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COMPLIMENTARY STARTER DRUGS

House Bill 4619 (Substitute H-1) First Analysis (10-29-97)

Sponsor: Rep. Sharon Gire
Committee: Health Policy

THE APPARENT PROBLEM:

The Public Health Code permits physicians, physicians' assistants, registered professional nurses, and pharmacists practicing in licensed health facilities or agencies to dispense complimentary starter dose drugs. These sample prescription drugs are distributed to the health professionals by pharmaceutical manufacturers and wholesale distributors, who then distribute them to their patients. This practice enables many indigent patients to receive prescription medication they may not otherwise have been able to afford. It also allows physicians and patients to experiment with medications for certain conditions, such as high blood pressure, to find a medication and dose that works for a patient before having a costly prescription order filled. However, prescription samples are exempt from the code's labeling requirements for prescription drugs. Many samples contain information on their packages, such as directions for use, but not all do. In addition, patients often forget their doctor's instructions and according to the Michigan Pharmacists Association, frequently bring drug samples to their local or hospital pharmacists to ask how and when to take a medication. In an attempt to address what is seen as public safety issue, legislation has been proposed to require health professionals to provide certain information when dispensing prescription samples.

with the information on it, such as the preprinted insert that came from the

THE CONTENT OF THE BILL:

The Public Health Code defines "complimentary starter dose" as "prescription drugs packaged, dispensed, and distributed in accordance with state and federal law that are provided to a dispensing prescriber free of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients." House Bill 4619 would amend the code to require that a prescription sample be accompanied by information that would include, but not be limited to, the directions for use, the name and strength of the drug, and the expiration date of the drug. The requirement could be met by either placing the sample prescription drug in a container with a label bearing the required information or by giving the patient a written document

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manufacturer or written directions from the physician. The bill would specify that this requirement would not supersede or modify, but would be in addition to, state or federal laws regulating the labeling of prescription drugs.

MCL 333.17745

FISCAL IMPLICATIONS:

The House Fiscal Agency reports that the bill would have no fiscal impact on either the state or local level. (10-28-97)

ARGUMENTS:

For:

The practice by which drug companies and distributors give prescription drug samples to physicians and pharmacists to distribute to patients fills a valuable need. Many patients are uninsured or underinsured, and so may not be able to afford prescription drugs. In other cases, especially when a patient may need long-term drug treatment, the samples allow the patient and doctor to experiment to find a medication and dose that the patient can tolerate and that effectively treats the condition. This lessens the chance that a patient will fill an expensive prescription only to find that he or she cannot tolerate the medication or that it is ineffective.

A concern has risen because, although many of the prescription drug samples have dosing information marked on the packages, not all do. Since patients do not always remember the instructions of their health care providers, it is not uncommon for patients to contact pharmacists to ask directions as to how and when to take a drug. Reportedly, some patients are not even sure of what the medication is meant to treat. The bill would address the public safety concerns that have arisen regarding prescription drug samples by requiring the dispensing prescriber to include in writing, either by labeling the container of the drug sample or on a separate document, the name and strength of the drug, directions for use, and the expiration date. The requirement can be

easily met by giving the patient the preprinted insert that comes with the drug sample or by writing the information on a piece of paper. To many in the health professions, it is very important that barriers to the distribution of these sample prescription medicines -- especially to the indigent and elderly populations -- not be placed before physicians. The committee version of the bill addresses the safety concerns raised, and because it meets current informal protocol for providers, it should not impede health professionals from distributing the sample medications to their patients.

POSITIONS:

The Michigan Osteopathic Association supports the bill. (10-28-97)

The Michigan Pharmacists Association supports the bill. (10-28-97)

The Department of Community Health supports the concept of providing information to patients relating to the proper administration of a drug. The department does not support placing barriers before physicians providing assistance to those who could not otherwise afford a prescription drug. (10-28-97)

The Michigan State Medical Society does not oppose the bill. (10-28-97)

Analyst: S. Stutzky

■ 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.