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SFA BILL ANALYSIS

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Senate Bills 1241 and 1242 (Substitutes S-1 as reported)
Sponsor: Senator John J. H. Schwarz, M.D.
Committee: Health Policy

CONTENT

Senate Bill 1241 (S-1) would amend the Insurance Code, and Senate Bill 1242 (S-1) would amend 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" would mean the use of a drug for clinical indications other than those stated in the labeling approved by the FDA.

Senate Bill 1241 (S-1) 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 (S-1) 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 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 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 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, prior approval, review program, or mechanism could not be more restrictive than for prescription coverage generally.

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

Legislative Analyst: George Towne

FISCAL IMPACT

The bills' fiscal impact would 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 content of these bills conflicts with this fact.

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 would be considered to be investigational or experimental and could be very costly in these types of circumstances. Also, even though the bills would require other external documentation (drug compendia, publication in peer reviewed literature, etc.) supporting the off-label use of drugs, a third party payer still could 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 would 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 would not meet the bills' criteria, it is possible that many of them would.

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

On another note, the bills would not mandate coverage if the drugs were not on a given plan formulary or could not be made available through the plan's formulary appeals process. The appeals process could determine how extensive coverage for these drugs would 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 would indicate that some of these delivery mechanisms, e.g., infusion-like devices, could be expensive, but definitive examples are not available at this time.

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