

**LEGISLATIVE SERVICES AGENCY
OFFICE OF FISCAL AND MANAGEMENT ANALYSIS**

301 State House
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FISCAL IMPACT STATEMENT

LS 7018
BILL NUMBER: SB 396

DATE PREPARED: Jan 6, 1999
BILL AMENDED:

SUBJECT: Insurance Coverage for Costs Associated with Clinical Trials.

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FUNDS AFFECTED: **GENERAL**
DEDICATED
FEDERAL

IMPACT: State & Local

Summary of Legislation: This bill defines "associated treatment cost" for purposes of payment for medically necessary treatment and drugs and devices associated with clinical trial treatments. The bill requires group health benefit plans for public employees, individual and group accident and sickness insurance policies, and individual and group health maintenance organization (HMO) contracts to provide coverage for associated treatment cost. The bill prohibits dollar limits, deductibles, copayments, or coinsurance requirements on coverage of associated treatment cost that are less favorable than those for physical illness generally. It also requires health benefit plan administrators, insurers, and HMOs to submit annual reports to the Commissioner of the Department of Insurance describing clinical trials for which associated treatment cost was covered. The bill also requires the Insurance Commissioner to compile information gathered and make an annual report available to the public.

The Work Group on Health Care Coverage for Associated Treatment Cost is established to study and make recommendations regarding costs and benefits of the coverage required under this act.

Effective Date: July 1, 1999.

Explanation of State Expenditures: At the state level, this bill impacts the Department of Insurance and, potentially, the costs to the state in providing health benefits to state employees.

Impact on Department of Insurance: The bill establishes the Work Group on Health Care Coverage for Associated Treatment Cost for the purposes of assessing the costs and benefits of health care coverage for medically necessary treatment associated with clinical trials. The 9-member Work Group is to: (1) develop a methodology for assessing the economic and clinical impact of this type of health care coverage; (2) collect from health care providers and payers aggregate clinical and financial data on insured treatments to assess differences in associated treatment costs and clinical outcomes; and (3) make recommendations to the Insurance Commissioner pertaining to coverage for associated treatment costs. The Work Group is to be

appointed before January 1, 2000, and will be in existence until the Work Group submits its final report to the Legislative Council on or before June 30, 2003.

Maryland passed similar legislation in 1998 and is in the early planning stages of their effort. The fiscal analysis for the Maryland bill estimated that the requirements of the bill could be met by a medical economist and an administrative assistant at a cost of about \$85,000 per year. This type of study could also be contracted out to universities or consulting firms, with the final costs being more or less depending upon the specific requirements of the contract.

A \$35 per diem plus travel expenses is to be paid to the 7 Work Group members who would not be state employees. This would amount to at least \$245 per meeting for per diems if all attended. The Work Group will be staffed and administered through the Department of Insurance.

Impact on State Employee Health Care Costs: This bill also mandates insurance coverage for the costs of medically necessary treatment associated with clinical trials. This could potentially add costs to the health plans providing health care benefits to state employees. Two of the eight state employee health plans responded to our request for their evaluation of the impact on their health plans. One responded that there would be no cost impact to their plan and another estimates increased costs in the amount of 1% of premiums. Increased costs may be reflected in increased premiums and enrollment fees. Increased premiums and fees, however, may or may not result in additional costs to the state, depending upon administrative action as to the determination of the employer/employee cost share for health plan benefits.

Explanation of State Revenues:

Explanation of Local Expenditures: Similar to the state, increased premiums and enrollment fees arising from the mandated coverage of medically necessary treatment associated with clinical trials, may or may not result in additional costs to local governments and school corporations, depending upon specific plan types and administrative action as to the determination of the employer/employee cost share for health plan benefits offered to employees.

Explanation of Local Revenues:

State Agencies Affected: All; Department of Insurance

Local Agencies Affected: Local Governments and School Corporations

Information Sources: Keith Beesley, Indiana Department of Personnel, 232-3062.
Liz Carroll, Indiana Department of Insurance, 232-2406.
Kathleen Loughran, Maryland Department of Insurance, (410) 468-2014.