FIRST REGULAR SESSION

SENATE BILL NO. 185

92ND GENERAL ASSEMBLY

INTRODUCED BY SENATOR WHEELER.

Pre-filed December 5, 2002, and 1,000 copies ordered printed.

TERRY L. SPIELER, Secretary.

0555S.01I

AN ACT

To amend chapters 192 and 338, RSMo, by adding thereto five new sections relating to mandatory reporting of pharmaceuticals, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapters 192 and 338, RSMo, are amended by adding thereto five new sections, to be known as sections 192.1010, 338.600, 338.605, 338.610, and 338.615, to read as follows:

192.1010. 1. There is hereby created the "Missouri Office of Pharmaceutical Reporting" within the department of health and senior services.

2. The office shall monitor the records required to be maintained by licensed pharmacists and pharmacies in this state using the reporting requirements pursuant to sections 338.600 to 338.610, RSMo.

3. The office shall implement an automated system to be used to collect and store information required pursuant to sections 338.600 to 338.610, RSMo. The automated system shall track pharmacy errors and any injuries the errors may cause to consumers.

4. The office shall have the authority to:

(1) Conduct random testing of controlled substances at pharmacies; and

(2) Hire more inspectors necessary to implement the provisions of this section.

5. The department shall promulgate rules necessary for the implementation of this section. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536,

RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2003, shall be invalid and void.

338.600. In addition the requirements specified pursuant to section 338.100, every licensed pharmacist and pharmacy in this state shall maintain records of ordering, receiving, dispensing, or transfer of controlled substances. These records are to be retrievable by the pharmacy for a period of three years and shall be archived in a uniform manner. In emergencies the records must be immediately retrievable to the pharmacy within forty-eight hours. The records shall be open for review, copying or seizure by the office of pharmaceutical reporting pursuant to section 192.1010, RSMo. These records shall include, but not be limited to the following:

(1) Invoices or other such documents verifying the ordering and receipt of controlled substances;

(2) A record of controlled substances dispensed directly to the patient to include the patient's name, date dispensed, dispensing pharmacist's name, name of drug, strength, dosage form, and quantity of the drug dispensed. The records shall also document drugs returned and credited;

(3) A record of compounded controlled substances that have been dispensed; and

(4) A perpetual inventory shall be maintained on all controlled substances awaiting destruction or return to the vendor.

338.605. 1. A pharmacist shall notify and compile a report to the office of pharmaceutical reporting of any unusual or increased prescription rates, unusual types of prescriptions, or unusual trends in pharmacy visits that may be potential causes of a public health emergency within forty-eight hours. Prescription-related events that require notification shall include, but are not limited to, the following:

(1) An unusual increase in the number of prescriptions or over-the-counter pharmaceuticals to treat conditions that the department of health and senior services identifies through regulations;

(2) An unusual increase in the number of prescriptions for antibiotics; and

(3) Any prescription that treats a disease that is relatively uncommon or may be associated with bioterrorism.

2. The report shall be made electronically or in writing to the office of pharmaceutical reporting. The report shall include as much of the following

information as is available:

(1) The specific illness or health condition that is the subject of the report;

(2) The patient's name, date of birth, sex, race, occupation, and current home and work address;

(3) The name and address of the health care provider, coroner, or medical examiner and of the reporting individual if different; and

(4) Any other information needed to locate the patient for follow-up.

For cases related to animal or insect bites, the suspected locating information of the biting animal or insect, and the name and address of any known owner, shall be reported.

3. As used in this section "public health emergency" means an occurrence or imminent threat of an illness or health condition that is believed to be caused by any of the following:

(1) Bioterrorism, as defined in section 44.010, RSMo;

(2) The appearance of a novel or previously controlled or eradicated infectious agent or biological toxin; or

(3) A chemical attack or accidental release;

which would result in a large number of deaths in the affected population; a large number of serious or long-term disabilities in the affected population; or widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.

4. Information reported pursuant to sections 338.600 to 338.605 is confidential and disclosure is prohibited except as required by state or federal law or with the written consent of the affected individual.

338.610. Each pharmacy shall display a sign concerning the reporting of prescription errors in a conspicuous location visible to consumers of prescription drugs. The sign shall measure a minimum of eight inches in height and ten inches in length and the lettering shall be in a size and style that allows such sign to be read without difficulty by consumers standing at the pharmacy prescription counter. The sign shall bear the following statement: "If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Office of Pharmaceutical Reporting, by calling (Office of Pharmaceutical telephone number)".

338.615. Every pharmacy or pharmacist who violates the provisions of sections 338.600 and 338.605 shall, upon conviction thereof, be guilty of a class C misdemeanor.