

NORTH CAROLINA GENERAL ASSEMBLY

LEGISLATIVE FISCAL NOTE

BILL NUMBER: Senate Bill 945 (Third Edition)

SHORT TITLE: Prescription Refill Safety Act

SPONSOR(S): Senators Rand, Ballantine, Cooper and Forrester

FISCAL IMPACT

Yes () No (x) No Estimate Available ()

FY 1997-98 FY 1998-99 FY 1999-00 FY 2000-01 FY 2001-02

EXPENDITURES

Negligible (See Assumptions and Methodology)

PRINCIPAL DEPARTMENT(S) &

PROGRAM(S) AFFECTED: Department of Human Resources, Department of Corrections, University of North Carolina Hospitals, East Carolina School of Medicine, University of North Carolina System Student Health Services, State Employees Health Plan, Department of Environment, Health, and Natural Resources, North Carolina Board of Pharmacy

EFFECTIVE DATE: July 1, 1997

BILL SUMMARY:

TO REQUIRE THE PRESCRIBER'S AND THE PATIENT'S CONSENT FOR INTERCHANGE OF A LIMITED CLASS OF DRUGS. Adds new GS 90-85.28(b1) providing that a prescription for a narrow therapeutic index drug (as defined in new GS 90-85.27(4a)) must be **refilled** with the same drug product by the same manufacturer unless the pharmacist notifies the prescriber before dispensing a different product *and* the prescriber and patient give written consent. ¹

Senate Committee Substitute Adopted April 22, 1997

Replaces 1st edition. Amends GS 90-85.27(4a) to require NC Board of Pharmacy to submit the list of narrow therapeutic index drugs to the codifier of rules in time for publication in January of each year in the NC Register. ²

House Committee Substitute, Adopted May 7, 1997

¹ *Daily Bulletin*, Institute of Government, UNC-Chapel Hill, Volume 1997, Number 46, April 17, 1997.

² *Daily Bulletin*, Institute of Government, UNC-Chapel Hill, Volume 1997, Number 48, April 22, 1997.

House committee substitute makes the following changes to 2nd edition. Revises GS 90-85.28(b1) by requiring that the prescriber and patient give documented consent (was, written consent) before a prescription for a narrow therapeutic index drug may be refilled with a different manufacturer's product.³

ASSUMPTIONS AND METHODOLOGY:

The fiscal impact of this legislation depends first on which drugs and how many will be designated as narrow therapeutic index drugs by the Secretary of Human Resources, as required by the bill. It is anticipated that this list will contain only a limited number of drugs which have a very narrow therapeutic range (i.e. a slight variance in dosage may cause serious problems for the patient or may result in an ineffective dose or treatment). In 1990 the U.S. Food and Drug Administration released the results of a study of 24 drugs considered to have a narrow therapeutic range. Earlier this year the State of Virginia passed legislation including a list of six drugs defined as having a narrow therapeutic index range.

It should be noted this bill applies to refills, not the initial prescription written by a physician, although the bill does define refill to "include a new prescription written at the expiration of a prescription which continues the patient's therapy on a narrow therapeutic index drug." Therefore, the bill will have no fiscal impact with respect to first time prescriptions, which pharmacists will continue to dispense in accordance with current practices. And since the bill applies only to refills for a limited number of drugs, and as a matter of practice, pharmacists typically refill prescriptions with the same product as previously dispensed, the overall fiscal impact of this bill is expected to be minimal.

Any fiscal impact on the state as a result of this act is expected to be in the following areas:

1. the administrative, operating and inventory costs for state supported pharmacies, including the costs of obtaining the required consent from both the prescribing physician and the patient prior to refilling a prescription with a brand other than the one previously dispensed;
2. the cost of narrow therapeutic index drugs for which the state reimburses.

This fiscal note evaluates the specific impact of Senate Bill 945 on several state agencies, including the Department of Human Resources, the Department of Environment, Health, and Natural Resources, the university system (UNC Hospitals, ECU Medical School, student health services), the Board of Pharmacy and the State Employees Health Plan. Most of these agencies indicate the fiscal impact, if any, will be negligible. The details of the potential impact for each agency are outlined below:

³ *Daily Bulletin*, Institute of Government, UNC-Chapel Hill, Volume 1997, Number 57, May 7, 1997

Department of Human Resources

According to the Department of Human Resources, it appears this bill will have little impact on the department's budget, for the following reasons:

1. The bill will have no impact on Medicaid expenditures because the state participates in an open formulary, in which virtually all manufacturers' brands are available. Currently 87% of all pharmaceutical reimbursements administered by the Division of Medical Assistance are for the manufactured name brand. Generic drugs are used infrequently because the state receives large volume discounts for name brands. In addition, physicians issue drug protocols "dispense as prescribed," and this directs the pharmacists to use a brand name, even if a generic equivalent is approved and available.
2. The impact on institutions in the Division of Mental Health, Developmental Disabilities and Substance Abuse Services is likely to be negligible since there are few narrow therapeutic index drugs, and the number of generic substitutes for these drugs is limited.
3. The Office of Rural Health believes the bill will have limited, if any, impact on the medical centers funded since only one or two fill prescriptions. The Office anticipates the bill requiring, at most, a few extra phone calls between the pharmacists and the providers.
4. Neither the Division of Services for the Blind, nor the Division of Services for the Deaf and Hard of Hearing purchase or provide reimbursement for drugs, therefore the bill has no impact on these divisions.

Department of Corrections

According to the Department of Correction (DOC), the bill will have no fiscal impact due to the following reasons:

1. "Narrow therapeutic index drugs" by their nature have a narrow range between risk and benefit. Inmates are less likely to be prescribed these drugs because of this narrow range. In current practice, only a small number of drugs that might be defined as having a narrow therapeutic index are prescribed for inmates.
2. DOC operates a Central Pharmacy and uses primarily non-generic drugs. These non-generic drugs are purchased through a national consortium at such low prices that most generic drugs cannot beat their prices. If inmates are given drugs from the "narrow" list, non-generic drugs would be purchased through the national consortium at a low price.
3. This bill applies to refills -- many inmates are not on prescribed medication when they enter the system -- in fact, many are receiving their first real physicals in years.

University of North Carolina Hospitals

Due to the limited number of drugs likely to be defined as narrow therapeutic index drugs, officials at UNC Hospitals believe the fiscal impact of this bill will be negligible. The agency estimates current expenses for such drugs to be approximately \$250,000 per year. Since the current standard of practice is such that pharmacists know which drugs present a narrow range and dispense the name brand accordingly to meet the patient's need, the bill will not result in a dramatic change to current practice.

In addition, officials at the School of Medicine believe the cost of implementing the requirements of this bill will be insignificant since the number of narrow therapeutic index drugs is small.

East Carolina University School of Medicine

According to officials at the ECU Medical School implementing the requirements of this bill will increase both administrative costs and pharmaceutical inventory costs. Pharmacists will spend additional time obtaining the appropriate authorization from physicians and patients prior to substituting a brand other than the one previously dispensed. Depending on which drugs are included on the list of narrow therapeutic drugs, the pharmacy may be required to expand its formulary to include additional brands at higher costs. However, because such costs are typically passed on to the patient, or if applicable, the patient's insurance company, the impact of any increase in costs on the General Fund is likely to be negligible.

University of North Carolina System Student Health Services

Narrow Therapeutic Index Drugs are not prescribed in high volumes through campus student health services. In the event any of these drugs are prescribed, staff time for handling the prescription and obtaining appropriate written permission prior to substituting another brand is expected to increase. However, the impact on operating costs is anticipated to be negligible due to the limited number of cases expected to involve narrow therapeutic index drugs, and the fact that students pay for drugs to cover overhead and operating costs of the pharmacy.

State Employees Health Plan

The bill does not affect the State Employee Health Plan's indemnity program upon which appropriations are based. The bill may affect the managed pharmacy benefits of the Plan's twelve Health Maintenance Organizations (HMOs), but any increased HMO costs will be paid by participating employees, not the State.

Department of Environment, Health, and Natural Resources

The Department of Environment, Health, and Natural Resources provides reimbursement for pharmaceuticals through its purchase of care program administered by the Division of Health Promotion. For the 1995-96 fiscal year, the department paid 1,740 claims for drugs which might be considered narrow therapeutic index drugs totaling \$24,208 for 801 patients. These claims include both manufacturers' name brands and generic substitutes. Due to the limited number of reimbursements made by the department for narrow therapeutic index drugs the bill is not expected to have a significant impact on purchase of care expenditures.

NC Board of Pharmacy

It is the opinion of the Board of Pharmacy that the legislation would have little additional dollar expense associated with its implementation. There is the possibility of pharmacists not being able to take advantage of lower prices of some generic drugs, but this statement must be modified by the difficulty in ascertaining the exact price of any generic drug, particularly when used by large organizations.

TECHNICAL CONSIDERATIONS: none

FISCAL RESEARCH DIVISION

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