Alan Van Dyne *Legislative Service Commission*

Sub. H.B. 377*

125th General Assembly
(As Reported by S. Health, Human Services and Aging)

Reps. Raga, Calvert, Carmichael, Cirelli, Clancy, Daniels, C. Evans, D. Evans, Flowers, Hagan, Martin, T. Patton, Schaffer, Schlichter, Schneider, Slaby, G. Smith, J. Stewart, Willamowski

BILL SUMMARY

- Permits the State Board of Pharmacy to establish and maintain a drug database to monitor the misuse and diversion of controlled substances and other dangerous drugs the Board includes in the database pursuant to rules.
- Requires the drug database, if established, to include prescription and drug purchase information that is to be submitted to the Board by designated pharmacies and all wholesale distributors of dangerous drugs licensed in Ohio.
- Specifies the persons and entities that may receive information from the database, if established.
- Requires the Pharmacy Board to submit biennial reports on the cost and effectiveness of the database, if established.

CONTENT AND OPERATION

Drug database

(R.C. 4729.75)

The bill authorizes the State Board of Pharmacy to establish and maintain an electronic drugs database. The database is to be used to monitor the misuse and

---

* *This analysis was prepared before the report of the Senate Health, Human Services and Aging Committee appeared in the Senate Journal. Note that the list of co-sponsors and the legislative history may be incomplete.*

diversion of controlled substances[1] and other dangerous drugs[2] the Board includes in the database pursuant to rules. In establishing and maintaining the database, the Pharmacy Board must electronically collect drug information from pharmacies and drug wholesalers and disseminate information from the database as authorized or required by the bill. The collection and dissemination of information must be conducted in accordance with rules the Board is to adopt for operation of the database.

Staffing

(R.C. 4729.76)

If the Pharmacy Board establishes and maintains a drug database, the 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.

---

[1] *"Controlled substance" means a drug, compound, mixture, preparation, or substance included in Schedule I, II, III, IV, or V, established pursuant to R.C. § 3719.41.*

[2] *"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 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 (R.C. 4729.01(F)).*

Submission of database information

(R.C. 4729.77 and 4729.78)

If the drug database is established and maintained, each pharmacy licensed as a terminal distributor of dangerous drugs that dispenses drugs to patients in Ohio and is included in the types of pharmacies specified in rules to be adopted by the Pharmacy Board must submit to the Board the following prescription information:[3]

(1) Terminal distributor identification;

(2) Patient identification;

(3) Prescriber[4] identification;

(4) Date prescription was issued by the 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.

---

[3] *"Terminal distributor of dangerous drugs" includes pharmacies, hospitals, nursing homes, 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 (R.C. 4729.01).*

[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, including podiatrists; and veterinarians (R.C. 4729.01(I)).*

The bill specifies that the requirement to submit prescription information does not apply to a prescriber personally furnishing or administering a drug to the prescriber's patient.

If the database is established and maintained, each wholesale distributor[5] of dangerous drugs that delivers drugs to prescribers in Ohio must 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.

Each pharmacy or wholesale distributor must transmit the information as specified in rules the Pharmacy Board is to adopt. The information must be submitted electronically in the format specified by the Board, unless the Board has granted a waiver allowing the pharmacy or wholesale distributor to submit the information in another format. The information must be submitted in accordance with any time limits specified by the Board, unless the Board grants the distributor an extension. If the pharmacy or wholesale distributor suffers a mechanical or electronic failure or cannot meet the deadline for other reasons beyond its control, or the Board is unable to receive electronic submissions, the Board may grant a distributor the extension.

---

[5] *"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 (R.C. 4729.01(O) and (Q)).*

Who may receive database information by request or order

(R.C. 4729.79(A) and (D))

If a drug database is established and maintained, the Pharmacy 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 regulation of licensed health 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 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 government entity that employs the officer.

(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 procedures established by the Board in rules, the Board may provide to the individual the individual's own database information.

The bill specifies that it does not require pharmacists or prescribers to obtain information about a patient from the database. 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

(R.C. 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 drug database. Pursuant to rules adopted by the Board, the Board may use these information request 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 responsible for regulation 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 government entity employing the officer of the individual who submitted the requests for database information.

Other public access to database and request information

(R.C. 4729.79(C))

The bill provides that information contained in the drug database and any information obtained from it is not a public record. Also, information contained in the records of requests for information from the database is not a public record. However, information that does not identify a person may be released in summary, statistical, or aggregate form.

Review of the database information

(R.C. 4729.80)

If the Pharmacy Board establishes and maintains a drug database, the Board must review the information in the database. If the Board determines from the review that a violation of law may have occurred, it must notify the appropriate law enforcement agency or a government entity responsible for the regulation 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.

Information retention schedule

(R.C. 4729.81)

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 a government entity that regulates health care professionals authorized to prescribe drugs has submitted a written request to the Board for retention of specific information that pertains to an open investigation.

Charging of fees

(R.C. 4729.82)

The bill prohibits the Pharmacy Board from imposing any charges to any terminal distributor, pharmacist, or prescriber associated with the establishment or maintenance of the database. The bill also prohibits the Board from charging fees for the transmission or receipt of data to and from the database, except that the Board may charge a reasonable fee to an individual who requests the individual's own dangerous drugs database information. The amount of the fee is to be specified by the Board in rules.

Rules for the drug database

(R.C. 4729.83)

For purposes of establishing and maintaining a drug database, the bill requires the Pharmacy Board to adopt rules in accordance with the Administrative Procedure Act (Revised Code Chapter 119.) to carry out and enforce the bill's provisions. The bill requires the Board's rules to specify all of the following:

(1) A means of identifying each patient, terminal distributor, and purchase at wholesale of dangerous drugs about which information is entered into the database;[6]

---

[6] *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 (R.C. 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 (R.C. 4729.54).*

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

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

(4) 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;

(5) 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 that agency or entity;

(6) 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;

(7) 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;

(8) A procedure whereby the Board can use database request records to document and report statistics and law enforcement outcomes;

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

(10) A reasonable fee the Board may charge for providing an individual with the individual's own database information;

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

(12) The types of pharmacies that are required to submit prescription information to the Board for purposes of the database.

Biennial reports

(R.C. 4729.84)

If the drug database is established and maintained, the Pharmacy Board must present a biennial report to the standing committees of the House and Senate primarily responsible for considering health and human services issues. The initial report must be presented not later than two years after the database is established. Each report must include all of the following:

(1) The cost to the state of establishing and maintaining the database.

(2) Information from terminal distributors, 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.

General enforcement authority regarding drugs

(R.C. 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.[7]

General rule-making authority regarding drugs and pharmacists

(R.C. 4729.26)

Current law authorizes the Pharmacy Board to adopt rules in accordance with the Administrative Procedure Act not inconsistent with law, as may be necessary to carry out the purposes of and to enforce the provisions of R.C.

---

[7] *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.*

Chapter 4729. pertaining to the practice of pharmacy.[8] The bill eliminates the phrase, "pertaining to the practice of pharmacy," thereby authorizing the Board to adopt rules as necessary to carry out the provisions of Chapter 4729.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	01-21-04	pp. 1500-1501
Reported, H. Health	05-05-04	pp. 1833-1834
Passed House (73-25)	05-11-04	pp. 1886-1887
Reported, S. Health, Human Services & Aging	---	---

h0377-rs-125.doc/kl

[8] *Currently, two sections authorize the Pharmacy Board to adopt rules: R.C. 4729.26 and 4729.66. The Pharmacy Board prefers that R.C. 4729.66 be repealed and the scope of the rulemaking authority in R.C. 4729.26 be broadened to include the rulemaking authority currently in R.C. 4729.66. (Telephone interview with Tim Benedict, State Board of Pharmacy, April 5, 2004.)*