

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

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HOUSE BILL 437*

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

Sponsors: Representative Dobson (Primary Sponsor).

For a complete list of Sponsors, refer to the North Carolina General Assembly Web Site.

Referred to: Health.

April 1, 2015

1 A BILL TO BE ENTITLED
2 AN ACT AMENDING THE PHARMACY PRACTICE ACT TO CREATE A PHARMACY
3 PERMIT EXEMPTION AND A DEVICE AND MEDICAL EQUIPMENT PERMIT
4 EXEMPTION FOR THE DISPENSING AND DELIVERY OF HOME RENAL
5 PRODUCTS.

6 The General Assembly of North Carolina enacts:

7 **SECTION 1.** Article 4A of Chapter 90 of the General Statutes is amended by
8 adding a new section to read:

9 "**§ 90-85.21C. Pharmacy permit exemption for dispensing and delivery of home renal**
10 **products.**

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

- 15 (1) The dialysate or drugs have been approved or cleared by United States Food
16 and Drug Administration.
17 (2) The dialysate or drugs are lawfully held by a manufacturer or an agent of the
18 manufacturer that is properly registered with the Board as a manufacturer or
19 a wholesaler, or both, as required by the Board.
20 (3) The dialysate or drugs are held, delivered, and dispensed in their original,
21 sealed packaging from the manufacturing facility.
22 (4) The dialysate or drugs are delivered only by the manufacturer or an agent of
23 the manufacturer and only upon receipt of a physician's order.
24 (5) The manufacturer or an agent of the manufacturer delivers the dialysate or
25 drugs directly to either or both of the following:
26 a. A patient with chronic kidney failure or a designee of the patient, for
27 self-administration of the dialysis therapy.
28 b. A health care provider, or health care facility licensed under Chapter
29 122C, 131D, or 131E of the General Statutes, for administration or
30 delivery of the dialysis therapy to a patient with chronic kidney
31 failure.

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

33 "**§ 90-85.22. Device and medical equipment ~~permits~~; exemptions.**

34 ...

35 (c) This section shall not apply to ~~either~~ any of the following:



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- 1 (1) A pharmaceutical manufacturer registered with the Food and Drug
2 Administration.
3 (2) A wholly owned subsidiary of a pharmaceutical manufacturer registered
4 with the Food and Drug Administration.
5 (3) The dispensing and delivery of home renal products in accordance with the
6 criteria specified in G.S. 90-85.21C."
7 **SECTION 3.** This act becomes effective October 1, 2015.