GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

H **D**

HOUSE BILL 437*
PROPOSED COMMITTEE SUBSTITUTE H437-PCS30309-TK-6

Short Title: Create Permit Exemptions/Home Renal Products. (Public)

Sponsors:

Referred to:

April 1, 2015

A BILL TO BE ENTITLED

AN ACT AMENDING THE 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 AND TO ALLOW FOR DIALYSIS FACILITIES TO BE DESIGNATED AS AGENTS TO RECEIVE HOME MEDICATIONS FOR PATIENTS WITH RENAL FAILURE.

The General Assembly of North Carolina enacts:

SECTION 1. Article 4A of Chapter 90 of the General Statutes is amended by adding two new sections to read:

"**§ 90-85.21C. Pharmacy permit exemption for dispensing and delivery of home renal products.**

Each location or facility within or outside this State from which dialysate or drugs necessary to perform home renal dialysis are dispensed and delivered to a patient in this State is exempt from the pharmacy permit requirements established by G.S. 90-85.21 and G.S. 90-8.21A, provided that all the following criteria are met:

(1) The dialysate or drugs have been approved or cleared by United States Food and Drug Administration.

(2) The dialysate or drugs are lawfully held by a manufacturer or an agent of the manufacturer that is properly licensed by the North Carolina Department of Agriculture and Consumer Services as a manufacturer, or as a wholesaler, or as both, as required by G.S. 106-145.3.

(3) The dialysate or drugs are held, delivered, and dispensed in their original, sealed packaging from the manufacturing facility.

(4) The dialysate or drugs are delivered only by the manufacturer, or an agent of the manufacturer, and only upon receipt of a physician's order.

(5) The manufacturer or an agent of the manufacturer delivers the dialysate or drugs directly to either of the following:

a. A patient with chronic kidney failure or a designee of the patient, for self-administration of the dialysis therapy.

b. 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.

"**§ 90-85.21D. Dialysis facilities as designated agents to receive home medications for patients with renal failure.**

Pharmacies may ship medications for home use by patients with renal failure to renal dialysis facilities for delivery to (i) patients who receive dialysis treatments in a Medicare certified dialysis facility or (ii) patients who self-dialyze at home, provided that all of the following criteria are met:

(1) 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.

(2) The pharmacy, whether in-state or out-of-state, is licensed as a pharmacy in North Carolina.

(3) The medications for home use are dispensed by the licensed pharmacist pursuant to a valid prescription order.

(4) 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.

(5) Medication packages are individually labeled with the patient name.

(6) The medications exclude controlled substances, as defined under G.S. 90-87."

SECTION 2. G.S. 90-85.22 reads as rewritten:

"**§ 90-85.22. Device and medical equipment ~~permits.~~permits; exemptions.**

…

(c) This section shall not apply to ~~either~~ any 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.

(3) The dispensing and delivery of home renal products in accordance with the criteria specified in G.S. 90-85.21C."

SECTION 3. This act becomes effective October 1, 2015.