Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986
TDD: (517) 373-0543

House Bill 5328 (Substitute H-2 as passed by the House)
Sponsor: Representative Edward Gaffney
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 6-29-04

CONTENT

The bill would amend the Public Health Code to require the Michigan Board of Pharmacy, in conjunction with the Michigan Medication Safety Coalition and the Michigan Pharmacists Association, to establish a process for the development and implementation of a prescription medication Quality Assurance Program, within one year after the bill's effective date.

At a minimum, the Quality Assurance Program would have to document, identify, assess, and prevent prescription medication errors that occur in pharmacies or that are attributable, in whole or in part, to the pharmacy or its personnel, a pharmacist, or a dispensing prescriber. The bill specifies that the Program's purpose would be to assist pharmacies, pharmacists, and dispensing prescribers to take appropriate action to prevent prescription medication errors and recurrence.

(The bill would define "prescription medication error" as a preventable event that occurred while the medication was in control of a health care professional or health facility that could cause or lead to inappropriate medication use or patient harm. A preventable event could be related to any step related to the health profession and its procedures or systems, including the prescribing, compounding, dispensing, or distribution of a prescription; the ordering or communication of the prescription to the dispensing prescriber; the labeling, packaging, or naming of the prescription; the monitoring of the prescription's use; and the educating of a patient regarding the prescription.)

The Program could include a peer review committee appointed by the State; an established professional standards review organization qualified under Federal or State law; or a foundation, organization, or group of professionals and experts nominated by the Michigan Medication Safety Coalition and the Michigan Pharmacists Association and acting pursuant to the Board's approval.

A person, organization, or entity could provide information, data, or records to the peer review committee. Information and records generated for and maintained as a component of the Program would be considered peer review documents, would be confidential, and could be used only for peer review purposes. In the absence of malice, a person, organization, or entity would not be civilly or criminally liable for providing information, data, or records, or for any act or communication in the use of the information, pursuant to the bill.

The Department of Community Health (DCH), in consultation with the Board and the Program, could promulgate rules establishing standards, policies, procedures, and requirements for a pharmacy licensed under the Code for the implementation of the Program.

Upon request, a pharmacist would have to provide to a prescription drug purchaser information about how to contact the Board or the Program if he or she had a complaint regarding the dispensing of his or her prescription, or believed that a prescription medication error had occurred.

Under the Code, a pharmacist who sells drugs at retail and a dispensing prescriber who sells prescription drugs must conspicuously display at each counter over which prescription drugs are dispensed or the location within the prescriber's practice where the dispensing occurs, a notice containing specified information regarding consumers' rights, as well as the address and phone number of the Board and the DCH. The bill would require that the notice include a statement informing a consumer that he or she could contact the Board or the Program if he or she believed that a prescription medication error had occurred.

The notice and consumer information requirements would take effect upon the implementation of the Program and receipt by the Secretary of State of written notice from the Board that the Program was operational.

MCL 333.17757 et al. Legislative Analyst: Julie Koval

FISCAL IMPACT

The bill would have an indeterminate fiscal impact on the Michigan Board of Pharmacy and the health professions regulatory staff of the Department. Providing an accurate cost estimate for this bill is not possible until further details of the Quality Assurance Program are developed. However, it is likely that additional staff would be needed to implement and staff the Program. In addition, costs would be incurred for information-gathering, travel, documentation, and holding meetings and public hearings related to the rule-making process.

Fiscal Analyst: Dana Patterson