Legislative Analysis

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DRUG COMPANIES & DISTRIBUTORS:
REQUIRE COMPREHENSIVE COMPLIANCE PROGRAM

House Bill 6158
Sponsor: Rep. Mary Valentine

House Bill 6159
Sponsor: Rep. Mike Simpson
Committee: Health Policy

Complete to 6-25-08

A SUMMARY OF HOUSE BILL 6158-6159 AS INTRODUCED 5-22-08

House Bills 6158 and 6159 would require a drug manufacturer or wholesale distributor to adopt a comprehensive compliance program complying with the OIG compliance program and PhRMA code described below, file an annual report of compliance, and subject any manufacturer or distributor who did not file the annual report to administrative fines up to $500,000, depending on the nature of the violation. The bills are tie-barred to each other. A detailed summary of each bill follows the description of the OIG and PhRMA publications.

OIG and PhRMA Publications

In May of 2003, the Office of Inspector General (OIG) of the United States Department of Health and Human Services issued its final Compliance Program for Pharmaceutical Manufacturers (68 Fed Reg 23, 731). According to the OIG, the "compliance guidance is intended to assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs and in evaluating and, as necessary, refining existing compliance programs" and "provides the OIG's views on the fundamental elements of pharmaceutical manufacturer compliance programs and principles that each pharmaceutical manufacturer should consider when creating and implementing an effective compliance program."

Among other things, the guide speaks to the interaction between the pharmaceutical industry and healthcare providers, such as cautioning drug manufacturers to be aware of the federal anti-kickback statute and the constraints it places on the marketing and promotion of products reimbursable by the federal health care programs such as Medicaid and Medicare.

Subsequently, the Pharmaceutical and Manufacturers of America (PhRMA) developed a document entitled "PhRMA Code on Interactions with Healthcare Professionals" that focuses on the interactions between manufacturers and healthcare professionals relating

to the marketing of pharmaceutical products. According to PhRMA, the Code reinforces its "intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine" and that the Code "is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience."

House Bill 6158

The bill would add a new section to the Public Health Code (MCL 333.17790) to require on or before March 1, 2009, each pharmaceutical manufacturer and wholesale distributor to adopt a comprehensive compliance program that complied with the publication entitled "Compliance Program Guidance for Pharmaceutical Manufacturers" published by the federal Office of Inspector General (OIG). In addition, policies for compliance with the publication entitled "Code on Interactions with Health Care Professionals" that is published by the Pharmaceutical Research and Manufacturers of America (PhRMA) would have to be included in the compliance program.

The Department of Community Health (DCH) could adopt by departmental order a subsequent revision of either publication if the publication provided at least the same or additional guidance. If DCH adopted new guidance, the department would have to publish the guidance and notify licensed manufacturers and distributors. A manufacturer or distributor would have up to six months after being noticed to make the conforming changes.

Comprehensive Compliance Program Requirements

The following would have to be included in a manufacturer's or distributor's program:

- Limits on gifts or incentives provided to prescribers, in accordance with the bill.
- A specific annual dollar limit on gifts, promotional materials, or items or activities given or provided by the manufacturer or distributor in accordance with the OIG and PhRMA publications or subsequent revisions adopted by DCH.

Drug Samples and Other Financial Support

The following would be exempt from any limits if provided in a manner that conformed to the OIG and PhRMA publications or subsequent revisions adopted by DCH:

- Drug samples given to prescribers intended for free distribution to patients.
- Financial support for continuing medical education forums and health educational scholarships.
- Payments for legitimate professional services provided by a prescriber. This would include, but not be limited to, consulting. The payment could not exceed the fair market value of the services provided.

Annual Report

A manufacturer or distributor would have to annually report to the DCH that it was in compliance with its comprehensive compliance program and the bill's provisions. The report would be on a form and in a manner prescribed by DCH. Further, the manufacturer or distributor would have to make its comprehensive compliance program and its annual report available to the public on its website, as well as provide a toll-free telephone number where a copy or copies of the program and report could be obtained.

House Bill 6158 would take effect January 1, 2009.

House Bill 6159

The bill would also add a new section to the Public Health Code (MCL 333.17791) to state that a manufacturer or wholesale distributor who neglected or refused to file a report under House Bill 6158 would be subject to an administrative fine of not more than $10,000; the fine maximum would be increased to $500,000 for intentionally providing a false report.

FISCAL IMPACT:

A fiscal analysis is in process.

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