

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2005

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HOUSE BILL 1481

Short Title: Compounding Pharmacy Permits/Fees. (Public)

Sponsors: Representative Wilkins.

Referred to: Finance.

April 21, 2005

1 A BILL TO BE ENTITLED  
2 AN ACT REQUIRING PHARMACIES ENGAGING IN THE COMPOUNDING OF  
3 DRUG PRODUCTS TO OBTAIN A COMPOUNDING PHARMACY PERMIT  
4 AND AUTHORIZING THE NORTH CAROLINA BOARD OF PHARMACY TO  
5 IMPOSE A FEE FOR THE PERMIT UNDER THE LAWS REGULATING THE  
6 PRACTICE OF PHARMACY.

7 The General Assembly of North Carolina enacts:

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

10 **"§ 90-85.21C. Compounding pharmacy permit; exemptions.**

11 (a) In addition to registration pursuant to G.S. 90-85.21 or G.S. 90-85.21A, every  
12 pharmacy that engages in the compounding activities described in this subsection shall  
13 register annually with the Board on a form provided by the Board and obtain a  
14 compounding pharmacy permit. The Board shall be entitled to charge and collect a fee  
15 not to exceed five hundred dollars (\$500.00) for registration of a compounding  
16 pharmacy. This section shall apply to pharmacies that compound any of the following:

17 (1) Capsules, suppositories, or other dosage forms from bulk active  
18 ingredients supplied in commercial quantities from chemical  
19 distributors.

20 (2) Reconstitution or mixing of manufactured sterile components.

21 (3) Compounded products containing cytotoxic ingredients, hormones, or  
22 other hazardous ingredients.

23 (4) Sterile compounded products.

24 (b) This section shall not apply to the following:

25 (1) The reconstitution of antibiotic powders or granules.

26 (2) The making of simple non-sterile topical preparations from the mixing  
27 of commercially available products.

28 (3) The occasional assembly, pursuant to a prescription order, of active  
29 ingredients commonly available from wholesale prescription drug

1                    distributors licensed by the North Carolina Department of Agriculture  
2                    and Consumer Services.

3            (4)    Locations accredited by accrediting organizations approved by the  
4                    Board."

5            **SECTION 2.** G.S. 90-85.32 reads as rewritten:

6    "**§ 90-85.32. Rules pertaining to pharmacies, the compounding of drug products,**  
7                    **and the filling, refilling, transfer, and mail or common-carrier delivery of**  
8                    **prescription orders.**

9            (a)    Except as otherwise provided in this section, the Board may adopt rules  
10 ~~governing regulating pharmacies, the compounding of drug products, and the filling,~~  
11 refilling and transfer of prescription orders not inconsistent with other provisions of law  
12 regarding the distribution of drugs and devices. The rules shall assure the safe and  
13 secure distribution of drugs and devices. Prescriptions marked PRN shall not be refilled  
14 more than one year after the date issued by the prescriber unless otherwise specified.

15            (b)    Notwithstanding G.S. 90-85.6, the Board shall not adopt rules pertaining to  
16 the shipment, mailing, or other manner of delivery of dispensed legend drugs that are  
17 more restrictive than federal statutes or regulations governing the delivery of  
18 prescription medications by mail or common carrier."

19            **SECTION 3.** This act is effective when it becomes law.