

Vermont Board of Pharmacy Policy on “Legend Devices”

To clarify when a license issued by the Vermont Board of Pharmacy is needed for a “legend device” the Board adopts this policy.

The Vermont Board of Pharmacy has jurisdiction over the practice of pharmacy which, is defined by 26 V.S.A. § 2022(14):

“Practice of pharmacy” means the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and *legend devices* (except labeling by a manufacturer, packer, or distributor of nonprescription drugs and commercially packaged legend drugs and *legend devices*); the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and *legend devices* and the maintenance of proper records therefor; the responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and *legend devices*; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy. A rule shall not be adopted by the Board under this chapter that shall require the sale and distribution of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist or otherwise interfere with the sale and distribution of such medicines. (emphasis added)

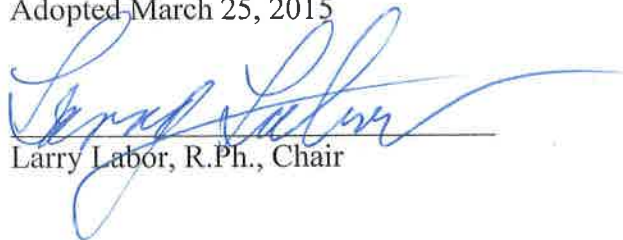
The Board of Pharmacy wishes to further the intent of the statute as it understands it and has implemented it over the years. The Board does not wish to regulate in areas which do not require its intervention. The Board wishes to distinguish legend devices containing drugs from medical and other devices which do not contain drugs.

Accordingly, The Board of Pharmacy defines “legend device” to mean a device containing a legend drug.

By means of example, a “legend device” as defined above would include: epinephrine injectors, auto-injectors which contain the drug within it, and drug patches. Durable medical equipment does not constitute a “legend device.”

A license issued by the Board of Pharmacy is required for distribution or sale of legend devices.

Adopted March 25, 2015



Larry Labor, R.Ph., Chair