Department of Legislative Services

Maryland General Assembly

FISCAL NOTE
Revised

Senate Bill 137 (Senator Bromwell. *et al.*)
Finance

Health Insurance - Medical Clinical Trials - Coverage

This bill requires insurers, nonprofit health service plans, and HMOs (carriers) to provide coverage for patient costs incurred as a result of treatment provided in a clinical trial for: (1) a life-threatening condition; or (2) prevention, early detection, and treatment studies on cancer. The coverage must be provided if: (1) the treatment is for all four phases of clinical trial for cancer, or the treatment is for Phases II, III, or IV clinical trials for other life-threatening conditions; and (2) the treatment meets other specified criteria. In conjunction with the above-mentioned coverage, a carrier must provide coverage for costs incurred by patients for FDA-approved drugs and devices, whether or not the FDA has approved the drug or device for treating the enrollee's particular condition.

The bill also directs the Insurance Commissioner to create an 11-member Workgroup on Insurance Coverage for Patient Care Cost in Clinical Trials to assess the costs and benefits of providing such a coverage.

The bill takes effect January 1, 1999 and applies to all policies issued on or after January 1, 1999. Any policy in effect before January 1, 1999 must comply with the bill's requirements by January 1, 2000.

Fiscal Summary

State Effect: General fund expenditures could increase by $67,200 in FY 1999, $83,400 in FY 2000 and possibly $86,300 in FY 2001. If the State chooses to include the bill's mandated benefit as part of the State Employee Health Benefit Plan, expenditures for the State health plan could increase by an indeterminate amount. Indeterminate minimal increase in general fund revenues.

(in dollars)	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003
GF Revenues	---	---	---	---	---

GF Expenditures	$67,200	$83,400	$86,300	---	---
Net Effect	($67,200)	($83,400)	($86,300)	---	---

Note: ( ) - decrease; GF - general funds; FF - federal funds; SF - special funds

Local Effect: Expenditures for local jurisdiction employee health benefits could increase by an indeterminate amount depending upon the current type of health care coverage offered and number of enrollees. Revenues would not be affected.

Small Business Effect: Potential minimal. To the extent that costs for carriers increase and carriers raise premiums, health insurance costs for small businesses/self-employed persons could increase.

Fiscal Analysis

Bill Summary: The coverage for drugs and/or devices applies only to the extent that they are not paid for by the manufacturer, distributor, or provider.

By June 1 each year, each carrier affected by the bill must report to the Insurance Commissioner on the clinical trials covered during the previous year. The Insurance Commissioner must compile an annual summary report of the information received from carriers and report to the Senate Finance Committee and the House Environmental Matters Committee.

The workgroup must: (1) develop a methodology for assessing the economic and clinical impact of the coverage; (2) request and collect clinical and financial data on patient treatment from health care providers and payers in order to assess the differences in patient care costs and clinical outcomes between patients treated in clinical trials and patients treated outside clinical trials; and (3) review any other necessary issues in order to make recommendations regarding the coverage for patient care costs in clinical trials. The workgroup must present a preliminary report of its findings to the Senate Finance Committee, the House Environmental Matters Committee, and the General Assembly by July 1, 2000. If the workgroup requests an additional year to complete its report, the final report must be presented by July 1, 2001. This provision takes effect July 1, 1998.

State Revenues: Medical care costs for some health plans subject to State mandates could increase as a result of this bill. The extent of the increase, however, cannot be reliably estimated because the following data are unavailable at this time: (1) the number of clinical trials currently being conducted; (2) the patient costs associated with clinical trials; (3) the number of health plans that currently cover patient costs incurred as a result of treatment provided in a clinical trial; and (4) the additional costs of prescription coverage for drugs or

devices that previously were not covered because they were not approved by the FDA for treating the enrollee's particular condition. In any event, the increase in medical care costs would cause the affected health plans to raise premiums, meaning that general fund revenues could increase by an indeterminate minimal amount as a result of the State's 2% insurance premium tax on increased premiums. The State's premium tax is only applicable to "for-profit" insurance carriers. In addition, general fund revenues could increase by an indeterminate minimal amount in fiscal 1999 if insurance companies have to file new rates and/or forms as a result of the bill's requirements and pay a $100 rate and/or form filing fee.

State Expenditures: General fund expenditures for the Insurance Administration could increase by approximately $67,159 in fiscal 1999, which reflects a 90-day start-up delay, and $83,386 in fiscal 2000. Depending on whether the workgroup would need an additional year to complete its report, general fund expenditures could increase by $86,341 in fiscal 2001. The estimate reflects the cost of contractual services for the Insurance Administration to provide technical support to the workgroup. It accounts for one Health Economist and one Administrative Assistant.

Compiling an annual summary report of the clinical trials covered by health carriers could be handled with existing resources.

Currently, the State Employee Health Benefit Plan does not provide coverage for any services that are "experimental" or "investigative" in nature, including services provided through clinical trials. Although the State is self-insured and not required to cover mandated health benefits, in the past the State Employee Health Benefit Plan has often included coverage for mandated health benefits. Therefore, if the State chooses to include the bill's mandated benefit, medical care costs to the State Employee Health Benefit Plan could increase. The extent of the increase, however, cannot be reliably estimated because of insufficient data.

As a result of this bill, future Medicaid capitation rates to managed care organizations (MCOs) could increase to accommodate the increased costs incurred by those MCOs that are also HMOs. Any increase, however, is expected to be minimal.

Information Source(s): Insurance Administration; Department of Health and Mental Hygiene (Medical Care Policy Administration, Community and Public Health Administration, Health Care Access and Cost Commission); Department of Budget and Management; Department of Legislative Services

Fiscal Note History: First Reader - February 4, 1998
lnc Revised - Senate Third Reader - March 25, 1998

Analysis by: Lina Walker
Reviewed by: John Rixey

Direct Inquiries to:
John Rixey, Coordinating Analyst
(410) 841-3710
(301) 858-3710