House
Legislative
Analysis
Section

House Office Building, 9 South
Lansing, Michigan 48909
Phone: 517/373-6466

OFF-LABEL DRUGS

Senate Bills 1241 and 1242 as passed by the Senate
Sponsor: Sen. John J. H. Schwarz, M.D.

House Committee: Insurance and Financial Services
Senate Commitee: Health Policy

Complete to 6-5-02

A SUMMARY OF SENATE BILLS 1241 AND 1242 AS PASSED BY THE SENATE

Senate Bill 1241 would amend the Insurance Code (500.3406q), and Senate Bill 1242 would amend the Nonprofit Health Care Corporation Reform Act (555.1416c), to require certain health insurance plans 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 supplies medically necessary to administer the drug. "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.

Coverage for an off-label use of an FDA-approved drug would apply if both of the following conditions were met:

- The drug was prescribed by an allopathic or osteopathic physician for the treatment of a "life-threatening condition" or a "chronic and seriously debilitating condition", as long as the drug was medically necessary to treat that life-threatening or debilitating condition and was on the plan formulary or accessible through the health plan's formulary procedures. "Life-threatening condition" would be defined in the bills as a disease or condition where the likelihood of death is high unless the course of the disease is interrupted or that has a potentially fatal outcome where the end point of clinical intervention is survival. The bills would define "chronic and seriously debilitating" as a disease or condition that requires ongoing treatment to maintain remission or prevent deterioration and that causes significant long-term morbidity.

- 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 allopathic or osteopathic physician would have to supply to an insurer, an HMO, or BCBSM, documentation supporting compliance with these conditions. Each bill states that it would not prohibit the use of a co-payment, deductible, sanction, or a 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, including prior approval or a drug utilization review program. Any copayment, deductible, sanction, prior approval, review program, or mechanism could not be more restrictive than for prescription coverage generally.

Analyst: S. Stutzky