

SENATE BILL 2253

By Norris

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10, Part 3; Title 53, Chapter 11, Part 3; Title 53, Chapter 11, Part 4 and Title 63, Chapter 1, Part 3, relative to controlled substance database, criminal penalties and enforcement of narcotic drugs and drug control.

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

SECTION 1. This act shall be known and may be cited as the "Tennessee Prescription Safety Act of 2012."

SECTION 2. Tennessee Code Annotated, Section 53-10-302, is amended by deleting the section in its entirety and by substituting instead the following:

53-10-302

As used in this part:

- () "Board" means the board of pharmacy created by title 63, chapter 10, part 3;
- () "Commissioner" means the commissioner of health;
- () "Committee" means the controlled substance database committee created by this part;
- () "Database" means the controlled substance database created by this part;
- () "Department" means the department of health;
- () "Dispense" means to physically deliver a controlled substance covered by this part to any person, institution or entity with the intent that it be consumed away from the premises on 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;
- () "Dispenser" means a pharmacist, a pharmacy, or any health care practitioner who has authority to dispense controlled substances;

() “Law enforcement personnel” means agents of the Tennessee bureau of investigation, agents of a judicial district drug task force, federal law enforcement officers commissioned by a federal government entity, certified law enforcement officers certified pursuant to Section 38-8-107, and certified law enforcement officers in other states;

() “Prescriber” means an individual licensed as a medical doctor, podiatrist, dentist, optometrist, veterinarian, osteopathic physician, or physician assistant who has the authority to issue prescriptions for controlled substances, or an advanced practice nurse with a certificate of fitness to prescribe and the required supervisory relationship with a physician;

() “Health care practitioner” means:

(A) A physician, dentist, optometrist, veterinarian, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense or administer a controlled substance in the course of professional practice; or

(B) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to prescribe, distribute, dispense, or administer a controlled substance in the course of professional practice;

() “Controlled substances” means a drug, substance or immediate precursor in Schedules I through VI defined or listed in title 39, chapter 17, part 4;

() “Physician extender” means a registered or licensed health care professional designated by a prescriber or dispenser.

SECTION 3. Tennessee Code Annotated, Section 53-10-303(a), is amended by deleting the word “advisory”.

SECTION 4. Tennessee Code Annotated, Section 53-10-303(f), is amended by deleting the subsection in its entirety and substituting instead the following:

(f) The commissioner of health shall have the authority to promulgate all rules and regulations, pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, necessary for implementation of this part. The commissioner of health shall promulgate rules regarding:

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

and

- (4) The sharing and dissemination of data and information in the database with other states.

SECTION 5. Tennessee Code Annotated, Section 53-10-304(d), is amended by deleting the subsection in its entirety and substituting instead the following:

(d) The data required by this part shall be submitted in compliance with this part to the database by any prescriber, dispenser, or physician extender who dispenses a controlled substance contained in Schedules II, III, and IV, and Schedule V controlled substances identified by the controlled substance database committee as demonstrating a potential for abuse. The reporting requirement shall not apply for the following:

- (1) A drug administered directly to a patient;
- (2) Tramadol dispensed by a licensed veterinarian; provided that the quantity dispensed for an animal to the animal owner or animal owner's agent is limited to an amount equal to the lesser of six hundred milligrams (600 mgs) or a maximum of ninety-six (96) hours;
- (3) Phenobarbital dispensed by a licensed veterinarian; provided that the quantity dispensed for an animal to the animal owner or animal owner's agent is

limited to an amount equal to the lesser of four hundred milligrams (400 mgs) or a maximum of ninety-six (96) hours;

(4) Any drug sample dispensed; or

(5) Any facility that is registered by the United States drug enforcement administration as a narcotic treatment program and is subject to the recordkeeping provisions of 21 CFR 1304.24.

SECTION 6. Tennessee Code Annotated, Section 53-10-305, is amended by deleting the section in its entirety and substituting instead the following:

53-10-305

(a) All prescribers, dispensers, and physician extenders in practice in Tennessee for more than three (3) calendar days per year shall be registered in the controlled substance database.

(b) Each prescriber or dispenser shall, regarding each controlled substance dispensed, submit to the database all of the following information below by a procedure and in a format established by the committee within twenty-four (24) hours. This information shall include:

(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;

(9) Date the prescription was issued by the prescriber;

- (10) Whether the prescription was new or a refill; and
- (11) Source of payment; and
- (12) Other relevant information as required by rule.

(c) If a prescriber or dispenser provides to the committee a statement in writing indicating why it creates a hardship for them to submit this information within twenty-four (24) hours, then they may be permitted up to seven (7) days to submit the information. This seven (7) day extension shall be valid for one (1) year from the date the statement is submitted to the committee or for as long as requested in the hardship statement, whichever is shorter, and may be renewed by the committee upon the written request of the prescriber or dispenser.

(d) A dispenser that uses a computerized system to record information concerning the dispensing of controlled substances, shall submit the required information to the database utilizing nationally recognized pharmacy telecommunications format standards.

(e) The board of pharmacy shall maintain the database in an electronic file or by other means established by the committee in such a manner so as not to 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 and dispensing practices and patterns of prescribing and dispensing controlled substances; and

(2) Individuals, facilities or entities receiving prescriptions for controlled substances from prescribers, and who subsequently obtain dispensed controlled substances from a dispenser 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.

(f) The committee or its designee shall review information in the database. If the committee or its designee determines from review that a violation of the law may have occurred, it shall notify the appropriate law enforcement personnel or board responsible for licensure, regulation, or discipline of prescribers or dispensers authorized to prescribe or dispense drugs and supply information required by the law enforcement personnel or board for an investigation of the violation of the law that may have occurred.

(g)

(1) The committee shall by rule establish the electronic format in which the information required under this section shall be submitted to the database and shall allow for waiver of electronic reporting for individual dispensers for whom it would cause undue hardship as determined by the committee. The waiver shall be valid for one (1) year from ratification by the committee.

(A) The committee may authorize a designee to initially approve a waiver subject to ratification by the committee.

(2) The committee shall ensure the database system records and shall maintain 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.

(h) The committee shall make rules to:

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

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

SECTION 7. Tennessee Code Annotated, Section 53-10-306(a), is amended by deleting the language “persons, and in accordance with the limitations stated and rules promulgated pursuant to this part.” and substituting instead the language “persons in accordance with the limitations stated and rules promulgated pursuant to this part, or as otherwise provided for in Section 53-10-311:”.

SECTION 8. Tennessee Code Annotated, Section 53-10-306(a)(2), is amended by deleting the subdivision in its entirety and substituting instead the following:

(2) Authorized committee, board, or department of health personnel or any designated agent thereof engaged in analysis of controlled substances prescription information as a part of the assigned duties and responsibilities of their employment;

SECTION 9. Tennessee Code Annotated, Section 53-10-306(a)(3), is amended by deleting the subdivision in its entirety and substituting instead the following:

(3) A prescriber conducting medication history reviews who is actively involved in the care of the patient; a prescriber or supervising physician of the prescriber conducting a review of all medications dispensed by prescription attributed to that prescriber; or a prescriber having authority to prescribe or dispense controlled substances, to the extent the information relates specifically to a current patient of the prescriber, to whom the prescriber has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance. Each user shall have a separate identifiable authentication for access;

SECTION 10. Tennessee Code Annotated, Section 53-10-306(a)(4), is amended by deleting the subdivision in its entirety and substituting instead the following:

(4) A dispenser conducting drug utilization or medication history reviews who is actively involved in the care of the patient; or a dispenser having authority to dispense controlled substances to the extent the information relates specifically to a current patient to whom that dispenser has dispensed, is dispensing, or considering dispensing any controlled substance. Each user shall have a separate identifiable authentication for access;

SECTION 11. Tennessee Code Annotated, Section 53-10-306(a)(6), is amended by adding the language “or violations under this part” after the language “controlled substances” and before the language “; and that any law”.

SECTION 12. Tennessee Code Annotated, Section 53-10-306(a), is amended by adding the following language as a new subdivision (7):

() A physician extender, who is acting under the direction and supervision of a prescriber or dispenser, and only to the extent the information relates specifically to a current patient to whom the prescriber or dispenser has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance. Each user shall have a separate identifiable authentication for access;

SECTION 13. Tennessee Code Annotated, Section 53-10-306(h), is amended by deleting the subsection in its entirety and substituting instead the following:

(h) Any licensed prescriber, dispenser or physician extender receiving patient-specific information pursuant to subdivision (a)(1), (a)(2), (a)(3), or (a)(4) shall not disclose the information to any person other than:

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

(2) Other dispensers or prescribers who are involved in the treatment of the patient, or dispensers or prescribers identified by the information for the purpose of verifying the accuracy of the information; or

(3) Any law enforcement personnel to whom reporting of controlled substances being obtained in a manner prohibited by Sections 53-11-401, 402(a)(3) and (a)(6) and required by Section 53-11-309.

SECTION 14. Tennessee Code Annotated, Section 53-10-306(j)(4), is amended by deleting the subdivision in its entirety and substituting instead the following:

(4) The results of the audit conducted pursuant to subdivision (j)(2) shall be discoverable by a prescriber or dispenser charged with violating any state or federal law involving controlled substances or under a notice of charges proffered by a licensing board for a violation of any law involving controlled substances, but only the results pertaining to that prescriber or dispenser are discoverable. If, however, there is an active criminal investigation involving a prescriber or dispenser or the prescriber or dispenser is under investigation by any investigations or prosecution unit of a board, the results of the audit conducted pursuant to subdivision (j)(2) shall not be discoverable by the prescriber or dispenser during either such period.

SECTION 15. Tennessee Code Annotated, Section 53-10-307(a), is amended by deleting the subsection in its entirety and substituting instead the following:

(a) The failure of a prescriber or 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 or renewal of licensure, or other disciplinary action against the prescriber or dispenser before the licensing board with jurisdiction over the prescriber or 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; or

(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.

SECTION 16. Tennessee Code Annotated, Section 53-10-307(d), is amended by deleting the subsection in its entirety and substituting instead the following:

(d) No prescriber or dispenser 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.

SECTION 17. Tennessee Code Annotated, Section 53-10-308(a), is amended by deleting the subsection in its entirety and substituting instead the following:

(a) Notwithstanding any other provision of this part or other state law to the contrary, the committee or its designee may release confidential information from the database regarding dispensers, prescribers, patients, or any of the above, to law enforcement personnel or a manager of any investigations or prosecution unit of a board, committee, or other governing body that licenses dispensers or prescribers and is

engaged in an investigation, adjudication, or prosecution of a violation under any state or federal law that involves a controlled substance. Notwithstanding any other provision of this part or other state law to the contrary, the committee or its designee shall release information from the database when ordered by a court to do so upon the court's finding that disclosure is necessary for the conduct of proceedings before the court regarding the investigation, adjudication, or prosecution of a violation under any state or federal law that involves controlled substances and after an appropriate protective order is issued regarding the information to be released to the court.

SECTION 18. Tennessee Code Annotated, Section 53-10-308(c), is amended by deleting the subsection in its entirety and substituting instead the following:

(c) No information may be released under this section until it has been reviewed by the committee or its designee, and certified that further investigation or prosecution is warranted and that release of the information is necessary to that continued investigation or prosecution. The committee or its designee shall not knowingly release any information which would otherwise violate applicable federal law or regulation protecting the privacy of said information.

SECTION 19. Tennessee Code Annotated, Section 53-10-309, is amended by deleting the word "pharmacist" and substituting instead the word "dispenser".

SECTION 20. Tennessee Code Annotated, Section 53-10-310, is amended by deleting the section in its entirety and substituting instead the following:

53-10-310

(a) Each practice site where a controlled substance is prescribed or dispensed shall provide for electronic access to the database at all times when a prescriber or dispenser provides health care services to a patient potentially receiving a controlled substance.

(b) This section shall not apply to any dispensers that are not required to report pursuant to Section 53-10-304(d).

(c) A violation of subsection (a) is punishable by a civil penalty not to exceed one hundred dollars (\$100) per day assessed against the prescriber or the pharmacy as defined in Section 63-10-204; provided, however, that the penalty shall only be imposed when there is a continued pattern or practice of not providing electronic access to the database.

(d) Any prescriber, dispenser, individual or entity who is authorized to access the database by this part shall not be subject to a suit for civil damages or held civilly liable for the failure to register in, report to, or for check the database, for actions taken after reasonable reliance on information in the database, or accessing the database to determine whether or not the prescriber or dispenser's professional medical credentials are being inappropriately used or for reporting the same to the appropriate authorities, except as otherwise provided in this part.

(e) All prescribers or dispensers, except otherwise exempted under this part, shall check the controlled substance database prior to prescribing or dispensing a controlled substance to a patient at the beginning of a new episode of treatment and shall check the controlled substance database for that patient at least every six (6) months of that episode of treatment.

(f) Each appropriate licensure board shall promulgate rules, pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, to establish penalties for prescribers and dispensers who fail to register in, report to, or check the controlled substance database as required. Failure to promulgate said rules does not prohibit any board, licensing body, or other regulatory entity from taking action as it deems appropriate for failure to comply with this part.

SECTION 21. Tennessee Code Annotated, Title 53, Chapter 10, Part 3, is amended by adding the following as a new section:

53-10-311

Notwithstanding any other provision to the contrary, the commissioner is authorized to enter into agreements with other states providing for the sharing and dissemination of data and information in the database. Disclosure of such agreements shall be consistent with the provisions and limitations set forth in this part. All such agreements shall specifically provide which prescribers, dispensers or law enforcement personnel who are licensed, registered, or certified in other states shall have access to the database.

SECTION 22. Tennessee Code Annotated, Section 53-11-309(a), is amended by adding the word “pharmacist,” after the word “veterinarian,” and before the word “advanced”.

SECTION 23. Tennessee Code Annotated, Section 53-11-402(b)(1), is amended by deleting the subdivision in its entirety and substituting instead the following:

(b)

(1) A violation of this section is a Class D felony, except that a violation of subdivision (a)(6) is a Class A misdemeanor and any violation of subdivision (a)(6) involving more than two hundred fifty (250) units of a controlled substance is a Class E felony.

(A) For purposes of this subdivision, a unit means an amount of a controlled substance in any form that would equate to the initial single individual dosage recommended by the manufacturer of the controlled substance.

SECTION 24. Tennessee Code Annotated, Section 63-1-309(c), is amended by deleting the subsection in its entirety and substituting instead the following:

(c) If any practitioner providing services at a pain management clinic dispenses or prescribes controlled substances for the treatment of chronic nonmalignant pain, the practitioner must document in the patient's record the reason for prescribing or dispensing that quantity.

SECTION 25. This act shall take effect on October 1, 2012, the public welfare requiring it.