HOUSE BILL 2571
By McCormick

SENATE BILL 2552

By Norris

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10; Title 63, Chapter 1; Chapter 791 of the Public Acts of 2014 and Chapter 880 of the Public Acts of 2012, relative to substance abuse.

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

SECTION 1. Tennessee Code Annotated, Section 53-10-301, is amended by deleting the section in its entirety and substituting instead the following:

This part shall be known and may be cited as the "Tennessee Prescription Safety Act of 2016."

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

As used in this part:

(1) "Board" means the board of pharmacy created by title 63, chapter 10, part 3;

(2) "Commissioner" means the commissioner of health;

(3) "Committee" means the controlled substance database committee created by § 53-10-303;

(4) "Controlled substances" means a drug, substance, or immediate precursor in Schedules I through VI defined or listed in the Tennessee Drug Control Act of 1987, compiled in title 39, chapter 17, part 4;

(5) "Database" means the controlled substance database created by § 53-10-304;

(6) "Department" means the department of health;

(7) "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. "Dispense" does not include the act of writing a prescription by a practitioner to be filled at a pharmacy licensed by the board. For purposes of this part, physical delivery includes mailing controlled substances into this state;

(8) "Dispenser" means a pharmacist, a pharmacy, or any healthcare practitioner who is licensed and has current authority to dispense controlled substances;

(9) "Dispensing practice" means an individual pharmacy location licensed by the board of pharmacy;

(10) "Healthcare 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 distribute, dispense, or administer a controlled substance in the course of professional practice;

(11) "Healthcare practitioner extender" means any registered or licensed healthcare professional, and up to two (2) unlicensed persons per prescriber or dispenser designated by the prescriber to act as agents of such prescriber or dispenser. A prescriber or dispenser shall have the ability to authorize a healthcare practitioner extender to check the controlled substance database as stipulated in § 53-10-310(e) for other prescribers in the authorizing prescriber's practice. The prescriber or dispenser shall be responsible for actions taken by their agents pursuant to this part;

(12) "Law enforcement personnel" means agents of the Tennessee bureau of investigation (TBI), agents of a judicial district drug task force, federal law enforcement officers commissioned by a federal governmental entity, United States attorneys, certified law enforcement officers certified pursuant to § 38-8-107, and certified law enforcement officers in other states;

(13) "Manufacturer" means any person, except a pharmacist compounding in the normal course of professional practice, engaged in the commercial production, preparation, propagation, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container and the promotion and marketing of such drugs or devices;

(14) "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; and

(15) "Wholesaler" means a person whose principal business is buying or otherwise acquiring drugs or devices for resale or distribution to persons other than consumers.

SECTION 3. Tennessee Code Annotated, Section 53-10-303, is amended by deleting the section in its entirety and substituting instead the following:

(a) There is created the controlled substance database committee. The committee members shall be:

(1) The executive director of the board of pharmacy;

(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 healthcare 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 board of optometry;

(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 title 8, chapter 44, part 1, regarding public meetings.

(f) The commissioner shall have the authority to promulgate rules, pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, necessary for implementation of this part. The commissioner 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 or other entities acting on behalf of a state.

(g) The committee shall advise the commissioner of health with respect to any contemplated rulemaking under this part. The committee may make formal recommendations to the commissioner.

(h)

(1) The committee shall have the duty to examine database information to identify unusual patterns of prescribing and dispensing controlled substances that appear to be higher than normal, taking into account the particular specialty, circumstances, patient-type, or location of the prescriber or dispenser.

(2)

(A) If the committee determines that a pharmacist or pharmacy has an unusually high pattern of dispensing controlled substances that is

not explained by other factors, it shall refer the pharmacist or pharmacy to the chief board of pharmacy investigator.

(B) When the pharmacy investigator completes the investigation of any pharmacy or pharmacist referred to it by the committee pursuant to this subsection (h), the investigator shall report the results of the investigation back to the committee as follows:

(i) The investigator shall report that the investigation was dismissed if the results of the investigation indicate that the pharmacist or pharmacy had an unusually high dispensing pattern for explainable, legitimate, and lawful reasons; or

(ii) The investigator shall report that the investigation was referred to the pharmacy board if the results indicate that a prescriber has an unusually high pattern of prescribing or dispensing controlled substances that are not explained by other factors.

(C) If the action taken by the board indicates that the pharmacist or pharmacy had an unusually high dispensing pattern for explainable, legitimate, and lawful reasons, the committee shall take that finding into consideration before it again refers the same pharmacist or pharmacy to the investigator based upon similar conduct.

(3)

(A) If the committee determines that a prescriber has an unusually high pattern of prescribing or dispensing controlled substances that are not explained by other factors, it shall refer the prescriber to the health-related boards' investigation unit.

(B) When the boards' investigator completes the investigation of any prescriber referred to it by the committee pursuant to this subsection (h), the investigator shall report the results of the investigation back to the committee as follows:

(i) The investigator shall report that the investigation was dismissed if the results of the investigation indicate that the prescriber had an unusually high dispensing pattern for explainable, legitimate, and lawful reasons; or

(ii) The investigator shall report that the investigation was referred to the health-related boards if the results indicate that a prescriber has an unusually high pattern of prescribing or dispensing controlled substances that are not explained by other factors.

(C) If the action taken by the board indicates that the prescriber had an unusually high dispensing or prescribing pattern for explainable, legitimate, and lawful reasons, the committee shall take that finding into consideration before it again refers the same prescriber to the health-related boards' investigation unit based upon similar conduct.

(4) If a pharmacy investigator or a member of the health-related boards' investigation unit has reason to believe during any part of an investigation that a prescriber or dispenser is in violation of a criminal law, the investigator is authorized to report the conduct to the appropriate district attorney general.

SECTION 4. Tennessee Code Annotated, Section 53-10-304, is amended by deleting the section in its entirety and substituting instead the following:

(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 executive director of the database 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, 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. Additionally, the board, upon concurrence of the committee, shall determine whether to operate the database within the board 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, criminal investigations, enforcement of state or federal laws involving controlled substances, and the education of healthcare 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 substances in Schedules II, III, and IV dispensed in this state, and Schedule V controlled substances identified by the controlled substance database committee as demonstrating a potential for abuse.

(d) The data required by this part shall be submitted in compliance with this part to the database by any dispenser, or dispenser's agent, 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) Any drug sample dispensed;

(3) Any drug dispensed by a licensed veterinarian; provided, that the quantity dispensed is limited to an amount adequate to treat the nonhuman patient for a maximum of forty-eight (48) hours;

(4) 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; or

(5) Any drug dispensed by a licensed healthcare facility; provided, that the quantity dispensed is limited to an amount that is adequate to treat the patient for a maximum of forty-eight (48) hours.

SECTION 5. Tennessee Code Annotated, Section 53-10-305, is amended by deleting the section in its entirety and substituting instead the following:

(a) All prescribers with DEA numbers who prescribe controlled substances and dispensers in practice providing direct care to patients in this state for more than fifteen (15) days per year shall be registered in the controlled substance database. New licensees shall have up to thirty (30) days after notification of licensure to register in the database. Licensed veterinarians who never prescribe a controlled substance in an amount intended to treat a nonhuman patient for more than forty-eight (48) hours shall not be required to register in the database.

(b)

(1) Each dispenser or dispenser's agent shall, regarding each controlled substance dispensed, submit to the database all of the following information:

(A) Prescriber identifier;

(B) Dispensing date of controlled substance;

(C) Patient identifier;

(D) Controlled substance dispensed identifier;

(E) Quantity of controlled substance dispensed;

(F) Strength of controlled substance dispensed;

(G) Estimated days supply;

(H) Dispenser identifier;

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

(J) Whether the prescription was new or a refill;

(K) Source of payment; and

(L) Other relevant information as required by rule.

(2) The information in the database, as required by subdivision (b)(1), shall be submitted by a procedure and in a format established by the committee, for each business day but no later than the close of business on the following business day; provided, that a veterinarian shall submit information at least once every seven (7) days and shall not be required to use a computerized system in order to submit required information pursuant to this section.

(c) The committee shall have the authority to shorten the length of time dispensers are required to submit information to the database through the promulgation of rules pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. When the committee shortens the length of time dispensers are required to submit information to the database, the department shall provide notice to all dispensers who are registered in the database at least sixty (60) days prior to the date in which the rule goes into effect. If the committee shortens the length of time which dispensers must submit information to the database, a dispenser may provide to the committee a written statement indicating why it creates a hardship for that dispenser to submit information within that time period, and the committee may grant an extension up to seven (7) days within which that dispenser must submit the information to the database. Such a

hardship extension shall be valid for two (2) years and may be renewed by the committee upon request of the dispenser.

(d) Any dispenser, except veterinarian dispensers, 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 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 by the committee for identification of:

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

(2) Individuals, facilities, or entities that receive 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 a designee appointed by the committee shall review information in the database. If the committee or its designee determines from review that a prescriber or dispenser may have committed a violation of the law, the committee shall notify the entity responsible for licensure, regulation, or discipline of that prescriber or dispenser and shall supply information required by the entity for an investigation of the violation of the law that may have occurred.

(g)

(1)

(A) 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 may be valid for two (2) years from ratification by the committee.

(B) 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 for a period of at least one (1) year or as determined by the committee:

(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 6. Tennessee Code Annotated, Section 53-10-306, is amended by deleting the section in its entirety and substituting instead the following:

(a) Information sent to, contained in, and reported from the database in any format is confidential and not subject to title 10, chapter 7, regarding public records, 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 in accordance with the limitations stated and rules promulgated pursuant to this part, or as otherwise provided for in § 53-10-311:

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

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

(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 or bona fide prospective 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 authorized individual referenced under this subdivision (a)(3) shall have a separate identifiable authentication for access;

(4) A dispenser or pharmacist not authorized to dispense controlled substances 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 or a bona fide prospective patient to whom that dispenser has dispensed, is dispensing, or considering dispensing any controlled substance.

Each authorized individual referenced under this subdivision (a)(4) shall have a separate identifiable authentication for access;

(5) A county medical examiner appointed pursuant to § 38-7-104 when acting in an official capacity as established in § 38-7-109; provided, any access to information from the database shall be subject to the confidentiality provisions of this part except where information obtained from the database is appropriately included in any official report of the county medical examiners, toxicological reports, or autopsy reports issued by the county medical examiner under § 38-7-110(c);

(6) Personnel of the following entities actively engaged in analysis of controlled substances prescription information as a part of their assigned duties and responsibilities related directly to TennCare:

(A) The office of inspector general;

(B) The Medicaid fraud control unit; and

(C) The bureau of TennCare's chief medical officer, associate chief medical directors, director of quality oversight, and associate director of pharmacy;

(7) A quality improvement committee as defined in § 68-11-272 of a hospital licensed under title 68 or title 33, as part of the committee's confidential and privileged activities under § 68-11-272(b)(4) with respect to the evaluation, supervision, or discipline of a healthcare provider employed by the hospital or any of its affiliates or subsidiaries, who is known or suspected by the hospital's administrator to be prescribing controlled substances for the prescriber's personal use;

(8) Law enforcement personnel; provided, that such personnel are engaged in the official investigation and enforcement of state or federal laws involving controlled substances or violations under this part; and that any law enforcement personnel receiving information from the database pursuant to this section shall comply with the requirements of this subsection (a), and the following:

(A)

(i) Any law enforcement personnel, United States attorney or judicial district drug task force that wants one (1) or more of its officers or agents to have the authorization to request information from the database shall first preapprove each such officer. Preapproval shall be by the applicant's supervisor. The list of preapproved applicants shall be sent to the district attorney general or United States attorney in the judicial district in which the agency or task force has jurisdiction;

(ii) By December 1 of each year, each district attorney general or United States attorney shall send to the board a list of applicants authorized to request information from the database from that general's or United States attorney's judicial district for the next calendar year;

(B)

(i) If the Tennessee bureau of investigation (TBI) wants one (1) or more of its agents to have the authorization to request information from the database, each such agent shall first be preapproved by the agent's immediate supervisor and division

head. Approved applicants shall be sent to the board by the director;

(ii) By December 1 of each year, the TBI director shall send to the board a list of applicants authorized to request information from the database from the TBI for the next calendar year;

(C) An application submitted by law enforcement personnel shall include, but not be limited to, the:

(i) Applicant's name; title; agency; agency address; agency contact number; agency supervisor; and badge number, identification number or commission number; and the business e-mail address of each applicant officer or agent, the appropriate district attorney general, United States attorney and, if a TBI agent, the TBI director and their business e-mail addresses; and

(ii) Signatures of the applicant, the applicant's approving supervisor, and the district attorney general or United States Attorney of the judicial district in which the applicant has jurisdiction, or the approving division head and the TBI director; and

(D) It shall be a duty of the board, as part of its duties to maintain the database pursuant to § 53-10-304(c), to receive and verify the lists of authorized applications sent to it by the district attorneys general, United States attorneys, and the director of the TBI pursuant to this subsection (a);

(9) The judge of a drug court treatment program, created pursuant to the Drug Treatment Court Act of 2003, compiled in title 16, chapter 22 to the extent the information relates specifically to a current participant in the drug court treatment program. Any judge or personnel of a drug court treatment program receiving information from the database pursuant to this subdivision (a)(9) shall comply with the requirements of this subsection (a) and the following:

(A) Any judge of a participating drug court requesting information from the database shall submit an application to the board pursuant to subdivision (a)(9)(B) that must include acknowledgment by the district attorney general of the judge's judicial district that the judge is seeking information from the database on a current participant in the drug court treatment program;

(B) An application submitted by the judge of a drug court treatment program shall include:

(i) The applicant's name, title, agency, agency address, and business e-mail address;

(ii) The signatures of the judge and the district attorney general of the judicial district in which the judge has jurisdiction; and

(iii) The names of any current participants in the drug court treatment program that the judge has a reasonable belief may not be in compliance with the guidelines or rules of participation in the drug court treatment program as they pertain solely to the participant's unauthorized use or misuse of controlled substances.

Such information shall not be considered a public record as defined by § 10-7-503; and

(C) The board shall, as part of the duty to maintain the database pursuant to § 53-10-305(e), receive the authorized application sent by the judge of the participating drug court treatment program pursuant to this subsection (a); or

(10) A healthcare practitioner extender, who is acting under the direction and supervision of a prescriber or dispenser as an agent of the prescriber or dispenser. Each authorized individual referenced under this subdivision (a)(10) shall have a separate identifiable authentication for access.

(b) When requesting information from the database, the board shall require law enforcement personnel to provide a case number as part of the process for requesting information from the database. The case number entered shall correspond with an official investigation involving controlled substances and information requested should directly relate to the investigation.

(c) The board of pharmacy shall by rule, establish a fee for providing information to a law enforcement agency, a judicial district drug task force, the offices of the United States attorney, the TBI, or a judge of a drug court treatment program pursuant to this section. In determining the fee and type of fee to be charged, the board shall consider options such as an annual fee or a per use, incremental cost basis fee, or other methods as the committee deems appropriate.

(d)

(1) Law enforcement personnel, judicial district drug task force agents, and agents of the offices of the United States attorneys who are authorized to request information from the database shall resubmit their identifying application

information that was submitted pursuant to subdivision (a)(8)(C) to the appropriate district attorney or United States attorney by November 20 of each year. Such resubmitted applications shall be sent by the appropriate district attorney general or United States attorney to the board by December 1 of each year. If during the calendar year a name is added to the list, removed from the list, or information about a person on the list changes, the appropriate district attorney or United States attorney shall immediately notify the board of any changes to the list submitted or in the information submitted for each officer or agent on the list application.

(2) TBI agents who are authorized to request information from the database shall resubmit their identifying application information that was submitted pursuant to subdivision (a)(8)(B) to the TBI director by November 20 of each year. Such resubmitted applications shall be sent by the TBI director to the board by December 1 of each year. If during the calendar year a name is added to the list, removed from the list, or information about a person on the list changes, the TBI director shall immediately notify the board of any changes to the list submitted or in the information submitted for each officer or agent on the list application.

(e)

(1) Information obtained by law enforcement personnel from the database may be shared with other law enforcement personnel or prosecutorial officials, only upon the direction of the officer or agent who originally requested the information and may only be shared with law enforcement personnel from other law enforcement agencies who are directly participating in an official joint investigation.

(2) Any information obtained from the database that is sent to a law enforcement official or a judicial district drug task force agent shall also be sent to the district attorney general of the judicial district in which such officer or agent has jurisdiction. Likewise, any database information sent to a TBI agent shall also be sent to the TBI director.

(3)

(A) Information obtained from the database by the judge of a drug court treatment program may be shared with personnel of a drug court treatment program.

(B) For the purposes of this subdivision (e)(3), "personnel of a drug court treatment program" includes a judge of a drug court and any person employed by the drug court and designated by the judge to require access to the information in order to efficiently administer the drug court treatment program.

(4) Any information obtained from the database that is sent to a judge of a drug court treatment program shall also be sent to the district attorney general of the judicial district in which the judge has jurisdiction.

(f)

(1) To ensure the privacy and confidentiality of patient records, information obtained from the database by law enforcement personnel shall be retained by the law enforcement personnel's respective department or agency. The information obtained from the database shall not be made a public record, notwithstanding the use of the information in court for prosecution purposes. Information obtained from the database shall be maintained as evidence in

accordance with each law enforcement agency's respective procedures relating to the maintenance of evidence.

(2) To ensure the privacy and confidentiality of patient records, information obtained from the database by a drug court treatment program shall be retained by the program director of the drug court treatment program. The information obtained from the database shall not be made a public record, notwithstanding the use of the information in court for prosecution purposes.

(g) Any information disseminated pursuant to subdivisions (a)(1)-(7) shall be released to the individual or entity requesting the information by the database manager or by password protected Internet access.

(h) Any prescriber, dispenser, or healthcare practitioner 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 or have a bona fide prospective involvement in the treatment of the patient, or dispensers or prescribers identified by the information for the purpose of verifying the accuracy of the information;

(3) Any law enforcement personnel to whom reporting of controlled substances being obtained in a manner prohibited by § 53-11-401, § 53-11-402(a)(3), or (a)(6), and required by § 53-11-309, or any agent of the prescriber who is directed by the prescriber to cause a report to law enforcement to be made in accordance with § 53-11-309(a) and (d); or

(4) A prescriber, healthcare practitioner extender, or dispenser who may place a copy of a patient's report obtained from the database pursuant to this section in that patient's medical records. Once placed in a patient's medical records, any copy of a patient's report obtained from the database pursuant to this section shall be subject to disclosure on the same terms and conditions as medical records defined under §§ 63-2-101 and 63-1-117.

(i) If a law enforcement officer, judicial district drug task force agent, TBI agent, or a judge of a drug court treatment program has probable cause to believe, based upon information received from a database request, that a prescriber or pharmacist may be acting or may have acted in violation of the law, the officer, agent, or judge shall consult with the board of pharmacy inspector's office, if a pharmacist, or the health-related boards' investigations unit, if a prescriber.

(j)

(1) At least every six (6) months, the board shall send a list to each district attorney general and United States attorney containing all requests made for database information during the previous six (6) months. The list shall include the name of the requesting officer or agent, the officer or agent's agency, the date of the request, and the nature of the request, including the case number, for each officer or agent making a request in such district attorney's judicial district. Likewise, a list shall be sent to the director of the TBI for all TBI agents making requests during the previous six (6) months.

(2) Each district attorney general and the TBI director shall use the list to perform an audit to determine if the database information requests made during the preceding six-month period correspond to specific cases under investigation

in the applicable judicial district or by the TBI and if the information requested is relevant and pertinent to an investigation.

(3) Each district attorney general and the TBI director shall verify all database information requests contained on the list received and send it back to the board within sixty (60) days of receipt. If a database information request does not correspond to an investigation in the applicable jurisdiction or if the information requested was not relevant or pertinent to the information requested, the district attorney general or director shall so note on the verified list and shall investigate the discrepancy and make a report back to the board within a reasonable period of time.

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

(k)

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

(2) 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.

(3) Intentional unauthorized use or disclosure of database information by law enforcement personnel, judicial district drug task force members, TBI agents, or agents of the offices of the United States attorneys shall be punishable as a Class A misdemeanor.

(4) Any law enforcement personnel, judicial district drug task force member, TBI agent, or agent of the offices of the United States attorneys charged with a violation of this section shall have such person's authorization to request information from the database suspended pending final disposition of any criminal prosecution. Any law enforcement personnel, judicial district drug task force member, TBI agent, or agent of the offices of the United States attorney found guilty of a violation of this subsection (k) shall have such person's authorization to request information from the database permanently revoked.

(5) Where an individual authorized under subsection (a) acts in good faith in accessing or using information from the database in accordance with the limitations under this part, that person shall not incur any civil or criminal liability as a result of that use or access.

(l)

(1) The following personnel of the department of mental health and substance abuse services actively engaged in analysis of controlled substances

prescription information as a part of their assigned duties and responsibilities shall have access to the database for controlled substances prescription information for specific patients or prescribers:

(A) The chief pharmacist;

(B) The state opioid treatment authority (SOTA) or SOTA designee; and

(C) The medical director.

(2) Aggregate controlled substances prescribing information from the database which does not contain personally identifiable data may be provided upon request by the following personnel of the department of mental health and substance abuse services, who are actively engaged in analysis of controlled substances prescription information as provided in this subsection (l), and may be provided upon request to other personnel of the department of mental health and substance abuse services and other state government agencies as needed to fulfill assigned duties and responsibilities:

(A) The chief pharmacist;

(B) The SOTA; or

(C) The medical director.

(m) Where an investigation is conducted under § 38-7-109, and information within the database is obtained pursuant to the requirements of this part, there exists a rebuttable presumption that the county medical examiner is acting in good faith.

(n) Authorized committee, board, or department personnel and any designee appointed by the committee engaged in analysis of controlled substances prescription information as a part of the assigned duties and responsibilities of their employment may publish, or otherwise make available to prescribers, dispensers, and the general public,

aggregate unidentifiable personal data contained in or derived from the database for the purpose of educational outreach.

(o) Prohibited access to, an inappropriate request for, or illegal disclosure of information from the database by a judge of a drug court treatment program shall be considered a violation of the canons of the code of judicial conduct, including Rules 1.2, 1.3, and 3.5.

SECTION 7. Tennessee Code Annotated, Section 53-10-307, is amended by deleting the section in its entirety and substituting instead the following:

(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 that 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 that 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 this part or rules promulgated pursuant to this part, shall not be subject to a suit for civil damages nor held individually liable for having done so.

(d) Submitting the information as required by this part shall not subject the person submitting the information to licensure disciplinary action or any action for breach of confidentiality, ethical duty to a patient, or the sharing of any professional secret.

SECTION 8. Tennessee Code Annotated, Section 53-10-308, is amended by deleting the section in its entirety and substituting instead the following:

(a) Notwithstanding any other provision of this part to the contrary, the committee or its designee:

(1) After consultation with the member of the committee who represents the board which has licensed the individual being considered for investigation, may release confidential information from the database regarding dispensers, prescribers, healthcare practitioner extenders, or patients, to a manager of any investigations or prosecution unit of an appropriate licensure board, committee, or other governing body that licenses or registers dispensers, prescribers, or healthcare practitioner extenders and is engaged in an investigation, adjudication, or prosecution of a violation under any state or federal law that involves a controlled substance;

(2) May release confidential information from the database regarding patients to law enforcement personnel engaged in an investigation, adjudication, or prosecution of a violation under any state or federal law that involves a controlled substance, pursuant to the procedure established in § 53-10-306(a)(8); and

(3) 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.

(b) Before the committee releases confidential information under this section, the applicant must petition the committee for the confidential information, 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 or its designee and the member of the committee who represents the board which has licensed the individual being considered for investigation, and certified that further investigation or prosecution is warranted and that release of the information is necessary to that continued investigation or prosecution. Any data authorized to be released under this section or § 53-10-306, other than aggregate data or data released to personnel of the department or a health-related board is limited to reports of drugs prescribed to specific patients or prescribed by specific providers. Nothing in this part shall create a right to other data such as provider query audits or registration information, nor does anything in this part require the committee or department to provide analytics or analysis of any data available in the database.

SECTION 9. Tennessee Code Annotated, Section 53-10-309, is amended by deleting the section in its entirety and substituting instead the following:

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 diversion of controlled substances in this state. The committee's annual report shall include information about the prescribing and dispensing patterns of prescribers and dispensers, and this data shall be made available electronically to prescribers and dispensers in a format that will allow them to compare their prescribing and dispensing patterns to those of their peers. The committee shall also file an annual report with the health and welfare committee of the senate and the health committee of the house of representatives starting on or by February 1, 2008, and each year thereafter to include a monthly analysis about tracking the individuals or entities that access the database and the security measures taken to ensure that only authorized persons or entities access the database. In addition to the annual report submitted to the general assembly by the committee, authorized committee, board, or department of health personnel engaged in analysis of controlled substance prescription information as a part of the assigned duties and responsibilities of their employment shall release information from the database requested by a member of the general assembly that is related to research, statistical analysis, or education of healthcare practitioners relative to controlled substances. However, no report released pursuant to this section shall contain the name or other identifying information of a specific prescriber, dispenser, or healthcare practitioner extender contained in the report. All information released from the database for such a report shall be in the aggregate.

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

(a) Each person or entity operating a practice site where a controlled substance is prescribed or dispensed to a human patient shall provide for electronic access to the

database at all times when a prescriber or dispenser provides healthcare services to a human patient potentially receiving a controlled substance.

(b) This section shall not apply to any dispensers that are not required to report pursuant to § 53-10-304(d) or § 53-10-305(g).

(c) A violation of subsection (a) is punishable by a civil penalty not to exceed one hundred dollars ($100) per day assessed against the person or entity operating the practice site; 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 check the database, or 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)

(1) All prescribers or their designated healthcare practitioner's extenders and all dispensing practices, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing or dispensing one (1) of the controlled substances identified in subdivision (e)(3) to a human patient at the beginning of a new episode of treatment and shall check the controlled substance database for that human patient at least annually when that prescribed controlled substance remains part of the treatment. A new episode of treatment means a prescription that has not been prescribed or dispensed by that prescriber or dispensing practice within the previous twelve (12) months.

(2) Before prescribing or dispensing, prescribers and dispensers shall have the professional responsibility to check the database or have a healthcare practitioner extender check the database if the prescriber or dispenser is aware or reasonably certain that a person is attempting to obtain a Schedule II-V controlled substance, identified by the committee as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of § 53-11-402.

(3) The controlled substances which trigger a check of the controlled substance database pursuant to subdivision (e)(1) include, but are not limited to, all opioids and benzodiazepines. By rule, the committee may require a check of the database for additional Schedule II-V controlled substances that are identified by the committee as demonstrating a potential for abuse.

(4) The board shall adopt rules in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, that establish standards and procedures to be followed by a dispenser regarding the review of patient information available through the database.

(5) Prescribers are not required to check the controlled substance database before prescribing or dispensing one (1) of the controlled substances identified in subdivision (e)(3) or added to that list by the committee if one (1) or more of the following conditions is met:

(A) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(B) The committee has determined that prescribers in a particular medical specialty shall not be required to check the database as a result

of the low potential for abuse by patients receiving treatment in that medical specialty;

(C) The controlled substance is prescribed or dispensed to a patient as a nonrefillable prescription as part of treatment for a surgical procedure that occurred in a licensed healthcare facility and is limited to a seven-day supply; or

(D) The controlled substance is prescribed for administration directly to a patient during the course of inpatient or residential treatment in a hospital or nursing home licensed under title 68.

(f) Each appropriate licensure board shall promulgate rules pursuant to the Uniform Administrative Procedures Act, to establish procedures, notice requirements, and penalties for prescribers and dispensers who fail to register in, report to, or check the controlled substance database as required.

(g) Notwithstanding any other provision of this part to the contrary, a prescriber, dispenser, or healthcare practitioner extender shall not be in violation of this part during any time period in which the controlled substance database is suspended or not operational, or the Internet is not operational or available as defined by rules promulgated by the commissioner after consultation with the committee.

SECTION 11. Tennessee Code Annotated, Section 53-10-311, is amended by deleting the section in its entirety and substituting instead the following:

Notwithstanding any other provision of this part to the contrary, the commissioner is authorized to enter into agreements with other states or other entities acting on behalf of a state for the purposes of 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, healthcare practitioner extenders, or law enforcement personnel who are licensed, registered, or certified in other states shall have access to the database.

SECTION 12. Tennessee Code Annotated, Section 53-10-312, is amended by deleting the section in its entirety and substituting instead the following:

(a) Wholesalers and manufacturers, as defined in § 63-10-204, that sell controlled substances at wholesale must at least report the following information to the committee in Automation of Reports and Consolidated Orders System (ARCOS) format or other mutually acceptable format:

(1) Wholesaler or manufacturer with a drug enforcement administration registration number; provided, that if this number is not applicable, then another mutually acceptable identifier;

(2) Purchaser's drug enforcement administration registration number; provided, that if this number is not applicable, then another mutually acceptable identifier;

(3) National drug code number of the actual drug sold;

(4) Quantity of the drug sold;

(5) Date of sale; and

(6) Transaction identifier or invoice number.

(b) The department of health shall establish such rules as are necessary to specify which medications shall be reported, the time frames for such reporting, and other reporting requirements as required.

(c) A wholesaler shall design and operate a system to disclose to the wholesaler suspicious orders of controlled substances. A wholesaler shall inform the board of pharmacy and the boards whose licensees have prescribing authority of suspicious

orders when discovered. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(d) In the event of the discovery of the theft or significant loss of controlled substances, a wholesaler shall report such theft or significant loss to the committee and local law enforcement within one (1) business day of discovery of the theft or loss.

SECTION 13. Section 29 of Chapter 880 of the Public Acts of 2012, is amended by deleting the following language:

The provisions of this act shall expire and be of no force and effect after June 30, 2016, and on July 1, 2016, the existing provisions of Tennessee Code Annotated, Title 53, Chapter 10, Part 3, shall be revived and reenacted as they were codified on March 1, 2012.

SECTION 14. Section 8 of Chapter 791 of the Public Acts of 2014, is amended by deleting the following language:

and expire June 30, 2016,

SECTION 15. If any provision of this act or the application of any provision of this act to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end the provisions of this act are declared severable.

SECTION 16. This act shall take effect upon becoming a law, the public welfare requiring it.