House Legislative Analysis Section

Washington Square Building, Suite 1025
Lansing, Michigan 48909
Phone: 517/373-6466

REVISE TRIPLICATE RX ACT

Senate Bill 297 as passed by the Senate
First Analysis (5-9-89)

Sponsor: Sen. Robert Geake
Senate Committee: Health Policy
House Committee: Public Health

THE APPARENT PROBLEM:

Public Act 60 of 1988 amended the Public Health Code to require that prescriptions for "Schedule 2" controlled substances (the most addictive of the legally prescribable drugs) be recorded on official, serially numbered triplicate forms. However, when the Department of Licensing and Regulation began planning implementation of the program, a number of technical problems with the act became evident. At the request of the department, legislation has been proposed to clarify the language of the act and eliminate some unnecessarily burdensome requirements on those falling under the act's provisions.

THE CONTENT OF THE BILL:

The bill would make a number of technical amendments to the section of the Public Health Code that details the requirements for triplicate prescription forms and prescribing practitioners. More specifically, the bill would:

- exempt methadone programs from the "one form, one prescription" requirement;
- change some of the information required on the forms;
- change some of the requirements for dispensing pharmacists and for prescribing and dispensing practitioners; and
- revise the section governing access to information gathered from the triplicate prescription program.

Methadone programs. Currently, only one prescription can be recorded on an official prescription form. The bill would allow an exception for licensed substance abuse programs using methadone to treat addiction. More specifically, the bill would require practitioners employed by (or under contract to) a state licensed substance abuse program to complete an official prescription form for the entire program on the first working day of each month and to forward copy 1 of the form to the Department of Licensing and Regulation (DLR) by the fifteenth of the same month. The practitioner would be required to indicate on the form the total amount of methadone administered or dispensed and the total number of patients who received the methadone during the previous month. The bill also would require the practitioner to comply with federal requirements regarding the confidentiality of client information.

Required Information. Currently, each official prescription form contains spaces for certain kinds of information, including the date the prescription is written, the date it is filled, the controlled substance prescribed (including dosage and instructions for use), information on the dispensing pharmacy (its name, address, and federal Drug Enforcement Administration number), the initials of the pharmacist who fills the prescription, information on the person for whom the prescription is written (name, address, and age), and, where applicable, information on the authorized agent for the ultimate user.

The bill would strike the provision regarding authorized agents, and would require the following additional information:

(a) The quantity, in both written and numerical terms, of the controlled substance prescribed;

(b) the state license number of the dispensing pharmacist;

(c) information on the prescribing practitioner (name, address, state license number, federal Drug Enforcement Administration (DEA) number, and signature);

(d) in the case of a veterinary prescription, information on the owner of the animal (name, address, and age); and

(e) a box to be checked when the drug was dispensed by a prescribing practitioner.

In addition, the bill would allow the signature or the initials of the pharmacist who fills the prescription.

Requirements for prescribing and dispensing practitioners. Presently, when prescribing Schedule 2 drugs, practitioners are required to fill in certain information on all three copies of the form (the date the prescription is written; the controlled substance prescribed, its dosage, and use; and information on the patient, animal's owner, or authorized agent for the ultimate user).

The bill would amend this section of the code to strike the provisions regarding authorized agents, and would require the additional following information to be filled in on the form by the prescribing practitioner:

(a) the quantity, in both written and numerical terms, of the drug prescribed; and

(b) in the case of veterinary prescriptions, the name of the animal.

In addition to providing this information when prescribing Schedule 2 drugs, if the prescribing practitioner also dispensed the drug he or she had prescribed, the practitioner also would be required to fill in all three copies of an official prescription form, giving the same information on the drug being dispensed that is (or would be) required of the drug being prescribed, as well as checking the box that would indicate that the prescribing practitioner also was the dispensing practitioner.

Prescribing practitioners presently are required to sign copies 1 and 2 of the form, and are in compliance if, in signing copy 1, a carbon copy of the signature is produced on copy 2. The bill would say that a prescribing practitioner was in compliance with the signature requirements for copy 2 if, in signing copy 1, a legible (rather than carbon) copy of the signature was produced on copy 2.

Pharmacists dispensing Schedule 2 drugs now are required to fill in certain information on copies 1 and 2 of official prescription forms, keep copy 2 for at least five years, and

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send copy 1 to the Department of Licensing and Regulation (DLR) by the fifteenth of the month following the month in which the prescription was written. The bill would require dispensing practitioners also to keep copy 2 of the official form ("as a dispensing record"), keep copy 3 for at least five years after the date on which the prescription was written, and forward copy 1 of the form to the DLR within the same timeframe as required of pharmacists. Dispensing practitioners also would be required to sign copies 1 and 2 of the official prescription forms, and would meet this requirement if, in signing copy 1, they produced a legible copy of their signature on copy 2.

Requirements for dispensing pharmacists. Dispensing pharmacists presently must sign copy 1 and send it to the DLR. The bill would allow pharmacists to sign or initial copy 1 before forwarding it to the DLR.

Prescriptions written by practitioners who live in states sharing a land border with Michigan and whose practice extends into Michigan (but who do not have an office in Michigan) do not have to use official state prescription forms. However, when pharmacists dispense drugs under such prescriptions, they are required to transmit to the DLR either a copy of the prescription or a document containing certain information concerning the prescription (the date it was written and filled, the controlled substance and dosage), the out-of-state practitioner (name, address, DEA number), the patient (name and address), and the dispensing pharmacist (name and address). The bill would specify that pharmacists, when filling prescriptions for such out-of-state practitioners, would be required either to forward to the DLR a copy of the prescription form used or a document provided by the DLR for each such prescription that contains the additional following information: the quantity of the controlled substance prescribed, the age of the patient, and the state license number of the dispensing pharmacist.

The act requires pharmacists to notify the department when an oral prescription for a Schedule 2 drug is not followed within 72 hours by a written official prescription form. The bill would change this mandatory reporting to a permissive reporting.

Access to information from official prescription forms. Presently, the director of the DLR can allow only certain individuals (and sometimes only under certain circumstances) access to information collected by the department under the triplicate prescription program. These include:

(a) DLR employees and agents, as authorized by the director;

(b) employees of the Department of State Police, as authorized by the Michigan Board of Pharmacy "for the purpose of cooperating and assisting a governmental agency which is responsible for the enforcement of laws relating to controlled substances;"

(c) a prescribing practitioner "concerning an individual suspected of attempting to obtain a controlled substance by fraud, deceit, or misrepresentation;" and

(d) someone whom the DLR has contracted with to administer the triplicate prescription program.

The bill would strike the reference to state police employees and replace it with "employees of a governmental agency that is responsible for the enforcement of laws pertaining to controlled substances," and would require the director's authorization for any access to triplicate prescription information gathered by the department under the code.

Note: The bill is identical to House Bill 4525 as passed by the House.

MCL 333.7334

FISCAL IMPLICATIONS:

Regarding an identical bill, House Bill 4525, the Department of Licensing and Regulations said there were no fiscal implications. (4-11-89)

ARGUMENTS:

For:

The only drug administered or dispensed in methadone programs is methadone. Maximum dosages and dispensing procedures are closely regulated both by state and by federal rules, and the federal Drug Enforcement Administration conducts regular audits of the dispensing records. Since some of these programs serve over 500 patients, requiring individual triplicate prescriptions would impose a paperwork and accounting burden on the program medical director far out of proportion to the usefulness of the information that would be produced. By allowing methadone programs to report monthly regarding the total amount of methadone administered or dispensed and the total number of patients involved, the bill would greatly ease the paperwork and accounting burden on these programs without forfeiting the collection of adequate data.

For:

The triplicate prescription act contains requirements for dispensing pharmacists, but it does not contain requirements for a prescribing practitioner who also is the dispensing practitioner. The bill would address the situation where the prescriber also is the dispenser, requiring the dispensing prescriber to maintain two copies of the triplicate form, one for a record of dispensing activity and one for the patient record.

For:

Public Act 28 of 1988, which was part of the package of legislation (including the triplicate prescription program act) designed to reduce the abuse of prescription drugs, requires that the quantity of a prescribed drug be entered on written prescriptions both in written and in numerical terms. The bill would amend Public Act 60 of 1988 to add the requirement that the quantity on the triplicate prescription form also be in written and numerical terms, making the act's language consistent with Public Act 28 of 1988.

For:

Presently the triplicate prescription act requires pharmacists dispensing oral prescriptions to notify the Department of Licensing and Regulation (DLR) if the pharmacist does not receive an official prescription form within 72 hours of dispensing the oral prescription. Since federal regulations already require pharmacists to notify the nearest office of the U.S. Drug Enforcement Administration (DEA) under these circumstances, substituting "may" for "shall" would recognize the existing federal role and avoid duplicating the federal role at the state level. (The Board of Pharmacy rule number 65 also requires notification of the DEA rather than the board or

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the DLR.) The department also will recommend in its triplicate prescription guide that a pharmacist report to the department when a pattern of non-compliance is noted so that the department may coordinate a response with the DEA.

For

The bill would eliminate the requirement that name, add ess, and age of the authorized agent for the ultimate use: be recorded on the triplicate prescription form for a num ber of reasons. In the first place, "authorized agent" is not defined in the health code. What is more, this information is difficult to confirm and would require additional information lines on an already crowded form. Finally, this requirement could have an adverse impact on elderly and disabled people, who often may have friends or relatives pick up their prescriptions for them. It would be better to allow pharmacists to use their professional judgement in deciding what identification to require of someone who claims to be an agent of a patient and in deciding whether to call the patient, prescriber or other sources to confirm the agent's authorized status.

For:

The language in the present triplicate prescription act is confusing in regard to who can authorize access to data gathered under the program, appearing to give both the director of the Department of Licensing and Regulation (DLR) and the Board of Pharmacy (the "administrator") such authority. The bill would clarify the role of the director of the DLR in authorizing access to triplicate prescription data.

For:

The bill would clarify a number of other points having to do with the information on the form and its accessibility for entry into computerized data systems. For example, the name, address, and other identifiers for prescribing practitioners will be printed on each triplicate prescription for ordered by a practitioner. The bill would make it clear that this information must be on the form. Secondly, the triplicate prescription act presently allows pharmacists to send a "document" for out-of-state prescriptions (from practitioners in adjacent states), instead of the triplicate prescription forms. By changing the language, the bill would eliminate the possibility of having an unworkable set of unique documents to be entered as data. Finally, by adding the license number of the dispensing pharmacist, the bill would require the key data control number needed for data entry.

POSITIONS:

The following organizations supported House Bill 4525, which is identical to Senate bill 297:

The Department of Licensing and Regulation (4-6-89)

The Michigan State Medical Society (4-6-89)

The Michigan Association of Osteopathic Physicians and Surgeons (4-7-89)

The Michigan Dental Association (4-6-89)

The Michigan Pharmacists Association (4-6-89)

The Office of Substance Abuse Services (4-11-89)