

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

301 State House
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FISCAL IMPACT STATEMENT

LS 6094

BILL NUMBER: SB 10

DATE PREPARED: Apr 8, 1999

BILL AMENDED: Apr 7, 1999

SUBJECT: Generic Drug Substitutions.

FISCAL ANALYST: Alan Gossard

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FUNDS AFFECTED: X GENERAL
DEDICATED
X FEDERAL

IMPACT: State

Summary of Legislation: (Amended) This bill requires the Medicaid program to provide coverage for certain single source legend drugs that are recommended by the Drug Utilization Review (DUR) Board. The bill modifies the conditions for the DUR Board to place a single source drug on prior approval, restrict the drug's use, or establish a drug monitoring program.

Except as provided by other laws, the bill requires a legend drug to be dispensed with the drug product specified on the prescription or drug order or by authorization of the practitioner. The bill also specifies that a "generically equivalent drug product" means a multiple source drug product containing identical active ingredients. It prohibits dispensing a legend drug except as provided in the Legend Drug Act. It also requires that only generically equivalent drug products may be substituted under the Generic Drugs Law.

This bill also adds advanced practice nurses to the definition of "practitioner" in the Generic Drugs Law. It also requires the pharmacist to inform the customer when a generic substitution is made. This bill also repeals the definition of "chemically equivalent drug products". (The introduced version of this bill was drafted by the Interim Study Committee on Health Issues.)

Effective Date: (Amended) Upon Passage; July 1, 1999.

Explanation of State Expenditures: (Revised) This bill requires that the Medicaid program and the program's agents, contractors, and vendors provide coverage and reimbursement for outpatient single source legend drugs in compliance with existing federal law and the state's Drug Utilization Review (DUR) statute (IC 12-15-35). The bill also modifies the conditions for the DUR Board to place a single source drug on prior approval, restrict the drug's use, or establish a drug monitoring program. Current statute prevents the DUR Board from considering anything other than medical reasons when placing an outpatient single source drug on prior approval or in restricting a drug's use. This bill would allow the consideration of health, economic, and cost data. Consequently, this bill would allow the DUR Board to make decisions that may result in lower costs to the Medicaid program than would be allowed under the current DUR statute.

Depending upon future decisions by the DUR Board and due to the current practice of the Medicaid managed care program, any additional costs to the state for drugs provided through a Medicaid managed care organization are attributable to compliance with the state DUR statute, federal statutes, and regulations and **not** to the provisions of this bill. [Note: This conclusion is due to state and federal provisions that only the DUR Board may establish a Medicaid outpatient drug formulary (rather than the unilateral establishment of a formulary by a managed care organization). According to the Health Care Financing Administration, a specific exemption allowed Medicaid managed care organizations under the federal drug rebate statute (42 USC 1396r-8(j)) applies only to rebates and not to the establishment of drug formularies. Consequently, a Medicaid managed care organization may not establish or use a drug formulary unless the formulary is approved by the state DUR Board (as required by existing state and federal statutes).]

Explanation of State Revenues: (Revised) See Explanation of State Expenditures, above, regarding costs in the Medicaid Program, a program cost-shared with the federal government.

Explanation of Local Expenditures:

Explanation of Local Revenues:

State Agencies Affected: Office of Medicaid Policy and Planning

Local Agencies Affected:

Information Sources: Larry Reed, Health Care Financing Administration, (410) 786-3325.