GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2015

H.B. 623 Apr 9, 2015 HOUSE PRINCIPAL CLERK

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HOUSE DRH40257-MGqq-127 (03/31)

Short Title:	Device & Medical Equipmt Permit Requirements.	(Public)
Sponsors:	Representative Dobson.	
Referred to:		_

A BILL TO BE ENTITLED

AN ACT REQUIRING CERTAIN DEVICE AND MEDICAL EQUIPMENT PERMIT HOLDERS AND APPLICANTS TO MAINTAIN AT LEAST ONE PHYSICAL LOCATION AND A MINIMUM AMOUNT OF INVENTORY IN THE STATE OF NORTH CAROLINA.

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 90-85.22 reads as rewritten:

"§ 90-85.22. Device and medical equipment permits.

- (a) Devices. Each place, whether located in this State or out-of-state, where devices are dispensed or delivered to the user in this State shall register annually with the Board on a form provided by the Board and obtain a device permit. A business that has a current pharmacy permit does not have to register and obtain a device permit. Records of devices dispensed in pharmacies or other places shall be kept in accordance with rules adopted by the Board.
- (b) Medical Equipment. Each place, whether located in this State or out-of-state, that delivers medical equipment to the user of the equipment in this State shall register annually with the Board on a form provided by the Board and obtain a medical equipment permit. A business that has a current pharmacy permit or a current device permit does not have to register and obtain a medical equipment permit. Medical equipment shall be delivered only in accordance with requirements established by rules adopted by the Board.
- Minimum Presence Requirement. Except as otherwise provided in this subsection, each applicant or holder of a device or medical equipment permit shall maintain (i) at least one physical location within this State or within 40 miles of the border of this State and (ii) a sufficient amount of inventory to respond to orders or requests within this State in a timely manner. This subsection does not apply to a disposable medical supply mail order company. However, a disposable medical supply mail order company that does not have a licensed physical location within this State shall comply with the regulations of the Federal Trade Commission, 16 C.F.R. 435.1 through 16 C.F.R. 435.3, and the United States Postal Service. Home medical equipment services providers whose employees, agents, or subcontractors enter a consumer's residence to service home medical equipment supplied by a mail order company or to instruct consumers in the use of such equipment shall not be considered mail order companies. As used in this section, "disposable medical supply mail order company" means a company that lists disposable medical supplies for purchase by consumers by telephone, mail order, or Internet order and delivers these supplies directly to the consumer through the United States Postal Service or a commercial courier service. The term "disposable medical supply mail order company" does not include a company that supplies respiratory care and oxygen equipment or any other equipment necessary to avert an immediate threat to a consumer's



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- health or safety, without which a consumer might be required to seek emergency medical treatment. The term also does not include home medical equipment services providers whose employees, agents, or subcontractors enter the consumer's residence to service home medical equipment supplied by a mail order company or to instruct consumers in the use of such medical equipment.
 - (c) <u>Exemption.</u> This section shall not apply to either of the following:
 - (1) A pharmaceutical manufacturer registered with the Food and Drug Administration.
 - (2) A wholly owned subsidiary of a pharmaceutical manufacturer registered with the Food and Drug Administration."

SECTION 2. This act becomes effective October 1, 2015.