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 enrolled) **PUBLIC ACTS 538 & 539 of 2002**
Sponsor: Senator John J. H. Schwarz, M.D.
Senate Committee: Health Policy
House Committee: Insurance and Financial Services

Date Completed: 1-15-03

CONTENT

Senate Bill 1241 amends the Insurance Code, and Senate Bill 1242 amends the Nonprofit Health Care Corporation Reform Act, 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" means the use of a drug for clinical indications other than those stated in the labeling approved by the FDA. The bills will take effect January 22, 2003.

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

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

-- The drug is 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 is medically necessary to treat the condition and is on the plan formulary or accessible through the health plan's formulary procedures. Under the bills, a "life threatening" condition is 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. A "chronic and seriously debilitating" condition is a disease or condition that requires ongoing treatment to maintain remission or prevent deterioration and that causes significant long-term morbidity.

-- The drug has been recognized for treatment of the condition for which it is 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 present data supporting the proposed off-label use or uses as generally safe and effective, unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

Upon request, the prescribing physician will have to supply to an insurer, an HMO, or BCBSM, documentation supporting compliance with these conditions.

Each bill states that it does not prohibit the use of a copayment, deductible, sanction, or a mechanism for appropriately controlling the utilization of a drug that is prescribed for a use different from the use for which the drug has been approved by the FDA, including prior approval or a drug utilization review program. Any copayment, deductible, sanction, prior approval, review program, or mechanism may not be more restrictive than for prescription coverage generally.

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

Legislative Analyst: George Towne

FISCAL IMPACT

The bills' fiscal impact will depend, in large part, on whether the activity contemplated by the bills is significantly different from that which is already occurring or will occur, in regard to the use and payment for the off-label use of drugs and the magnitude of those events.

Two things should be noted here. First, there is no existing prohibition against physicians' engaging in off-label prescribing. The only real risk they run is in the area of liability, if a doctor prescribes a drug off-label and an untoward event occurs. The second is that until the late '90s, a drug manufacturer could not advertise, to the prescribing community, an FDA-approved drug for its potential off-label uses. More recent court cases and legislation have significantly reduced that prohibition.

An additional consideration is that, historically, third party payers, including Medicare and Medicaid, have not provided for reimbursement of investigational or experimental procedures (including drug use) except under explicitly defined circumstances. One of the key factors in terms of potential costs is the extent to which the bills conflict with this practice.

The issue addressed in these bills is the off-label use of and payment for drugs in situations in which it is believed that it is medically necessary to avert death or to alleviate, control, etc. chronic and seriously debilitating disorders. It is probable that the off-label use of drugs will be considered to be investigational or experimental and might be very costly in these types of circumstances. Also, even though the bills require other external documentation (drug compendia, publication in peer reviewed literature, etc.) supporting the off-label use of drugs, a third party payer still may consider the drugs to be investigational or experimental.

Therefore, the potential fiscal impact depends on how many drugs are currently in use or will be used under circumstances in which third party reimbursement is not readily available but will be required with the passage of these bills. It is unlikely that this information can be determined. There are literally thousands of clinical trials being run across the country on drugs for everything ranging from acne to tardive dyskinesia. While many of these will not meet the bills' criteria, it is possible that many of them will.

The bottom line is that these bills will increase costs to third party payers, including those covering State employees, and everyone who directly or indirectly pays health insurance premiums. (Third party payers do not include Medicaid, which is not a covered entity under the bills.)

On another note, the bills do not mandate coverage if the drugs are not on a given plan formulary or not made available through the plan's formulary appeals process. The appeals process may determine how extensive coverage for these drugs will be in the long run. Finally, this analysis does not include the potential cost impact related to the coverage for reasonable "delivery" costs of these drugs. Anecdotal claims indicate that some of these delivery mechanisms, e.g., infusion-like devices, may be expensive, but definitive examples are not available at this time.

Fiscal Analyst: John Walker

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