



HOUSE BILL 437: Create Permit Exemptions/Home Renal Products

2015-2016 General Assembly

Committee:

Introduced by:

Analysis of: S.L. 2015-28

Date:

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Legislative Analyst

SUMMARY: *S.L. 2015-28 amends the North Carolina Pharmacy Practice Act to create a pharmacy permit exemption for dispensing and delivery of dialysate or drugs necessary to perform home renal dialysis; to allow pharmacies to ship medications for home use by patients with renal failure to dialysis facilities; and to create an exemption from device and medical equipment permits for home renal products.*

This act became effective October 1, 2015.

CURRENT LAW:

G.S. 90-85.21 and G.S. 90-85.21A regulate pharmacy permits.

- Each pharmacy in North Carolina is required to annually register with the Board of Pharmacy (Board) and include specified information about its pharmacist-manager and all pharmacy personnel.
- Physicians who dispense prescription drugs must annually register with the Board and with the licensing board having jurisdiction over the physician.
- Out-of-state pharmacy operations which ship, mail, or deliver prescription drugs must also annually register with the Board. The out-of-state operations must certify that they employ a pharmacist who is responsible for dispensing, shipping, mailing, or delivering prescription drugs into this State or in a state approved by the Board and has met requirements for licensure equivalent to the requirements for licensure in North Carolina. The out-of-state pharmacist must agree in writing to be subject to the jurisdiction of the Board, the provisions of the Pharmacy Practice Act, and the rules adopted by the Board.

G.S. 90-85.22 pertains to medical devices and equipment and requires each location where devices are dispensed or delivered, or that deliver medical equipment, to a user in North Carolina to register annually with the Board, unless the business already has a current pharmacy permit.

G.S. 106-145.3 requires every wholesale distributor of prescription drugs in this State to obtain a license from the Department of Agriculture for each location from which prescription drugs are distributed and renew the license annually.

BILL ANALYSIS:

Section 1 of the act adds a new section, G.S. 90-85.21C, to create a pharmacy permit exemption for any location or facility within or outside of North Carolina from which dialysate or drugs necessary to perform home renal dialysis are dispensed and delivered to a patient in North Carolina if all of the following criteria are met:

- The dialysate or drugs have been approved or cleared by the United States Food and Drug Administration.

O. Walker Reagan
Director



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- The dialysate or drugs are lawfully held by a manufacturer, or agent of the manufacturer, or wholesaler that is properly licensed in North Carolina.
- The dialysate or drugs are held, delivered, and dispensed in their original sealed packaging from the manufacturing facility.
- The dialysate or drugs are delivered only by the manufacturer or agent of a manufacturer and only upon receipt of a physician's order.
- The manufacturer or agent of the manufacturer delivers the dialysate drugs to either of the following:
 - A patient with chronic kidney failure or a designee of the patient, for self-administration of the dialysis therapy.
 - A health care provider or health care facility licensed under Chapter 122C, 131D, or 131E of the General Statutes, for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

Section 1 of the act also creates G.S. 90-85.21D to allow pharmacies to ship medications for home use by patients with renal failure to dialysis facilities for delivery to: (i) patients receiving dialysis treatment in a Medicare certified dialysis facility, or (ii) the patient's home for self-dialysis. All of criteria below must be met before a pharmacy may mail medications to the renal dialysis facilities.

- The patient authorizes, in writing, the dialysis facility staff to act as the patient's designated agent for the purpose of receiving mailed medical packages at the dialysis facility.
- The pharmacy, whether in-state or out-of-state, is licensed as a pharmacy in North Carolina.
- The medications for home use are dispensed by the licensed pharmacist pursuant to a valid prescription order.
- The delivered medication packages are held in a secure location in an area not accessible to the public and delivered by the dialysis facility staff, unopened, to the patient.
- Medication packages are individually labeled with the patient name.
- The medications exclude controlled substances (as defined under G.S. 90-87).

Section 2 of the act exempts the dispensing and delivery of home renal products from requiring a device and medical equipment permit.

EFFECTIVE DATE: The act became effective October 1, 2015.