

Legislative Analysis



REBATE FOR MULTIPLE SCLEROSIS TREATMENT NOT PROHIBITED

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Senate Bill 502 (S-3) as reported from House committee
Sponsor: Sen. Jim Marleau
House Committee: Health Policy
Senate Committee: Health Policy
Complete to 3-16-16

Analysis available at
<http://www.legislature.mi.gov>

(Enacted as Public Act 80 of 2016)

BRIEF SUMMARY: The Health Care False Claim Act contains exceptions to the general prohibition against kickbacks, bribes, and rebates for furnishing health care goods, services, and benefits. Senate Bill 502 would amend the act to include among those exceptions a payment from a drug manufacturer for a health care service associated with the use of a multiple sclerosis drug ("qualified drug" in the bill). The bill would take effect 90 days after enactment.

FISCAL IMPACT: This bill would have no fiscal impact on state or local government.

THE APPARENT PROBLEM:

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.

THE CONTENT OF THE BILL:

Section 4 of the Health Care False Claims Act states that it is a felony to solicit, offer, pay, or receive a kickback or bribe in connection to provision of health services, or receive a rebate in return for referring one person to another for the furnishing of health care benefits. Certain rebates, discounts, and monetary payments are exempted from the prohibition, and Senate Bill 502 would add a category to the list of exceptions.

Specifically, Section 4 states:

A person who solicits, offers, pays, or receives a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part by a health care corporation or health care insurer, or who receives a rebate of a fee or charge for referring an individual to another person for the furnishing of health care benefits, is guilty of a felony, punishable by imprisonment for not more than four years, or by a fine of not more than \$50,000.00, or both.

Senate Bill 502 provides that the prohibition does not apply to a monetary payment from a drug manufacturer to a consumer, the consumer's health professional, or a vendor that has a contract with the drug manufacturer, for a health care service required or recommended in conjunction with use of the multiple sclerosis drug. The bill also lists the applicable services that may be recommended or required along with the multiple sclerosis drugs.

"Qualified drug" refers to a drug that has a U.S. Food and Drug Administration-approved indication to serve multiple sclerosis. *"Consumer's health professional"* refers to a health professional who did not prescribe the qualified drug or who did not have a financial relationship to the health professional who prescribed it.

MCL 752.1004a

HOUSE COMMITTEE ACTION:

The members of the House Health Policy committee reported out the Senate-passed version of Senate Bill 502 without amendment.

BACKGROUND INFORMATION:

This bill would specifically address the services the multiple sclerosis drug Gilenya requires in conjunction with its use. The Food and Drug Administration requires an observation period of six hours after administration of Gilenya, to monitor for brachycardia or other cardiac abnormalities. Reportedly, this is the only drug to require this observation and testing, and 46 other states have already provided this exception to kickback statutes.

POSITIONS:

- The Michigan Association of Health Plans support this bill. (3-8-16)
- The National Multiple Sclerosis Society-Michigan Chapter supports the bill. (3-8-16)
- A representative of Novartis (the drug manufacturer) testified in support. (3-8-16)

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