

DRUG MANUFACTURER GIFTS TO PRESCRIBERS

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House Bill 4357 as introduced
Sponsor: Rep. John R. Roth
Committee: Health Policy
Complete to 3-10-21

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

SUMMARY:

House Bill 4357 would amend the Public Health Code to prohibit a drug manufacturer or wholesale distributor from giving or offering certain gifts to prescribers and provide other requirements concerning the sale, promotion, or marketing of drugs to prescribers.

Under the bill, a drug manufacturer or wholesale distributor or its employees could not offer or give a *gift* to a prescriber while engaged in a sales, promotional, or other marketing activity for a prescription drug. The Michigan Board of Pharmacy could promulgate rules to implement this provision.

Gift would mean a payment, an advance, a forbearance, or the rendering or deposit of money, services, or anything else of value, the value of which exceeds \$63 in any one-month period. It would not include a salary paid to an employee or anything of value provided by the manufacturer or distributor to its salaried employees.

Gift also would not include any of the following:

- Providing a sample of a drug to a prescriber for distribution to a patient.
- A “modest meal” provided in connection with an informational presentation.
- One or more items with a combined retail value totaling up to \$63 in any one-year period.
- A publication or educational material.
- An item designed primarily for the education of a patient or prescriber.
- A payment to the sponsor of a medical conference, professional meeting, or other educational program that was not made directly to a prescriber and was used solely for bona fide educational purposes.
- Funding for a continuing medical or pharmacy education activity, including a scholarship or educational funding for continuing education, consistent with standards of the Accreditation Council for Continuing Medical Education or the Accreditation Council for Pharmacy Education.
- Reasonable compensation, including payment of expenses, for a prescriber’s professional or consulting services.
- Reasonable compensation, including payment of expenses, for a prescriber to speak or serve on the faculty at a professional or educational conference or meeting, including one organized by the manufacturer or distributor.

A manufacturer or wholesale distributor would have to provide the Board of Pharmacy with a list identifying its employees who sell, promote, or market drugs to prescribers.

A manufacturer or wholesale distributor would have to ensure the compliance of its employees with all of the following requirements:

- If the employee provides information about a prescription drug to a prescriber, that the employee provides to the prescriber, in writing, the wholesale acquisition cost of the drug.
- That the employee does not engage in deceptive or misleading marketing of a prescription drug, which would include knowingly leaving out, misstating, or making a misleading representation of a material fact.
- That the employee does not attend a patient examination without the prior consent of the patient.

Section 16299 of the Public Health Code provides that a person who violates or helps another to violate Article 15 of the code is, with some exceptions, guilty of a misdemeanor punishable by imprisonment for up to 90 days or a fine of up to \$100, or both, for a first offense. For a second or subsequent offense, the person is guilty of a misdemeanor punishable by imprisonment for at least 90 days and up to 6 months, or a fine of at least \$200 and up to \$500, or both.

The bill is tie-barred to HB 4358, which means that it could not take effect unless HB 4358 were also enacted.

Proposed MCL 333.17748g and 333.17748h

BACKGROUND:

The bill is a reintroduction of House Bill 5940 from the 2019-20 legislative session. It is identical to the H-1 substitute for HB 5940,¹ which was considered by the House Health Policy committee and referred to the House Ways and Means committee in September of 2020.

FISCAL IMPACT:

House Bill 4357 would have an indeterminate fiscal impact on the state and on local units of government. Individuals convicted of violating the bill could be subject to penalties under MCL 333.16299. Currently, under section 16299 of the Public Health Code, unless otherwise stated, a person who violates any provision within Article 15 of the act is guilty of a misdemeanor. New misdemeanor convictions would increase costs related to county jails and/or local misdemeanor probation supervision. Costs of local incarceration in county jails and local misdemeanor probation supervision, and how those costs are financed, vary by jurisdiction. The fiscal impact on local court systems would depend on how provisions of the bill affected court caseloads and related administrative costs. Any

¹ <http://www.legislature.mi.gov/documents/2019-2020/billanalysis/House/pdf/2019-HLA-5939-102F5CB8.pdf>

increase in penal fine revenue would increase funding for public and county law libraries, which are the constitutionally designated recipients of those revenues. Because there is no practical way to determine the number of violations that will occur under provisions of the bill, an estimate of costs to the state or to local units, or revenue for libraries cannot be made.

The bill would not have a significant fiscal impact on the Department of Licensing and Regulatory Affairs. Any miscellaneous administrative costs that may arise, including those for rules promulgation, would likely be sufficiently covered by existing departmental appropriations.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.