



**Senate Fiscal Agency**  
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BILL



ANALYSIS

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Senate Bill 502 (as enacted)  
Sponsor: Senator Jim Marleau  
Senate Committee: Health Policy  
House Committee: Health Policy

**PUBLIC ACT 80 of 2016**

Date Completed: 2-13-17

**RATIONALE**

Michigan law prohibits kickbacks and bribes related to the provision of health care goods or services paid for by a health insurer, but allows pharmaceutical manufacturers to provide rebates and discounts to consumers without violating 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 period of time after taking the first dose, to ensure that they do not experience potentially serious side effects. In particular, a promising new medication to treat multiple sclerosis might 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 significant financial burden to consumers, depending on their insurance coverage. Pharmaceutical manufacturers, however, were not able to offer discounts or rebates to defray the cost through patient assistance programs because the exemption from the kickback prohibition applied only to the drug itself. Therefore, it was suggested that the exemption be extended to the necessary services connected with the use of that drug.

**CONTENT**

**The bill amended the Health Care False Claim Act to provide that payment from a drug manufacturer to a consumer, consumer's health professional, or vendor for a health care service that is required or recommended for initiating a multiple sclerosis drug therapy, does not violate a prohibition against kickbacks, bribes, and rebates for furnishing health care goods or services.**

Under Section 4 of the Act, it is a felony to solicit, offer, pay, or receive a kickback or bribe in connection with the provision 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 provision of health care benefits. The felony is punishable by imprisonment for up to four years, a maximum fine of \$50,000, or both.

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 his or her use of the drug does not violate Section 4.

Under the bill, Section 4 also is not violated by 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 that the prescribing information of a qualified drug requires or recommends for initiating drug therapy.

The bill defines "qualified drug" as a drug that has a U.S. Food and Drug Administration approved indication to treat multiple sclerosis.

The bill defines "health care service" as any of the following:

- Monitoring for bradycardia or atrioventricular conduction.
- Monitoring blood pressure.
- An electrocardiogram.
- A cardiac evaluation by a physician.
- A complete blood count test.
- A liver function test.
- An eye examination for macular edema.
- A pulmonary function test, if clinically indicated.
- A vaccination.
- An additional service included in the prescribing information by the U.S. Food and Drug Administration.

The bill defines "consumer's health professional" as a health professional who did not prescribe the qualified drug or who does not have a financial relationship with the health professional who prescribed the qualified drug. "Health professional" means an individual who is licensed or otherwise authorized to engage in a health profession under Article 15 of the Public Health Code.

The bill took effect on July 11, 2016.

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 for serious diseases and conditions, including multiple sclerosis. 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. Regarding the multiple sclerosis drug that can cause a patient's heart rate to slow, some patients must either go to a special center for the necessary observation or have it done at home, because many of the physicians prescribing the drug are not cardiologists. Even if insurance covers these services, some insurance plans have high out-of-pocket maximums totaling thousands of dollars per year. By creating an exemption to the kickback prohibition for health care services needed in conjunction with the use of this drug, or another drug approved to treat multiple sclerosis, the bill will facilitate access to available drug options and reduce out-of-pocket costs for consumers who have this condition.

Legislative Analyst: Suzanne Lowe

## **FISCAL IMPACT**

The bill will 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.