

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2005

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HOUSE DRH50324-LUF-114 (04/13)

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

Sponsors: Representative Wilkins.

Referred to:

A BILL TO BE ENTITLED

AN ACT REQUIRING PHARMACIES ENGAGING IN THE COMPOUNDING OF
DRUG PRODUCTS TO OBTAIN A COMPOUNDING PHARMACY PERMIT
AND AUTHORIZING THE NORTH CAROLINA BOARD OF PHARMACY TO
IMPOSE A FEE FOR THE PERMIT UNDER THE LAWS REGULATING THE
PRACTICE OF PHARMACY.

The General Assembly of North Carolina enacts:

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

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

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

- (1) Capsules, suppositories, or other dosage forms from bulk active ingredients supplied in commercial quantities from chemical distributors.
- (2) Reconstitution or mixing of manufactured sterile components.
- (3) Compounded products containing cytotoxic ingredients, hormones, or other hazardous ingredients.
- (4) Sterile compounded products.

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

- (1) The reconstitution of antibiotic powders or granules.
- (2) The making of simple non-sterile topical preparations from the mixing of commercially available products.

1 (3) The occasional assembly, pursuant to a prescription order, of active
2 ingredients commonly available from wholesale prescription drug
3 distributors licensed by the North Carolina Department of Agriculture
4 and Consumer Services.

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

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

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

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

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

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