

Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

SFA**BILL ANALYSIS**

Telephone: (517) 373-5383
Fax: (517) 373-1986
TDD: (517) 373-0543

Senate Bills 1241 and 1242 (as introduced 4-23-02)
Sponsor: Senator John J. H. Schwarz, M.D.
Committee: Health Policy

Date Completed: 5-7-02

CONTENT

Senate Bill 1241 would amend the Insurance Code, and **Senate Bill 1242** would amend the Nonprofit Health Care Corporation Reform Act, to provide that certain health insurance plans would have to provide coverage for an off-label use of a drug approved by the Federal Food and Drug Administration (FDA) and the reasonable cost of the drug's administration. Under the bills, "off-label" would mean the use of a drug for clinical indications other than those stated in the labeling approved by the FDA.

Senate Bill 1241 would apply to an expense-incurred hospital, medical, or surgical policy or certificate that provided pharmaceutical coverage, and to a health maintenance organization (HMO) contract. Senate Bill 1242 would apply to a Blue Cross and Blue Shield of Michigan (BCBSM) group or nongroup certificate that provided pharmaceutical coverage.

The bills specify that coverage for an off-label use of a drug would apply if all of the following conditions were met:

- The drug was approved by the FDA.
- The drug was prescribed by a licensed health care professional (or a licensed participating or affiliated health care professional), for the treatment of a "life-threatening condition"; or for the treatment of a "chronic and seriously debilitating condition", as long as the drug was medically necessary to treat that debilitating condition and was on the plan formulary or accessible through the health plan's formulary procedures.
- The drug had been recognized for treatment of the condition for which it was prescribed by the American Medical Association drug evaluations; the American Hospital Formulary Service drug information; the U.S. Pharmacopoeia Dispensing Information, Volume 1, "Drug Information For The Health Care Professional"; or two articles from major peer-reviewed medical journals that presented data supporting the proposed off-label use or uses as generally safe and effective, unless there was clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

Upon request, a prescribing health care professional would have to supply to an insurer, an HMO, or BCBSM, documentation supporting compliance with these conditions.

(Under the bills, "life-threatening" would mean a disease or condition where the likelihood of death was high unless the course of the disease was interrupted, or that had a potentially fatal outcome where the end point of clinical intervention was survival. "Chronic and seriously debilitating" would mean a disease or condition that required ongoing treatment to maintain remission or prevent deterioration and that caused significant long-term morbidity.)

Each bill states that it would not prohibit the use of a co-payment or similar mechanism for appropriately controlling the utilization of a drug that was prescribed for a use different from the use for which the drug had been approved by the FDA.

Proposed MCL 500.3406q (S.B. 1241)
Proposed MCL 550.1416c (S.B. 1242)

Legislative Analyst: George Towne

FISCAL IMPACT

Fiscal information is not available at this time.

Fiscal Analyst: John Walker