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Governor

STATE OF MAINE  
DEPARTMENT OF PROFESSIONAL  
AND FINANCIAL REGULATION  
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION  
**BOARD OF PHARMACY**  
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**Proposed Pharmacy Rule Chapter 34-A  
“Licensure of Retail Suppliers of Prescription Medical Devices”**

While finalizing the adoption and filing of a rule that would require a limited pharmacy license for retail suppliers of prescription medical devices, the Board has decided that the rule as contemplated by the Board and other stakeholders would be counterproductive at this time. This decision flows from the Board’s determination that its jurisdiction over suppliers of prescription medical devices is limited to those entities that supply devices that are required under federal or state law to be both prescribed by a practitioner and dispensed by a pharmacist.

The Maine Pharmacy Act defines the term “device” in 32 M.R.S. § 13702-A(8) as follows:

“Device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, that is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

Maine’s definition of “device” is much narrower than the federal definition. Not all things that are commonly understood to be medical devices are “devices” for purposes of the Maine Pharmacy Act. In sum, the Board’s position is that entities that sell or supply medical instruments or articles that do not fall within the definition of “device” in 32 M.R.S. § 13702-A(8) are not subject to regulation by the Board by virtue of the sale and/or supply of such items. Therefore, the Board has decided not to pursue the adoption and filing of proposed Pharmacy Rule Chapter 34-A.

Unanimously accepted by the Maine Board of Pharmacy on: August 6, 2015  
Joseph Bruno, R.Ph., Board President

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