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Senate Bill 502 (Substitute S-2 as reported)
Sponsor: Senator Jim Marleau
Committee: Health Policy

Date Completed: 12-17-15

RATIONALE

Michigan law prohibits kickbacks and bribes related to the furnishing of health care goods or services paid for wholly or partly by a health insurer, but allows pharmaceutical manufacturers to provide rebates and discounts to consumers without running afoul of the prohibition. In recent years, medical advances have led to the development of a number of drugs that require users to be monitored for an extended time period after taking the first dose, to ensure that they do not experience potentially serious side effects. For example, a promising new medication to treat multiple sclerosis may cause a patient's heart rate to drop. Thus, as a condition of approving the drug, the U.S. Food and Drug Administration requires first-time users to undergo six hours of observation by medical staff. Reportedly, these services can be expensive, and may present a substantial cost burden to consumers depending on their insurance coverage. Pharmaceutical manufacturers, however, cannot offer discounts or rebates to defray the cost through existing patient assistance programs because the statutory exemption from the kickback prohibition applies only to the drug itself. Therefore, it has been suggested that the exemption be extended to the necessary services connected with the use of a drug.

CONTENT

The bill would amend the Health Care False Claim Act to revise an exemption to a prohibition against kickbacks, bribes, and rebates for furnishing health care goods, services, and benefits.

Under Section 4 of the Act, it is a felony to solicit, offer, pay, or receive a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made wholly or partly by a health care corporation or health care insurer, or to receive a rebate of a fee or charge for referring an individual to another person for the furnishing of health care benefits. The felony is punishable by imprisonment for up to four years and/or a maximum fine of \$50,000.

The Act provides that a rebate or discount from a drug manufacturer or a company that licenses or distributes a manufacturer's drugs to a consumer for that consumer's use of the drug does not violate Section 4. Under the bill, this exception would apply to a rebate or discount to a consumer or other person on the consumer's behalf for the consumer's use of the drug, or a similar monetary payment from the drug manufacturer or company to the consumer or other person on the consumer's behalf for health care items or services related to that use.

The bill specifies that "other person on the consumer's behalf" would not include a prescriber or a person with a financial relationship to the prescriber. "Prescriber" would mean that term as it is defined in the Public Health Code, i.e., a licensed dentist; doctor of medicine, osteopathic medicine and surgery, or podiatric medicine and surgery; optometrist certified to administer and prescribe therapeutic pharmaceutical agents; veterinarian; or other health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor.

The bill would take effect 90 days after it was enacted.

MCL 752.1004a

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Advances in pharmaceutical efficacy have improved treatment of serious diseases and conditions such as multiple sclerosis, cancer, and autoimmune disorders. These advances often are accompanied by increased drug complexity, and users of some newly developed drugs must be monitored for serious adverse side effects. Extensive observation by the appropriate specialists can be very expensive and the costs can be onerous to patients. Even if insurance covers such services, some insurance plans have high out-of-pocket maximums totaling thousands of dollars per year. As drug complexity increases and requirements for observation and other services become more common, the consumer cost burden increasingly could prevent access to promising treatments. By extending the kickback exemption to the health care services needed in conjunction with prescription drug use, the bill would facilitate access to all available drug options and reduce out-of-pocket costs for consumers.

Response: Reportedly, many insurance plans already cover observation or other services associated with the use of prescription drugs, so the necessity of this legislation is questionable. Additionally, there is some uncertainty as to whether the Health Care False Claims Act is the appropriate law to amend. Evidently, none of the states that already have adopted this type of legislation did so through their false claim statutes. The proposed use of this particular avenue for expanding the scope of pharmaceutical assistance programs has raised concerns that consumers could be steered toward a specific drug.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bill would have no fiscal impact on State or local government.

Fiscal Analyst: Ryan Bergen

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.