



Sub. H.B. 475

124th General Assembly

(As Reported by H. Health and Family Services)

Reps. Raga, Brinkman, Jolivette, Patton, McGregor, Mason, Roman, Kearns

BILL SUMMARY

- Requires the State Board of Pharmacy to establish and maintain an electronic database to monitor the use, misuse, and diversion of dangerous drugs.
- Requires distributors of dangerous drugs to submit to the Pharmacy Board for entry into the database certain information on each dangerous drug sold in this state.
- Specifies the persons and entities that may receive information from the database.
- Requires the Pharmacy Board to submit biennial reports on the database's cost and effectiveness.

CONTENT AND OPERATION

Dangerous drugs database

(secs. 4729.75, 4729.76, and 4729.81)

The bill requires the State Board of Pharmacy to establish and maintain an electronic dangerous drugs database. The bill specifies that the database is to be used to monitor the use, misuse, and diversion of dangerous drugs designated by the Pharmacy Board either by schedule or by specific drug.¹ The bill requires the

¹ "Dangerous drug" includes all of the following: (1) any drug that is required under the "Federal Food, Drug, and Cosmetic Act" to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement or that may be dispensed only on a prescription, (2) any drug that under Ohio's pure food and drug or controlled substances law may be dispensed only on

Pharmacy Board to electronically collect and disseminate information on prescription drugs distributed in this state by wholesale distributors and by certain types of terminal distributors designated by the Pharmacy Board.²

The Pharmacy Board's executive director must establish staff support for the database by doing all of the following:

(1) Employing and fixing the compensation of an administrator to manage and direct the duties of staff employed to operate the database. The administrator must be a person who is trained and experienced in areas related to the duties of the database.

(2) Employing and fixing the compensation of any professional, technical, and clerical staff necessary to operate the database;

(3) Employing, or hiring on a consulting basis, any other technical services required for the operation of the database.

Rules for operating the database

(sec. 4729.81)

The bill requires the Pharmacy Board to adopt rules for operation of the database. The rules must be adopted in accordance with the Administrative Procedure Act (Chapter 119.) and specify all of the following:

(1) A means of identifying each patient and each purchase at wholesale of dangerous drugs about which information is entered into the database;

a prescription, (3) any drug that contains a controlled substance that can be obtained without a prescription, such as the drugs in certain cough syrups, (4) any drug intended for administration by injection into the human body other than through a natural orifice of the body (sec. 4729.01(F)).

² *"Wholesale distributor" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale. "Terminal distributor" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs (sec. 4729.01(O) and (Q)).*

(2) An electronic format for the submission of information from terminal distributors and wholesale distributors of dangerous drugs;

(3) A procedure whereby a terminal distributor or wholesale distributor of dangerous drugs unable to submit information electronically may obtain a waiver to submit information in another format;

(4) A procedure whereby the Pharmacy Board may grant a request from a law enforcement agency or a government entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe drugs that information that has been stored for two years be retained when the information pertains to an investigation being conducted by that agency;

(5) A procedure whereby a terminal or wholesale distributor may apply for an extension of the time by which information must be transmitted to the Pharmacy Board;

(6) A procedure whereby a person or government entity to which the Pharmacy Board is authorized to provide information may submit a request to the Board for the information and the Board may verify the identity of the requestor;

(7) A procedure whereby the Board can use records requests for information from the database to document and report statistics and law enforcement outcomes;

(8) A procedure whereby an individual may request the individual's own database information and the Board may verify the identity of the requestor;

(9) A reasonable fee the Board will assess for providing an individual with the individual's own database information.

The Board must specify, either by schedule or by specific drug name, which dangerous drugs are to be monitored by the database. The Board must also designate which types of terminal distributors are required to submit prescription information to the database.³

³ *Each terminal distributor, whether located within or outside this state, who sells dangerous drugs at retail for delivery or distribution to persons residing in this state, must be licensed as a terminal distributor of dangerous drugs (sec. 4729.551). For the purposes of terminal distributor licensure, dangerous drugs are divided into three categories. There are six license categories for terminal distributors of dangerous drugs, granted according to the category of dangerous drugs the distributor supplies (sec. 4729.54).*

Information submission

(secs. 4729.77, 4729.78, and 4729.79)

Under the bill, each licensed terminal distributor of dangerous drugs required to submit prescription information to the Pharmacy Board must submit the following information:

- (1) Patient identification;
- (2) Identification of the drug dispensed;
- (3) Quantity of the drug dispensed;
- (4) Date of dispensing;
- (5) Directions for use;
- (6) Serial number of the drug assigned by the terminal distributor;
- (7) Terminal distributor's license number issued by the Pharmacy Board;
- (8) Identification of the prescriber.⁴

A prescriber need not submit to the database prescription information for instances in which the prescriber personally furnished or administers a drug to the physician's patient.⁵

Each wholesale distributor of dangerous drugs required to submit purchase information to the Board must submit the following information:

- (1) Purchaser identification;
- (2) Identification of the drug sold;

⁴ "Prescriber" means an individual authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including the following professionals licensed under Ohio law: dentists; nurses who hold a certificate to prescribe; optometrists licensed to practice optometry under a therapeutic pharmaceutical agents' certificate; physicians authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine; and veterinarians (sec. 4729.01(I)).

⁵ "Physician" in this provision should be "prescriber." This drafting error could be corrected by an amendment.

- (3) Quantity of the drug sold;
- (4) Date of sale;
- (5) The wholesale distributor's license number issued by the Pharmacy Board.

Each terminal or wholesale distributor must submit the required information electronically in the format specified by the Pharmacy Board, unless the Board has granted a waiver allowing the distributor to submit the information in an alternate format. The information must be transmitted as designated by rule of the Board, unless the Board grants the distributor an extension. If the distributor suffers a mechanical or electronic failure or cannot meet the deadline established by the Board for other reasons beyond the distributor's control, or the Board is unable to receive electronic submissions, the Board may grant a distributor an extension to the time by which the required information must be submitted.

The bill requires that the information collected for the database be retained in the database for two years. After two years, the information must be destroyed unless a law enforcement agency or the State Medical Board, in accordance with the rules adopted by the Pharmacy Board, has submitted a written request to the Board for retention of specific information that pertains to an open investigation. Information contained in the database and any information obtained from it is not a public record.

Who may receive database information

(sec. 4729.79(A))

The Pharmacy Board may provide information from the database to all the following:

- (1) A person who is a designated representative of a government entity responsible for the licensure, regulation, or discipline of licensed health professionals authorized to prescribe drugs and is involved in an investigation of a person licensed, regulated, or subject to discipline by the entity;

- (2) A state, federal, county, township, or municipal officer of this or any other state, or the United States, whose duty is to enforce the laws relating to drugs and who is actively engaged in a specific investigation of a specific person or drug specified by the officer;

- (3) A properly convened grand jury pursuant to a subpoena properly issued;



(4) A pharmacist or prescriber who requests the information and certifies in a form specified by the Board that it is for the purpose of providing medical or pharmaceutical treatment to a current patient of the pharmacist or prescriber;

(5) An individual who requests the individual's own dangerous drugs database information in accordance with procedures established by the Board in rules.

The bill specifies that it does not require pharmacists or prescribers to obtain information about a patient from the database while treating a patient. It provides further that a pharmacist or prescriber cannot be held liable in damages to any person in any civil action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database.

Information request records

(sec. 4729.79(B) and (C))

The bill requires the Pharmacy Board to maintain a record of each individual or entity that requests information from the dangerous drug database. Pursuant to rules adopted by the Board, the Board can use these information request records to document and report statistics and law enforcement outcomes. Information contained in the database information request records is not a public record. The bill limits access to the information request records to certain individuals. The Board can provide records of an individual's database information requests to the following individuals:

(1) A designated representative of a government entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe drugs and is involved in an investigation of the individual who submitted the database information request;

(2) A federal, state, county, township, or municipal officer of this or any other state, or the United States, whose duty is to enforce the law relating to drugs and who is actively engaged in a specific investigation of the individual who submitted the database information request.

Charging of fees prohibited

(sec. 4729.79(F))

The bill prohibits the Board from charging any fees to pharmacists or prescribers associated with the establishment or maintenance of the database, except that the Board may charge a fee to an individual who requests the

individual's own dangerous drugs database information. The bill also prohibits the Board from charging fees for the transmission or receipt of data to and from the database.

Review of the database information

(sec. 4729.80)

The Pharmacy Board must review the information in the database. If the Board determines that a violation of law may have occurred, it may notify the appropriate law enforcement agency or a government entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe drugs and supply information required for an investigation.

Biennial reports

(sec. 4729.81(D))

The bill requires the Pharmacy Board to present to the standing committees of the House and Senate primarily responsible for considering health and human services issues biennial reports of the following:

- (1) The cost to the state of implementing and maintaining the database.
- (2) Information from pharmacists, prescribers, and the Board regarding the Board's effectiveness in providing information from the database.
- (3) The Board's timeliness in transmitting information from the database.

Changes to existing law

(secs. 4729.25; 4729.63 and 4729.64, repealed)

The Revised Code requires the Pharmacy Board to enforce, or cause to be enforced, the laws regulating the wholesale and retail distribution of dangerous drugs, to investigate possible violations, and take such action as it considers appropriate in accordance with enforcement rules the Board has adopted. The Revised Code also includes provisions specifically requiring the Pharmacy Board to investigate possible violations related to registration and licensure of distributors and file complaints if it finds probable cause. The bill repeals the provisions specifically dealing with licensure and registration violations but

retains the broader requirement that the Pharmacy Board enforce all the laws governing distribution of dangerous drugs.⁶

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	01-16-02	p. 1242
Reported, H. Health & Family Services	05-15-02	pp. 1774-1775

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⁶*According to Tim Benedict and Mark Keeley of the Pharmacy Board, the specific requirement concerning licensure and registration is unnecessary because the laws governing those matters can be enforced under the Board's broader authority to enforce the laws governing distribution of dangerous drugs.*