



This Bill Analysis reflects the contents of the bill as it was presented in committee.

HOUSE BILL 437: Create Permit Exemptions/Home Renal Products

2015-2016 General Assembly

Committee: House Health
Introduced by: Rep. Dobson
Analysis of: PCS to First Edition
H437-CSTK-6

Date: April 10, 2015
Prepared by: Amy Jo Johnson
Committee Counsel

SUMMARY: House bill 437 would amend the North Carolina Pharmacy Practice Act to create a pharmacy permit exemption and a device and medical equipment permit exemption for the dispensing and delivery of home renal products. The PCS makes technical changes and adds provisions allowing dialysis facilities to be designated agents to receive home medications for patients with renal failure.

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 also 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.

With regards to medical devices and equipment, G.S. 90-85.22 requires each location where devices are dispensed or delivered, or that delivers medical equipment, to a user in North Carolina must 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:

The PCS to House Bill 437 would exempt 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 from the requirement to obtain a pharmacy permit as required by G.S. 90-85.21 and G.S. 90-85.21A if the following criteria are met:

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



House Bill 437

Page 2

- 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 2 of the bill would also exempt such dispensing and delivery of home renal products from requiring a device and medical equipment permit.

The PCS would also create a new G.S. 90-85.21D which would allow pharmacies to mail medications for home use by patients with renal failure to renal dialysis facilities for use in one of two specified locations: a Medicare certified dialysis facility or the patient's home for self-dialysis. The bill contains various criteria that must be met before a pharmacy may mail medications to the renal dialysis facilities.

EFFECTIVE DATE: This act becomes effective October 1, 2015.