sellers together, for the sale or shipment of prescription drugs.

NOTE: Companies performing any of the above activities requiring licensure will be required during random license compliance audits to also provide verification to the Board that any/all companies they do business with or further contract/subcontract out any of these activities to, are also licensed with the Board in order to ensure the integrity and safety of the prescription drug supply chain, drug pedigree, and chain of custody/control for all prescriptions products which eventually are distributed/sold in Vermont.

Relevant Law

26 V.S.A. §§ 2061(a)&(b) provide that:

(a) All drug outlets shall biennially register with the Board of Pharmacy.
(b) Each drug outlet shall apply for a license in one or more of the following classifications:
(1) Retail.
(2) Institutional.
(3) Manufacturer.
(4) Wholesale distributor.
(5) Investigative and research projects.
(6) Compounding.
(7) Outsourcing.
(8) Home infusion.
(9) Nuclear.

Board Rule 1.10(28) defines *Manufacturing* to mean:

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the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

Board Rule 1.10(53) defines *Wholesale Distributor* to mean:

any person engaged in wholesale distribution of drugs, including but not limited to manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions.