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OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION
DIVISION OF HEALTH PROFESSIONS
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Board Policy on Licensure of Virtual Drug/Device Manufacturers, Contact Manufacturers, Virtual Distributors, Brokers/Intermediaries/Facilitators, and Repackagers/Relabelers

I. For the purposes of interpreting proper licensure requirements for the above noted entities, the New Hampshire Board of Pharmacy interprets the New Hampshire Statutes and Administrative Rules of the Board, cited in Section II of this notice, to **require the licensure of <u>all</u> of the following entities as "Prescription Drug or Device Manufacturers/Wholesalers/Distributors":**

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

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

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

4. Brokers/Facilitators/Intermediaries – defined as 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, medical gases, or prescription medical equipment/devices; and

II. Current New Hampshire Statutes and Rules which address the licensure of the above entities[1]:

NH RSA 318:1 Definitions
VIII. "Manufacturing" means the production, preparation, propagation, conversion or processing of

[1] *Only excerpts of applicable sections of Board laws/rules are listed in this document for purposes of this ruling – for full details on all the licensure requirements of the Board, see the full Pharmacy Laws/Rules at: https://www.oplc.nh.gov/pharmacy/laws-rules.htm*

a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices for resale. Manufacturing shall be governed by Good Manufacturing Practices as adopted and enforced by the federal Food and Drug Administration.

NH RSA 318:51-a Licensing of Manufacturers and Wholesalers Required. –
I. No person shall manufacture legend drugs or controlled drugs as that term is defined in RSA 318-B:1, VI and no person as a wholesaler, distributor, or reverse distributor shall supply the same without first having obtained a license to do so from the board. Such license shall expire annually on June 30. An application together with a reasonable fee as established by the board shall be filed annually on or before July 1.

Ph 701.02 Definitions. Except where the context makes another meaning manifest, the following words mean:

(c) "Distributor" means a person or persons who supplies or facilitates the supply of prescription drugs or devices to someone other than the patient, including, but not limited to, manufacturers, repackagers, brokers and wholesale drug distributors.

(t) "Wholesale drug distribution" means distribution of prescription drugs other than to the patient, including, but not limited to distribution by manufacturers, repackers, own label distributors, jobbers, and wholesale drug distributors.

Ph 404.02 Definitions.

(v) "Manufacturing" means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices for resale.

CHAPTER Ph 1000 STANDARDS OF PRACTICE FOR MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS

PART Ph 1001 LICENSING

Ph 1001.01 License Required.

(a) No person shall manufacture or act as a wholesale distributor of prescription drugs or prescription devices without first obtaining a license to do so from the board pursuant to this chapter. No license shall be issued or renewed for a manufacturer or wholesale drug distributor unless the same shall be operated in a manner prescribed by law and according to the rules adopted by the board of pharmacy with respect thereto.

(b) Separate licenses shall be required for each manufacturing and distribution site owned or operated by a manufacturer or wholesale distributor. Provided however, that an agent or employee of any licensed manufacturer or wholesale distributor shall not be required to be licensed under this section and may lawfully possess prescription drugs and devices if he is acting in the usual course of his business or employment.

III. Further, 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 / device supply chain, drug pedigree, and chain of custody/control for all prescriptions products which eventually are distributed/sold in New Hampshire.

Sincerely,

Michael D. Bullek, R.Ph.
Board Administrator /
Chief of Compliance