

CHAPTER NO. 840

SENATE BILL NO. 2534

By McNally, Crowe, Henry, Rochelle, Carter, Burks, Herron

Substituted for: House Bill No. 2450

By Shepard, Tidwell, Black, Caldwell, Hagood, Pinion, Buck, Kent, Ralph Cole

AN ACT To amend Tennessee Code Annotated, Title 53, Chapter 10, relative to controlled substances and to enact the "Controlled Substance Monitoring Act of 2001".

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, is amended by deleting Part 3 in its entirety and by substituting instead the following:

53-10-301. This part shall be known and may be cited as the "Controlled Substance Monitoring Act of 2002".

53-10-302. As used in this part:

(1) "Board" means the Board of Pharmacy created in Tennessee Code Annotated, Title 63, Part 10;

(2) "Commissioner" means the Commissioner of Commerce and Insurance;

(3) "Committee" means the Controlled Substance Database Advisory Committee created in this part;

(4) "Database" means the controlled substance database created in this part;

(5) "Department" means the Department of Commerce and Insurance;

(6) "Dispense" means to physically deliver a controlled substance covered by this chapter to any person, institution or entity with the intent that it be consumed away from the premises in which it is dispensed. It does not include the act of writing a prescription by a practitioner to be filled at a pharmacy licensed by the board; and

(7) "Dispenser" means any Health Care Practitioner who has authority to dispense controlled substances, pharmacists, and pharmacies that dispense to any address within this state.

53-10-303. (a) There is created the controlled substance database advisory committee. The committee members shall be:

(1) The executive director of the Board of Pharmacy, who shall serve as database manager;

(2) The director of the Department of Health's Division of Health-related Boards;

(3) The executive director of the Board of Medical Examiners;

(4) One (1) of the Governor-appointed and licensed members of each of the following health care professional licensure boards or committees to be chosen by the licensing board or committee:

(A) The Board of Medical Examiners;

(B) The Board of Osteopathic Examination;

(C) The Board of Dentistry;

(D) The Board of Registration in Podiatry;

(E) The Optometry Board;

(F) The Board of Veterinary Medical Examiners;

(G) The Board of Nursing;

(H) The Board of Medical Examiners' Committee for Physician Assistants; and

(I) The Board of Pharmacy; and

(5) One (1) of the members of the Board of Pharmacy and one (1) of the members of the Board of Medical Examiners who were appointed to those boards to represent the general public. The boards shall choose those representatives.

(b) The committee shall have a chair and vice-chair, who shall be elected annually from its members.

(c) The committee shall meet at least annually and as often as deemed necessary either at the call of the chair or upon request of at least three (3) members of the committee. A quorum for purposes of official actions by the committee shall be seven (7) members.

(d) The members of the committee chosen to serve by the individual licensure boards and committees, while serving on this committee, shall be deemed to be performing official duties as members of their original board or committee and shall be entitled to the same per diem and travel reimbursements as they would receive for performing their duties for their original board or committee. The member's original board or committee shall pay those per diems and travel reimbursements.

(e) At all times, except when considering, reviewing, discussing, advising or taking action in reference to specifically named individuals or dispensers identified from information contained in, or reported to the database, the committee shall be subject to the provisions of Tennessee Code Annotated, Title 8, Chapter 44, Part 1.

(f) The Commissioner of Commerce and Insurance shall have the authority to promulgate all rules and regulations, pursuant to the Uniform Administrative Procedures Act, necessary for implementation of the provisions of this part. The Commissioner of Commerce and Insurance shall promulgate rules regarding:

- (1) Establishing, maintaining, and operating the database;
- (2) Access to the database and how access is obtained; and
- (3) Control and dissemination of information contained in the database.

(g) The committee shall advise the Commissioner of Commerce and Insurance with respect to any contemplated rulemaking under this part. The committee may make formal recommendations to the Commissioner of Commerce and Insurance.

53-10-304. (a) There is created within the department a controlled substance database to be attached administratively and for purposes of staffing to the Board of Pharmacy. The director of the Board of Pharmacy shall be responsible for determining staffing.

(b) The board and the committee shall establish, administer, maintain and direct the functioning of the database in accordance with this part. The Board of Pharmacy upon concurrence of the committee may, under state procurement laws, contract with another state agency or private entity to establish, operate, or maintain the database. The Board of Pharmacy upon concurrence of the committee shall determine whether to operate the database within the Board of Pharmacy or contract with another entity to operate the database, based on an analysis of costs and benefits.

(c) The purpose of the database is to assist in research, statistical analysis and the education of health care practitioners concerning patients who, by virtue of their conduct in acquiring controlled substances, may require counseling or intervention for substance abuse, by collecting and maintaining data as described in this part regarding all controlled substance in Schedules II, III and IV dispensed in this state.

(d) The data required by this part shall be submitted in compliance with this part to the committee by any practitioner, or person under the supervision and control of the practitioner, pharmacist or pharmacy who dispenses a controlled substance contained in Schedules II, III and IV. The reporting requirement shall not apply for the following:

- (1) A drug administered directly to a patient;
- (2) Any drug dispensed by a licensed health care facility provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours;
- (3) Any drug sample dispensed; or

(4) Any facility that is registered by the United States Drug Enforcement Administration as a narcotic treatment program and is subject to the record keeping provisions of Title 21 CFR 1304.24.

53-10-305. (a) Each dispenser shall, regarding each controlled substance dispensed, submit to the committee all of the following information by a procedure and in a format established by the committee at least monthly within ten (10) days following the last day of each calendar month:

- (1) prescriber identifier;
- (2) dispensing date of controlled substance;
- (3) patient identifier;
- (4) controlled substance dispensed identifier;
- (5) quantity of controlled substance dispensed;
- (6) strength of controlled substance dispensed;
- (7) estimated days supply;
- (8) dispenser identifier; and
- (9) other relevant information as required by rule.

(b) A pharmacy dispenser that uses a computerized system to record information concerning the dispensing of controlled substances listed in Schedule II, III, or IV shall submit the required information to the committee or its agent utilizing nationally recognized pharmacy telecommunications format standards.

(c) The Board of Pharmacy shall maintain the database in an electronic file or by other means established by the committee in such a manner as to not infringe on the legal use of controlled substances, and in such a manner as to facilitate use of the database for identification of:

(1) Prescribing practices and patterns of prescribing and dispensing controlled substances; and

(2) Individuals, facilities or entities receiving prescriptions for controlled substances from licensed practitioners, and who subsequently obtain dispensed controlled substances from a pharmacy in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance, or by means of forged or otherwise false or altered prescriptions.

(d) (1) The committee shall by rule establish the electronic format in which the information required under this section shall be submitted to the committee and shall allow for waiver for individual dispensers for whom it would cause undue hardship.

(2) The committee shall ensure the database system records and maintains for reference:

(A) Identification of each person who requests or receives information from the database;

(B) The information provided to each person; and

(C) The date and time the information is requested or provided.

(e) The committee shall make rules to:

(1) Effectively enforce the limitations on access to the database as described in this chapter; and

(2) Establish standards and procedures to ensure accurate identification of individuals requesting information or receiving information from the database without a request.

53-10-306. (a) Information sent to, contained in, and reported from the database in any format is confidential and not subject to the provisions of Tennessee Code Annotated, Title 10, Chapter 7, and not subject to subpoena from any court and shall be made available only as provided for in 53-10-308 and to the following persons, and in accordance with the limitations stated and rules promulgated pursuant to the part, except that the information shall be subject to production pursuant to an order of a circuit or criminal court in a criminal investigation or pending prosecution subject to the provisions of subsection (b):

(1) Personnel of the committee specifically assigned to conduct analysis or research;

(2) Authorized committee, board, or Departments of Health and Commerce and Insurance personnel engaged in analysis of controlled substances prescription information as a part of the assigned duties and responsibilities of their employment;

(3) A licensed health care practitioner having authority to prescribe or dispense controlled substances, to the extent the information relates specifically to a current patient of the practitioner, to whom the practitioner has prescribed or dispensed or is prescribing or dispensing or considering prescribing or dispensing any controlled substance; or

(4) A licensed pharmacist having authority to dispense controlled substances to the extent the information relates specifically to a current patient to whom that pharmacist has dispensed, is dispensing or considering dispensing any controlled substance.

(b) The District Attorney may apply for an order of a circuit or criminal court directed to the committee to disclose specific information to the District Attorney for purposes of a criminal investigation or pending prosecution. The application for the order shall be accompanied by an affidavit reciting the specific information sought

relative to a specific individual and the nature of the offense under investigation. The affidavit shall be by the District Attorney or other law enforcement officer but only the District Attorney shall have the authority to request the order. The judge may issue an order if the affidavit recites probable cause to believe that a violation of the criminal law has occurred and that the information in the database will be of material assistance in the investigation or prosecution. A copy of the application, affidavit and order shall be retained by the judge issuing the order. A return shall be made promptly to the judge executing the order as to the information acquired by said order. The application, affidavit, order and information may remain under seal and may only be disclosed by the judge issuing the order or by the judge having jurisdiction over the prosecution. A violation of this subsection shall result in the suppression of the information or collateral use of such information in any civil or criminal proceeding. Information obtained through this court order shall remain confidential except to the extent it is used in court for prosecution purposes. Unauthorized use or disclosure of this information shall be subject to the penalties set forth in § 53-10-306.

(c) Any information disseminated pursuant to subsections (a)(3) or (4) shall be sent under the auspices of the committee but shall be sent on the letterhead and under the authority of the licensing board that regulates the licensee who is the recipient and signed by the member of the committee representing that licensing board.

(d) Any licensed practitioner or pharmacist receiving information pursuant to subsections (a)(1) or (2) shall not disclose the information to any person other than:

(1) The patient to whom the information relates and then only for the purpose of adjusting the patient's treatment plans or counseling the patient to seek substance abuse treatment; and

(2) Other dispensers identified by the information and then only for the purposes of verifying the accuracy of the information.

(e) Any person who obtains or attempts to obtain information from the database by misrepresentation or fraud is guilty of a Class A misdemeanor.

(f) Any person who knowingly uses, releases, publishes, or otherwise makes available to any other person or entity any information submitted to, contained in, or obtained from the database for any purpose other than those specified in this part is guilty of a Class A misdemeanor.

53-10-307. (a) The failure of a dispenser to submit information to the database required under this part after the committee has submitted a specific written request for the information or when the committee determines the individual has a demonstrable pattern of failing to submit the information as required is grounds for the denial of licensure, renewal of licensure, or other disciplinary action against the dispenser before the licensing board with jurisdiction over the dispenser and for the committee to take the following actions:

(1) Recommend to the appropriate licensure board that it should refuse to issue a license to the individual;

(2) Recommend to the appropriate licensure board that it should refuse to renew the individual's license; and

(3) Recommend to the appropriate licensure board that it should commence disciplinary action against the licensee seeking revocation, suspension or other appropriate discipline including civil penalties.

(b) An individual or entity who has submitted information to the database in accordance with this part and in good faith shall not be subject to a suit for civil damages nor held civilly liable for having submitted the information.

(c) An individual or entity who in good faith disseminates information contained in, or derived from the database to the individuals authorized by this part to receive it in, the manner authorized by the part or rules promulgated pursuant thereto shall not be subject to a suit for civil damages nor held individually liable for having done so.

(d) No health care practitioner licensed by any board or committee shall be subject to licensure disciplinary action for submitting the information required by this part to the committee and the submission of the information shall not be deemed to be a breach of any confidentiality, ethical duty to a patient, or the sharing of any professional secret.

53-10-308. Notwithstanding any other provision of this part to the contrary, the committee may release confidential information from the database regarding practitioners, patients, or both to the following persons:

(a) A manager of any investigations or prosecution unit of a board, committee, or other governing body that licenses practitioners and is engaged in any investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.

(b) Before the committee releases confidential information under this section, the applicant must petition the committee for it, particularly describe the information required, and demonstrate to the committee that the applicant has reason to believe that a violation under any state or federal law that involves a controlled substance has occurred and that the requested information is reasonably related to the investigation, adjudication, or prosecution of the violation.

(c) No information may be released under this section until it has been reviewed by the committee, including a member of the committee who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data, and until the committee, including that member, has certified that further investigation or prosecution is warranted and that release of the information is necessary to that continued investigation or prosecution.

53-10-309. The committee shall report annually on the outcome of the program with respect to its effect on distribution and abuse of controlled substances, including recommendations for improving control and prevention of the diversion of controlled substances in this state.

SECTION 2. (a) Except as provided hereinafter, the department shall assess the Board of Pharmacy for the costs reasonably associated with providing the services and information pursuant to this act. Further, the department shall provide to the Department of Health all costs reasonably associated with the transmission of such services and information to the boards of providers regulated by the Department of Health and represented in this act.

(b) Notwithstanding any other provision of this act, initial, nonrecurring costs associated with the implementation of this act shall be funded from the reserve account of the Board of Pharmacy.

(c) Recurring costs shall be funded by the Board of Pharmacy (on a pro rata basis according to the number of licensed pharmacists) and the participating health-related boards (on a pro rata basis according to the number of each board's licensees having statutory authority to write prescriptions for controlled substances). All funds received by either the department or the Department of Health through contributions, donations or grant funds specifically designated for the controlled substance database program shall be applied to recurring costs.

SECTION 3. Tennessee Code Annotated, Section 4-29-225(a), is amended by adding a new item thereto, as follows:

() Controlled Substance Database Advisory Committee, created by § 53-10-303;

SECTION 4. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

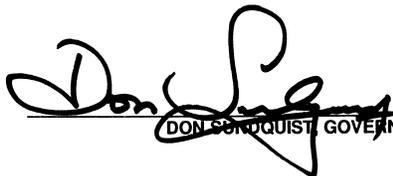
SECTION 5. For purposes of convening the committee, setting up the database for receipt of data and for promulgating rules, this act shall take effect upon becoming law, the public welfare requiring it. For all other purposes, this act shall become effective January 1, 2003, the public welfare requiring it.

PASSED: June 30, 2002


JOHN S. WILDER
SPEAKER OF THE SENATE


JIMMY NAIFEH, SPEAKER
HOUSE OF REPRESENTATIVES

APPROVED this 3rd day of July 2002


DON SUNDQUIST, GOVERNOR