House
Legislative
Analysis
Section

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# OFF-LABEL DRUGS

**Senate Bills 1241 and 1242 as passed by the Senate**
**First Analysis (6-13-02)**

**Sponsor: Sen. John J. H. Schwarz, M.D.**
**House Committee: Insurance and Financial Services**
**Senate Committee: Health Policy**

## *THE APPARENT PROBLEM:*

When the federal Food and Drug Agency (FDA) approves a new drug, it also specifies what diseases or conditions the drug is approved to treat; this information is listed on the drug's label. Quite often, however, ongoing research reveals that a drug indicated for use for a particular disease or condition can also be beneficial in treating a different disease or condition. When a drug is used to treat a disease or condition other than what is listed in the drug's label, it is referred to as an "off-label use." Though it is legal for a physician to prescribe an FDA-approved drug for an off-label use, an insurance company may not pay for the drug when used for off-label purposes.

In 1989, legislation was enacted to require Blue Cross Blue Shield of Michigan, health maintenance organizations, and commercial insurance companies to pay for, if certain conditions were met, the use of an FDA-approved drug used in antineoplastic therapy regardless of whether the malignancy being treated was the specific type of neoplasm for which the drug had received federal approval. Legislation is now being offered to expand this provision to cover other medically recognized off-label uses for drugs.

## *THE CONTENT OF THE BILLS:*

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. ("Morbidity" refers to the frequency of illness, sickness, and diseases contracted by a person or a group.)

- 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.

## *BACKGROUND INFORMATION:*

Reportedly, 39 states, including Michigan, have passed legislation or issued regulations that require health care insurers to provide coverage for off-label drug uses for a variety of situations. Public Acts 57, 58, and 59 of 1989 amended the Blue Cross Blue Shield of Michigan act, the Public Health Code (HMOs), and the Insurance Code (commercial insurers), respectively, to require coverage, if certain conditions were met, for a federally-approved drug used in antineoplastic therapy and for the reasonable cost of its administration regardless of whether the specific neoplasm (cancer) for which the drug was being used was the specific neoplasm for which the drug had received federal approval. This legislative package also required insurers to offer or include coverage for breast cancer diagnostic services (including mammography screening), breast cancer outpatient treatment services, and breast cancer rehabilitative services in their group and individual health insurance coverages.

## *FISCAL IMPLICATIONS:*

Fiscal information is not available.

## *ARGUMENTS:*

### *For:*

In 1989, Public Acts 57, 58, and 59 amended various acts to require insurers to cover antineoplastic cancer-fighting drugs even if used for a different type of malignancy than what was listed on the FDA-approved label. The 1989 legislation recognized that medical research and technological advances can discover new treatments faster than the time period needed for the FDA to approve a new label and for the drug companies to print the revised literature. The bills would expand this provision to cover other drugs when used to treat diseases and conditions other than what they were initially approved to treat. The benefits to individuals, families, and to society are easy to see.

Currently, a health plan can refuse to pay for the use of drug simply because it is used for an off-label purpose, even when the off-label usage is medically recognized and approved by medical organizations, researchers, and the pharmacy industry. This can pose a hardship to the individual who is faced with dealing with a life-threatening or disabling condition and now must find a way to pay for his or her drug therapy. Yet, having greater access to life-saving or life-improving drugs can significantly improve outcomes, which may, in some cases, actually reduce the overall treatment costs. The majority of states require coverage for off-label drug uses to some extent. Senate Bills 1241 and 1242 are modeled after a California law. The bills would require insurers to cover off-label uses; however, the bills do establish criteria that must be met first such as restricting coverage to drugs prescribed by M.D.s and D.O.s only, and then only for life-threatening or chronic and seriously debilitating conditions.

### *Against:*

Besides requiring insurers to pay for off-label drug uses, insurers would also have to pay for the reasonable cost of supplies medically necessary to administer the drug. This means that a health care insurer might be required to pay for a procedure or for supplies not otherwise covered under a person's health plan. This provision could significantly increase costs, which ultimately would be passed on to consumers in the form of higher premiums. As premiums increase, individuals and employers may not be able to afford the higher premiums. Since prescription drug benefits are optional, the decisions as to which drugs and for what uses coverage would apply should be left up to the health insurer and the purchaser of the coverage.

### *Response:*

The Senate-passed versions are narrower than the bills as first introduced. Amendments adopted on the Senate floor would require that the drug under consideration be medically necessary to treat the condition and that the drug be on the health plan formulary or be accessible through the plan's formulary procedures. The amended bills would also

allow for a copayment, deductible, or sanction to be applied, as well as a mechanism for appropriately controlling the utilization of a drug for off-label purposes. These amendments should further narrow the cases in which the bills would apply, as would provisions restricting coverage to life-threatening and chronic and seriously debilitating conditions, requiring the use to be medically recognized by various organizations and research, and requiring a physician to supply documentation (upon request) to the insurer that the conditions and restrictions in the bills were adhered to. Further, it should be remembered that the bills only apply to those health plans that offer a pharmacy benefit. If prescription drugs were not ordinarily covered, the bills would not apply. Besides, in the case of chronic conditions that carry a higher risk of developing other medical conditions (for example, multiple sclerosis and diabetes can affect the kidneys, which in turn affect the heart, and also impair circulation leading to a higher incidence of amputations), a newly discovered use of a drug for an off-label purpose may reduce the possibility of more serious and costly complications, thus saving money overall.

## *POSITIONS:*

The Office of Financial and Insurance Services is not opposed to the bills. (6-5-02)

Analyst: S. Stutzky

■This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.