

AN ACT

To amend sections 4729.25 and 4729.26, to enact sections 4729.75 to 4729.84, and to repeal sections 4729.63 and 4729.66 of the Revised Code to permit the State Board of Pharmacy to establish and maintain a drug database to monitor the misuse and diversion of controlled substances and certain dangerous drugs.

Be it enacted by the General Assembly of the State of Ohio:

SECTION 1. That sections 4729.25 and 4729.26 be amended and sections 4729.75, 4729.76, 4729.77, 4729.78, 4729.79, 4729.80, 4729.81, 4729.82, 4729.83, and 4729.84 of the Revised Code be enacted to read as follows:

Sec. 4729.25. (A) The state board of pharmacy shall enforce, or cause to be enforced, this chapter. If it has information that any provision of this chapter has been violated, it shall investigate the matter, and take such action as it considers appropriate ~~in accordance with its rules adopted under section 4729.26 of the Revised Code. With regard to violations of sections 4729.51 to 4729.62 of the Revised Code, the board's actions also shall be taken in accordance with section 4729.63 of the Revised Code.~~

(B) Nothing in this chapter shall be construed to require the state board of pharmacy to enforce minor violations of this chapter if the board determines that the public interest is adequately served by a notice or warning to the alleged offender.

Sec. 4729.26. The state board of pharmacy may adopt rules in accordance with Chapter 119. of the Revised Code, not inconsistent with the law, as may be necessary to carry out the purposes of and to enforce the provisions of this chapter ~~pertaining to the practice of pharmacy.~~ The rules shall be published and made available by the board to each pharmacist licensed under this chapter.

Sec. 4729.75. The state board of pharmacy may establish and maintain a drug database. The board shall use the drug database to monitor the misuse and diversion of controlled substances, as defined in section 3719.01 of the Revised Code, and other dangerous drugs the board includes in the database pursuant to rules adopted under section 4729.83 of the Revised Code. In

establishing and maintaining the database, the board shall electronically collect information pursuant to sections 4729.77 and 4729.78 of the Revised Code and shall disseminate information as authorized or required by sections 4729.79 and 4729.80 of the Revised Code. The board's collection and dissemination of information shall be conducted in accordance with rules adopted under section 4729.83 of the Revised Code.

Sec. 4729.76. If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the executive director of the board shall do all of the following:

(A) Employ an administrator to manage and direct the duties of staff employed to operate the drug database. The administrator shall be a person who has had training and experience in areas related to the duties of the database.

(B) Employ such professional, technical, and clerical employees as are necessary, and employ or hire on a consulting basis other technical services required for the operation of the database;

(C) Fix the compensation of the administrator and all other staff employed to operate the database.

Sec. 4729.77. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each pharmacy licensed as a terminal distributor of dangerous drugs that dispenses drugs to patients in this state and is included in the types of pharmacies specified in rules adopted under section 4729.83 of the Revised Code shall submit to the board the following prescription information:

(1) Terminal distributor identification;

(2) Patient identification;

(3) Prescriber identification;

(4) Date prescription was issued by prescriber;

(5) Date prescription was dispensed;

(6) Indication of whether prescription dispensed is new or a refill;

(7) Name, strength, and national drug code of the drug dispensed;

(8) Quantity of drug dispensed;

(9) Number of days' supply of drug dispensed;

(10) Serial or prescription number assigned by the terminal distributor;

(11) Source of payment for the prescription.

(B) The information shall be transmitted as specified by the board in rules adopted under section 4729.83 of the Revised Code.

(1) The information shall be submitted electronically in the format specified by the board, except that the board may grant a waiver allowing the distributor to submit the information in another format.

(2) The information shall be submitted in accordance with any time limits specified by the board, except that the board may grant an extension if either of the following occurs:

(a) The distributor suffers a mechanical or electronic failure, or cannot meet the deadline for other reasons beyond the distributor's control.

(b) The board is unable to receive electronic submissions.

(C) This section does not apply to a prescriber personally furnishing or administering dangerous drugs to the prescriber's patient.

Sec. 4729.78. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each wholesale distributor of dangerous drugs that delivers drugs to prescribers in this state shall submit to the board the following purchase information:

(1) Purchaser identification;

(2) Identification of the drug sold;

(3) Quantity of the drug sold;

(4) Date of sale;

(5) The wholesale distributor's license number issued by the board.

(B) The information shall be transmitted as specified by the board in rules adopted under section 4729.83 of the Revised Code.

(1) The information shall be submitted electronically in the format specified by the board, except that the board may grant a waiver allowing the distributor to submit the information in another format.

(2) The information shall be submitted in accordance with any time limits specified by the board, except that the board may grant an extension if either of the following occurs:

(a) The distributor suffers a mechanical or electronic failure, or cannot meet the deadline for other reasons beyond the distributor's control.

(b) The board is unable to receive electronic submissions.

Sec. 4729.79. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board may provide information from the database in accordance with the following:

(1) On receipt of a request from a designated representative of a government entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe drugs, the board may provide to the representative information from the database relating to the professional who is the subject of an active investigation being conducted by the government entity.

(2) On receipt of a request from a federal officer, or a state or local

officer of this or any other state, whose duties include enforcing laws relating to drugs, the board may provide to the officer information from the database relating to the person who is the subject of an active investigation being conducted by the officer's employing government entity.

(3) Pursuant to a subpoena issued by a grand jury, the board may provide to the grand jury information from the database relating to the person who is the subject of an investigation being conducted by the grand jury.

(4) On receipt of a request from a pharmacist or prescriber, the board may provide to the requestor information from the database relating to a current patient of the requestor, if the requestor certifies in a form specified by the board that it is for the purpose of providing medical or pharmaceutical treatment to the patient who is the subject of the request.

(5) On receipt of a request from an individual seeking the individual's own database information in accordance with the procedure established in rules adopted under section 4729.83 of the Revised Code, the board may provide to the individual the individual's own database information.

(B) The state board of pharmacy shall maintain a record of each individual or entity that requests information from the database pursuant to this section. In accordance with rules adopted under section 4729.83 of the Revised Code, the board may use the records to document and report statistics and law enforcement outcomes.

The board may provide records of an individual's requests for database information to the following:

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

(2) A federal officer, or a state or local officer of this or any other state, whose duties include enforcing laws relating to drugs and who is involved in an active investigation being conducted by the officer's employing government entity of the individual who submitted the requests for database information.

(C) Information contained in the database and any information obtained from it is not a public record. Information contained in the records of requests for information from the database is not a public record. Information that does not identify a person may be released in summary, statistical, or aggregate form.

(D) Nothing in this section requires a pharmacist or prescriber to obtain

information about a patient from the database. A pharmacist or prescriber shall not 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.

Sec. 4729.80. If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board shall review the information in the drug database. If the board determines from the review that a violation of law may have occurred, it shall 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 by the agency or entity for an investigation of the violation of law that may have occurred.

Sec. 4729.81. If the state board of pharmacy establishes a drug database pursuant to section 4729.75 of the Revised Code, the information collected for the database shall be retained in the database for two years. The information shall then be destroyed unless a law enforcement agency or a government entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe drugs has submitted a written request to the board for retention of specific information in accordance with rules adopted by the board under section 4729.83 of the Revised Code.

Sec. 4729.82. If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board shall not impose any charge on a terminal distributor of dangerous drugs, pharmacist, or prescriber for the establishment or maintenance of the database. The board shall not charge any fees for the transmission of data to the database or for the receipt of information from the database, except that the board may charge a fee in accordance with rules adopted under section 4729.83 of the Revised Code to an individual who requests the individual's own database information under section 4729.79 of the Revised Code.

Sec. 4729.83. For purposes of establishing and maintaining a drug database pursuant to section 4729.75 of the Revised Code, the state board of pharmacy shall adopt rules in accordance with Chapter 119. of the Revised Code to carry out and enforce sections 4729.75 to 4729.82 of the Revised Code. The rules shall specify all of the following:

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

(B) Requirements for the transmission of information from terminal distributors and wholesale distributors of dangerous drugs for purposes of

the database:

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

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

(E) A procedure whereby the 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 open investigation being conducted by the agency or entity;

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

(G) A procedure whereby a person or government entity to which the 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;

(H) A procedure whereby the board can use the database request records required by division (B) of section 4729.79 of the Revised Code to document and report statistics and law enforcement outcomes;

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

(J) A reasonable fee that the board may charge under section 4729.82 of the Revised Code for providing an individual with the individual's own database information pursuant to section 4729.79 of the Revised Code;

(K) The specific dangerous drugs other than controlled substances that must be included in the database;

(L) The types of pharmacies licensed as terminal distributors of dangerous drugs that are required to submit prescription information to the board pursuant to section 4729.77 of the Revised Code.

Sec. 4729.84. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board shall present a biennial report to the standing committees of the house of representatives and the senate that are primarily responsible for considering health and human services issues. The initial report shall be presented not later than two years after the database is established.

(B) Each report presented under this section shall include all of the following:

- (1) The cost to the state of establishing and maintaining the database:
- (2) Information from terminal distributors of dangerous drugs, 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.

Sub. H. B. No. 377

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SECTION 2. That existing sections 4729.25 and 4729.26 and sections 4729.63 and 4729.66 of the Revised Code are hereby repealed.

Speaker _____ *of the House of Representatives.*

President _____ *of the Senate.*

Passed _____, 20____

Approved _____, 20____

Governor.

The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

Director, Legislative Service Commission.

Filed in the office of the Secretary of State at Columbus, Ohio, on the
____ day of _____, A. D. 20____.

Secretary of State.

File No. _____ Effective Date _____