House
Legislative
Analysis
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PHARMACISTS: PROSPECTIVE DRUG REVIEWS

House Bill 4686 as passed by the House Second Analysis (8-18-94)

Sponsor: Rep. Michael J. Bennane
Committee: Public Health

THE APPARENT PROBLEM:

The federal Omnibus Budget Reconciliation Act (OBRA) of 1990 required that, as of January 1, 1993, pharmacists counsel Medicaid patients about their prescriptions and drug interactions. At the request of certain pharmacy chains, legislation has been introduced that would put these federal requirements into state law and extend them to all patients.

THE CONTENT OF THE BILL:

Basically, the bill would incorporate federal standards required of pharmacists dispensing drugs to Medicaid patients and extend these requirements to all pharmacy patients. Thus, the bill would amend the Public Health Code to require pharmacists to keep certain information on patients, to conduct prospective drug reviews before filling certain prescriptions, and to offer to discuss with patients presenting certain prescriptions "appropriate" information regarding the prescription. In addition, the bill would require pharmacists to notify prescribers (i.e. physicians or dentists) of any potential drug therapy problems identified by the pharmacist as a result of a prospective drug review or discussion.

Prospective drug reviews. The bill would require pharmacists and "dispensing prescribers" (such as physicians and dentists) to conduct prospective drug reviews before dispensing or delivering a new prescription or refilling a prescription ("to the extent considered appropriate by the pharmacist in his or her professional judgment"). Pharmacists would have to consider all of the following in conducting a prospective drug review:

(1) Potential drug problems from "therapeutic duplication";

(2) interactions between drugs, including over-the-counter drugs;

(3) incorrect drug dosage or duration of drug use;

(4) allergic reactions to drugs;

(5) clinical abuse or misuse; and

(6) contraindication of drugs for a disease if the diagnosis was included on the prescription by the prescriber.

Patient counseling. Unless a prescription were dispensed in a hospital or unless, in the pharmacist's professional judgment, a face-to-face discussion would be unnecessary or inappropriate, the bill would require pharmacists (or their designees) and dispensing prescribers to offer to discuss, face-to-face, with the patient (or the person presenting the prescription on behalf of the patient) "appropriate" information regarding a prescription. (If a pharmacist decided that a face-to-face offer to discuss prescription information was unnecessary or inappropriate, he or she could offer to discuss the information in writing, by telephone, or "in a manner determined appropriate by the pharmacist.") If a pharmacist's offer to discuss the prescription were accepted, the pharmacist would be required to conduct the discussion face-to-face, if practicable, or by telephone. Pharmacists could supplement their discussions with additional electronic, printed, or video information. If a pharmacist's offer were refused, he or she wouldn't be required to give the information proposed under the bill.

In making a professional judgment about offering to discuss a prescription (and about the content of the prescription), pharmacists could consider the patient information that the bill would require pharmacists to keep on patients (see below). But at the very least, the pharmacist would have to include in his or her discussion "elements of medication information considered appropriate by the pharmacist," including, but not limited to, all of the following:

(1) The name and description of the prescribed drug;

(2) the drug form and dose, how it was to be taken, and how long to take it;

(3) if the diagnosis is included on the prescription, the intended use and expected effects of the drug;

(4) special directions and precautions for preparing, taking, and using the drug;

(5) common severe or adverse effects or interactions with other drugs and "therapeutic contraindications" (that is, reasons why the drug wouldn't be appropriate to the patient's condition);

(6) ways the patient can monitor his or her use of drugs;

(7) how to store the drug properly;

(8) information on prescription refills; and

(9) comments relevant to the patient's drug therapy, including, but not limited to, information about the particular patient or the prescribed drug.

Records on patients. The bill would require pharmacists (or their designees) to make "reasonable" efforts to obtain, record, and keep the following patient information at the pharmacy:

* the patient's name, address, telephone number, date of birth or age, and gender;

* if considered significant by the pharmacist, an individual patient history including, but not limited to, each patient's known drug allergies and reactions, a "comprehensive" list of drugs and devices used by the patient, and the patient's chronic conditions or diseases (if that information is available); and

* additional comments by the pharmacist "relevant to the patient's drug use."

Pharmacists would record the above information on patients in the patient's manual or electronic profile, and could include documentation of the pharmacist's offer to discuss the prescription or a patient's refusal of the offer (the offer and any refusal also could be recorded in the prescription signature log "or any other system of records"). If there were no record that a patient had refused a pharmacist's offer to discuss a prescription, there would be a presumption that the pharmacist had made the offer, the patient accepted the offer, and the pharmacist provided the discussion.

Information collected under the bill would be subject to the same confidentiality requirements that currently apply to prescriptions (and equivalent records) under the health code. That is, currently, prescriptions (and equivalent records) are not public records, and someone having custody of, or access to, such records is prohibited from disclosing their contents or providing copies without the patient's authorization to anyone, with certain exceptions: the patient for whom the prescription was issued (or another pharmacist on behalf of the patient); the prescriber who issued the prescription, or a licensed health professional who currently is treating the patient; government agencies or agents responsible for enforcing drug laws; someone authorized by court order; and researchers engaged in projects or studies with protocols that have been approved by the board of pharmacy.

MCL 333.17707, 333.17712, and 333.17713

BACKGROUND INFORMATION:

The 1990 federal Omnibus Budget Reconciliation Act requires states to "provide by not later than January 1, 1993, for a drug use review program. . . for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results." These state drug review programs are to be designed to educate physicians and pharmacists (1) so they can "identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs," and (2) about potential and actual severe adverse reactions to drugs. The programs specifically are to include "education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse."

Each state drug use review program must meet certain requirements for covered outpatient drugs.

These requirements include prospective drug reviews, retrospective drug use reviews, and educational programs "to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices."

Prospective drug reviews. Before a prescription is filled or delivered to someone receiving Medicaid benefits, the act requires a prospective drug review which must include the following:

"[1] screening for potential drug therapy problems due to therapeutic duplication,

[2] drug-disease contraindications,

[3] drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs),

[4] incorrect drug dosage or duration of drug treatment,

[5] drug-allergy interactions, and

[6] clinical abuse/misuse."

Counseling. The act requires states to establish certain statutory standards for pharmacists to counsel Medicaid recipients. The pharmacist must offer to discuss certain things, which in the pharmacist's professional judgment, are significant, and must do this in person, whenever practicable. (If the discussion takes place by telephone, a toll-free telephone number must be offered.) However, in addition to allowing for a pharmacist's "professional judgment" regarding what matters are to be discussed with Medicaid patients, the act also specifies that the pharmacist must include the following information:

"[1] the name and description of the medication;

[2] the route, dosage, route of administration, and duration of drug therapy;

[3] special directions and precautions for preparation, administration and use by the patient;

[4] common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

[5] techniques for self-monitoring drug therapy;

[6] proper storage;

[7] prescription refill information; [and]

[8] action to be taken in the event of a missed dose."

Patient records. The act also requires pharmacists to make a "reasonable effort . . . to obtain, record, and keep at least the following information" on Medicaid patients:

"[1] name, address, telephone number, date of birth (or age) and gender;

[2] individual history where significant, including disease state or states, known allergies and drug reactions, and

[3] a comprehensive list of medications and relevant devices; [and]

[4] pharmacist comments relevant to the individual's drug therapy."

FISCAL IMPLICATIONS:

Fiscal information is not available. (8-18-94)

ARGUMENTS:

For:

The bill basically would put into statute federal requirements regarding pharmacists conducting prospective drug reviews and counseling of Medicaid patients and would extend these requirements to all patients, not just those on Medicaid. However, it would not require pharmacists to counsel patients on drugs that the pharmacist wasn't aware the patient was taking. By requiring that the same kinds of records and counseling be kept on both Medicaid and non-Medicaid patients, the bill would both simplify pharmacists' recordkeeping and would benefit patients as well by ensuring that they understood the prescriptions that were prescribed for and dispensed to them.

POSITIONS:

The Michigan Pharmacists Association supports the bill. (8-15-94)

The Michigan State Medical Society supports the bill. (8-10-94)

The Department of Public Health has no position on the bill. (8-11-94)