Title 53 Food, Drugs And Cosmetics
Chapter 10 Legend Drugs
Part 3 Tennessee Prescription Safety Act of 2016

Tenn. Code Ann. § 53-10-301 thru § 53-10-312 (2016)

53-10-301. Short title.

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

HISTORY: Acts 2016, ch. 1002, § 1.

53-10-302. Part definitions.

As used in this part, unless the context requires otherwise:

(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 1989, 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) "Director" means the director of the controlled substance database, who shall be a Tennessee licensed pharmacist designated by the commissioner, in consultation with the executive director of the board of pharmacy and with the committee, to administer, maintain, and direct the operation and function of the controlled substance database;

(8) "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;

(9) "Healthcare practitioner," for the purposes of this part only, means:

(A) A person licensed, registered, or otherwise permitted to prescribe, distribute, or dispense a

controlled substance in the course of professional practice;

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

(C) A certified registered nurse anesthetist (CRNA) as described in § 63-7-103;

(10) "Healthcare practitioner delegate" means any person authorized to practice pursuant to title 63, and up to two (2) unlicensed persons per healthcare practitioner designated by the healthcare practitioner to act as agents of the healthcare practitioner, upon registering the delegates and providing any information required by the department. A healthcare practitioner shall have the ability to authorize a healthcare practitioner delegate to check the controlled substance database as stipulated in this part. The healthcare practitioner shall be responsible for actions taken by their healthcare practitioner delegates pursuant to this part;

(11) "Law enforcement personnel" means agents of the Tennessee bureau of investigation, agents of a judicial district drug task force, drug enforcement administration agents, and certified law enforcement officers certified pursuant to § 38-8-107, and certified law enforcement officers by other states;

(12) "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;

(13) "Operations committee" means the operations committee created by this part to consult with and confirm or deny decisions made by the commissioner within the authority granted to the commissioner by this part; and

(14) "Wholesaler" or "wholesale distributor" means a person primarily engaged in the wholesale distribution of drugs or devices; provided, that "wholesaler" or "wholesale distributor" does not include licensed third-party logistics providers. For the purposes of this part, transfers and sales of drugs or devices from one (1) licensed pharmacy to another shall not constitute wholesale distribution of drugs or devices.

HISTORY: Acts 2016, ch. 1002, § 2.

53-10-303. Controlled substance database committee.

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

(1) One (1) of the governor-appointed 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 podiatric medical examiners;

(E) The board of optometry;

(F) The board of veterinary medical examiners;

(G) The board of nursing;

(H) The board of medical examiners' committee on physician assistants; and

(I) The board of pharmacy; and

(2) 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 respective licensure boards and committees, while serving on this committee, shall be deemed to be performing official duties as members of their respective 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 respective board or committee. The respective board or committee of each member shall pay such per diem and travel reimbursement.

(e) At all times, except when considering, reviewing, discussing, advising, or taking action in reference to specifically named individuals or healthcare practitioners 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. Pursuant to § 53-10-311 the commissioner may 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 control, 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 with respect to any contemplated rulemaking under this part. The committee may make formal recommendations to the commissioner.

(h) (1) The committee and the commissioner shall have the right to examine database information to identify unusual patterns of prescribing, distributing, or dispensing controlled substances that appear to be higher than normal, taking into account the particular specialty, circumstances, patient type, or location of the healthcare practitioner.

(2) If the committee or the commissioner determines that a healthcare practitioner has an unusually high pattern of prescribing, distributing, or dispensing controlled substances that is not explained by other factors, the committee or the commissioner shall refer the healthcare practitioner to the appropriate licensing board.

(3) If an investigator in service of a health-related board as licensed under title 63 or title 68 has reason to believe during any part of an investigation that a healthcare practitioner is in violation of a criminal law, the investigator is authorized to report the conduct to the appropriate law enforcement personnel.

HISTORY: Acts 2016, ch. 1002, § 3.

53-10-304. Controlled substance database -- Director -- Administration -- Requirements.

(a) There is created within the department a controlled substance database. The director of the controlled substance database shall be responsible for determining staffing in consultation with the executive director of the board of pharmacy.

(b) The director shall administer, maintain, and direct the functioning of the database in accordance with this part. The department in consultation with the committee and board may, under state procurement laws, contract with another state agency or private entity to establish, operate, or maintain the database. Additionally, the department, in consultation with the committee and board, shall determine whether to operate the database within the department 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 increase the quality of patient care by equipping healthcare

practitioners with accurate, timely information that the practitioners can use to determine when patients 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. Further, the database is to be used to assist in research, statistical analysis, criminal investigations, enforcement of standards of health professional practice, and state or federal laws involving controlled substances.

(d) The data required by this part shall be submitted in compliance with this part to the database by any healthcare practitioner who dispenses a controlled substance contained in Schedules II, III, and IV, and Schedule V controlled substances identified by the committee as demonstrating a potential for abuse, or by any healthcare practitioner delegate who is designated to submit data on a healthcare practitioner's behalf. The reporting requirement shall not apply for the following:

(1) A drug administered directly to a patient;

(2) Complimentary packages of medicinal drugs that are labeled as a drug sample or complimentary drug dispersed to the practitioner's own patients adequate to treat the patient for a maximum of forty-eight (48) hours in the regular course of practice without the payment of a fee or remuneration of any kind;

(3) A sample of a schedule IV or schedule V controlled substance in a quantity limited to an amount that is adequate to treat a patient for a maximum of seventy-two (72) hours or a sample of a non-narcotic schedule V controlled substance in a quantity limited to an amount that is adequate to treat a patient for a maximum of fourteen (14) days, provided without charge by a medical doctor, osteopathic physician, advanced practice nurse with certificates of fitness to prescribe, or physician assistant working at a pain management clinic from providing to that practitioner's patient;

(4) 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 five (5) days;

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

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

HISTORY: Acts 2016, ch. 1002, § 4.

53-10-305. Submission of information -- Data format.

(a) All healthcare practitioners who prescribe or dispense controlled substances in practice providing direct care to patients in this state by prescribing or dispensing on more than fifteen (15) days in a

calendar year total and are required to have a federal drug enforcement administration (DEA) registration pursuant to federal law shall be registered in the controlled substance database. Healthcare practitioners or their agents shall have up to thirty (30) calendar days after receiving a DEA number to register in the database; such privilege shall apply equally to both prescribers and dispensers. Licensed veterinarians who never prescribe or dispense controlled substances in an amount intended to treat a nonhuman patient for more than five (5) days shall not be required to register in the database.

(b) (1) Each healthcare practitioner or healthcare practitioner'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 fourteen (14) days and shall not be required to use a computerized system in order to submit required information pursuant to this section.

(c) The commissioner, pursuant to § 53-10-311, shall have the authority to change the length of time in which healthcare practitioners 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 in which healthcare practitioners are

required to submit information to the database, the department shall provide notice to all healthcare practitioners 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, pursuant to § 53-10-311, shortens the length of time in which healthcare practitioners must submit information to the database, a healthcare practitioner may provide to the committee a written statement indicating why it creates a hardship for that healthcare practitioner to submit information within that time period, and the committee may grant an extension of up to seven (7) days within which that healthcare practitioner shall 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 healthcare practitioner.

(d) Any healthcare practitioner, except veterinarian healthcare practitioners, 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 commissioner, pursuant to § 53-10-311, shall maintain the database in an electronic file or by other means established by the commissioner 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 that receive prescriptions for controlled substances from healthcare practitioners, and who subsequently obtain dispensed controlled substances from a healthcare practitioner 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 the commissioner or a designee appointed by the committee or commissioner may review information in the database. If the committee or commissioner or their designee determines from review that a healthcare practitioner has committed a violation of the law, the committee or commissioner shall notify the entity responsible for licensure, regulation, or discipline of that healthcare practitioner 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 commissioner, pursuant to § 53-10-311, shall by rule establish the electronic format in which the information required under this section shall be submitted to the database, and the committee shall allow for waiver of electronic reporting for individual healthcare practitioners 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 commissioner shall ensure the database system records and maintains for reference, for a period of at least one (1) year:

(A) The 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 commissioner, in consultation with 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.

HISTORY: Acts 2016, ch. 1002, § 5.

53-10-306. Confidentiality -- Disclosure of information -- Penalties.

(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 their assigned duties and responsibilities;

(3) A healthcare practitioner conducting medication history reviews who is involved in the care of a patient or making decisions regarding patient care or patient enrollment; a healthcare practitioner or supervising physician of a healthcare practitioner conducting a review of all medications dispensed by prescription attributed to that healthcare practitioner or a healthcare practitioner 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 healthcare practitioner, to whom the healthcare practitioner has prescribed or dispensed, is prescribing, dispensing, approving of the 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 licensed pharmacist conducting drug utilization or medication history reviews who is actively

involved in the care of the patient or making decisions regarding care of the patient or patient enrollment. Each authorized individual referenced under this subdivision (a)(4) shall have a separate identifiable authentication for access;

(5) The state chief medical examiner, or deputy state chief medical examiner appointed pursuant to § 38-7-103, or 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, state chief medical examiner, or deputy state chief 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 the TennCare program:

(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 directors of pharmacy;

(7) Personnel of the bureau of TennCare who request aggregate controlled substances prescribing information from the database which does not contain personally identifiable data but only on request by the following personnel of the bureau:

(A) The chief medical officer;

(B) Associate chief medical directors;

(C) Director of quality oversight; and

(D) Directors of pharmacy;

(8) 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 healthcare practitioner's personal use;

(9) (A) 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 this subsection (a);

(B) Any law enforcement personnel; provided, that for an officer or agent to have the authorization to request information from the database, the officer or agent shall first be preapproved. Preapproval shall require:

(i) Agents of a judicial drug task force employed by the United States department of justice, law enforcement officers certified pursuant to § 38-8-107, and law enforcement officers certified by other states to require:

(a) The list of preapproved agents to be sent to the district attorney general in the judicial district in the district in which the task force has jurisdiction; and

(b) By December 1 of each year, each district attorney general shall send to the director a list of applicants authorized to request information from the database from that general's judicial district; or

(ii) Tennessee bureau of investigation (TBI) agents or drug enforcement administration agents to require:

(a) Preapproval by the assistant special agent in charge or the agent's immediate supervisor and division head. Approved applicants shall be sent to the board by the director; and

(b) By December 1 of each year, the TBI director or the assistant special agent in charge shall send to the director of the controlled substance database, committee, or commissioner a list of applicants authorized to request information from the database;

(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, DEA agent, 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 of the judicial district, assistant special agent in charge in which the applicant has jurisdiction, or the approving division head and the TBI director; and

(D) It shall be a duty of the committee or commissioner, through the director, as part of the duties to maintain the database pursuant to § 53-10-305(e), to receive and verify the lists of authorized applications sent to it by the district attorneys general, assistant special agent in charge, and the director of the TBI pursuant to this subsection (a);

(10) The judge of a drug court treatment program, created under the Drug Court Treatment Act of 2003, compiled in title 16, chapter 22, and pursuant to this part 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)(10) shall comply with 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 director pursuant to subdivision (a)(10)(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 commissioner, through the director, shall, as part of the duty to maintain the database pursuant to this part, receive the authorized application sent by the judge of the participating drug court treatment program pursuant to this subsection (a); and

(11) A healthcare practitioner delegate, who is acting under the direction and supervision of a healthcare practitioner as an agent of a healthcare practitioner. Each authorized individual shall have a separate identifiable authentication for access.

(b) When requesting information from the database, law enforcement personnel shall 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 commissioner, in consultation with the committee, may, by rule, establish a fee for providing information to a law enforcement agency, judicial district drug task force, 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 commissioner may consider options such as an annual fee or a per use, incremental cost basis fee, or other methods as the commissioner deems appropriate.

(d) Law enforcement personnel, who are authorized to request information from the database, shall resubmit their identifying application information that was submitted pursuant to this section to the appropriate district attorney, United States attorney, TBI director, or assistant special agent in charge by November 20 of each year. Such resubmitted applications shall be sent by the appropriate district

attorney general, TBI director, or assistant special agent in charge 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 special agent in charge, shall immediately notify the director of the controlled substance database, committee, or commissioner of any changes to the list submitted or in the information submitted for each attorney, 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 law enforcement personnel shall also be sent to the district attorney general of the judicial district to the district in which such officer or agent has jurisdiction. Likewise, any database information sent to a TBI agent or DEA agent shall also be sent to the TBI director or the assistant special agent in charge.

(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. Any information used in a criminal or administrative action from the controlled substance monitoring database shall be placed under seal or have patient names and all other personally identifying information of patients redacted. 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 healthcare practitioner or healthcare practitioner delegate 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;

(2) Other healthcare practitioners who are involved or have a bona fide prospective involvement in the treatment of the patient, or healthcare practitioners 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, or § 53-11-402(a)(3) or (a)(6), is required by § 53-11-309, or any agent of the healthcare practitioner who is directed by the healthcare practitioner to cause a report to law enforcement to be made in accordance with § 53-11-309(a) and (d); or

(4) A healthcare practitioner or healthcare practitioner delegate 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 under §§ 63-2-101 and 63-1-117.

(i) If law enforcement personnel or a judge of a drug court treatment program has probable cause to believe, based upon information received from a database request, that a healthcare practitioner may be acting or may have acted in violation of the law, the officer, agent, or judge shall consult with the appropriate licensing board as established under title 63 or title 68.

(j) (1) (A) At least every six (6) months, the committee or commissioner or their designee shall send a list to each district attorney general containing all requests made for database information during the previous six (6) months.

(B) The list shall include:

(i) The name of the requesting attorney, officer, or agent;

(ii) The attorney, officer, or agent's agency;

(iii) The date of the request; and

(iv) The nature of the request, including the case number for each attorney, officer, or agent making a request in such district attorney's judicial district.

(C) Likewise, a list shall be sent to the director of the TBI for all TBI agents or the assistant special

agent in charge for all DEA agents making requests during the previous six (6) months.

(2) Each district attorney general, or assistant special agent in charge 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 bureau and if the information requested is relevant and pertinent to an investigation.

(3) Each district attorney general, assistant special agent in charge, 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, assistant special agent in charge, or TBI director shall so note on the verified list and shall investigate the discrepancy and make a report back to the director of the controlled substance database within a reasonable period of time.

(4) The results of the audit conducted pursuant to subdivision (j)(2) shall be discoverable by a healthcare practitioner or healthcare practitioner delegate 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 healthcare practitioner or healthcare practitioner delegate are discoverable. If, however, there is an active criminal investigation involving a healthcare practitioner or healthcare practitioner delegate or the healthcare practitioner or healthcare practitioner delegate 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 healthcare practitioner or the healthcare practitioner delegate 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 is a Class A misdemeanor.

(4) Any law enforcement personnel whom the department has reason to suspect of violation of this section or who has been charged with a violation of this section shall have such person's authorization to request information from the database suspended. Any law enforcement personnel, 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 healthcare practitioners:

(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 healthcare practitioners and to 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.

HISTORY: Acts 2016, ch. 1002, § 6.

53-10-307. Failure to submit information -- Liability.

(a) The failure of a healthcare practitioner to submit information to the database required under this part after the committee or the commissioner has submitted a specific written request for the information, or when the committee or the commissioner 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 healthcare practitioner before the licensing board with jurisdiction over the healthcare practitioner 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 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.

(e) (1) Failure to submit the required information by any healthcare practitioner shall not be considered a violation if a good faith effort was made and the failure of the report to be transmitted was due to technical difficulties or the inability to have the report received by the database.

(2) Technical difficulties shall include the failure of the database to receive the transmission of any report, the failure of any healthcare practitioner's system or switch used in the transmission of a report, electrical problems, natural disasters, fires, flooding, or other unforeseen circumstances as defined in rules by the commissioner pursuant to § 53-10-311.

HISTORY: Acts 2016, ch. 1002, § 7.

53-10-308. Release of confidential information.

(a) Notwithstanding this part to the contrary, the committee or the commissioner:

(1) May release confidential information from the database regarding healthcare practitioners, healthcare practitioner delegates, or patients to department personnel 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 healthcare practitioners, healthcare practitioner delegates, or 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) 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, and nothing in this part creates 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.

HISTORY: Acts 2016, ch. 1002, § 8.

53-10-309. Reports.

The commissioner or commissioner's designee 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, its designee, or the commissioner shall also file an annual report with the health and welfare committee of the senate and the health committee of the house of representatives by March 1, 2017, and each March 1 thereafter, to include 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 commissioner, authorized committee, board, or department 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 healthcare practitioner or specific healthcare practitioner delegate contained in the report. All information released from the database for such a report shall be in the aggregate.

HISTORY: Acts 2016, ch. 1002, § 9.

53-10-310. Practice sites where a controlled substance dispensed required to provide for electronic access to the controlled substance database -- Exceptions -- Violations and penalties.

(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 healthcare practitioner provides healthcare services to a human patient potentially receiving a controlled substance.

(b) This section shall not apply to any person or entity that is 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 healthcare practitioner, 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 for accessing the database to determine whether or not the healthcare practitioner's professional credentials are being inappropriately used, or for reporting the same to the appropriate authorities, except as otherwise provided in this part.

(e) (1) When prescribing a controlled substance, all healthcare practitioners, unless otherwise exempted under this part, shall check the controlled substance database prior to prescribing one (1) of the controlled substances identified in subdivision (e)(4) 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. An authorized healthcare practitioner's delegate may check the controlled substance database on behalf of the healthcare practitioner. A new episode of treatment means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous twelve (12) months.

(2) When dispensing a controlled substance, all healthcare practitioners, unless otherwise exempted under this part, shall check the controlled substance database prior to dispensing one (1) of the controlled substances identified in subdivision (e)(4) to a human patient the first time that patient is dispensed a controlled substance at that practice site. The dispenser shall check the controlled

substance database again at least once every twelve (12) months for that human patient after the initial dispensing. The initial dispensing check fulfills the first annual check. An authorized healthcare practitioner's delegate may check the controlled substance database on behalf of the healthcare practitioner.

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

(4) The controlled substances that trigger a check of the controlled substance database pursuant to subdivisions (e)(1) and (2) include, but are not limited to, all opioids and benzodiazepines. By rule, the commissioner, pursuant to § 53-10-311, may require a check of the database for additional Schedule II-V controlled substances that are identified by the committee or commissioner as demonstrating a potential for abuse.

(5) The commissioner, pursuant to § 53-10-311, 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 healthcare practitioner regarding the review of patient information available through the database.

(6) Healthcare practitioners are not required to check the controlled substance database before prescribing or dispensing one (1) of the controlled substances identified in subdivision (e)(4) or added to that list by the committee or commissioner if one (1) or more of the following conditions are met:

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

(B) The committee has determined that healthcare practitioners 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 quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven-day treatment period and does not allow a refill; 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 may promulgate rules pursuant to the Uniform Administrative Procedures Act, to establish procedures, notice requirements, and penalties for healthcare practitioners who fail to register in, report to, or check the controlled substance database as required.

(g) Notwithstanding this part to the contrary, a healthcare practitioner or healthcare practitioner

delegate 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.

HISTORY: Acts 2016, ch. 1002, ◊ 10.

53-10-311. Establishment of operations committee -- Agreements with federal government and other jurisdictions for sharing and dissemination of data and information.

(a) There is created an operations committee. The committee shall be composed of:

(1) The board of medical examiners' medical director for special projects;

(2) An epidemiologist employed by the department of health;

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

(4) The director of the controlled substance database;

(5) A member of the controlled substance database committee;

(6) The executive director of the board of nursing as an ex officio non-voting member; and

(7) The executive director of the board of medical examiners as an ex officio non-voting member.

(b) (1) The commissioner shall have the duty to convene the operations committee at least annually and request approval by that committee of actions taken under the authority granted by this part prior to those actions becoming final. The operations committee shall meet at such other times as needed and as convened by the commissioner to confirm or deny decisions made by the commissioner pursuant to the authority granted to the commissioner by this part.

(2) The operations committee's approval shall be necessary for all rules, agreements, and policies concerning:

(A) Access to the database and how that access is obtained;

(B) Dissemination of data and information in the database and control over that data; and

(C) The control, sharing, and dissemination of data and information in the database with other states or other entities acting on behalf of a state.

(3) The operations committee's approval shall not be necessary for any rules, agreements, or policies that concern the daily operations decisions, which may be delegated to the director of the database,

concerning establishing, maintaining, or operating the database. The operations committee shall not set fees.

(4) The operations committee may make formal recommendations to the commissioner with respect to any contemplated rulemaking under this part, which does not require its approval.

(c) Three (3) voting members of the operations committee shall constitute a quorum for official actions. A majority of those voting members present shall be necessary to approve an action proposed by the commissioner.

(d) The operations committee shall not be subject to title 8, chapter 44, part 1, regarding public meetings.

(e) (1) Notwithstanding this part to the contrary, the commissioner is authorized to enter into agreements with the federal centers for disease control and prevention (CDC), 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.

(2) Any information disseminated pursuant to this subsection (e) shall be for:

(A) Analysis of controlled substance prescriptions for public health research by other state or federal entities charged with protecting the public health; or

(B) Interstate data sharing; provided, the sharing shall only be consistent with the requirements of § 53-10-306.

(3) The commissioner shall have any agreements that the commissioner enters into with the CDC, other states, or other entities acting on behalf of a state or federal government, approved by the operations committee prior to that agreement becoming final.

(4) All agreements entered into by the commissioner subject to this subsection (e) shall be governed by a contract entered into between the two (2) parties.

HISTORY: Acts 2016, ch. 1002, § 11.

53-10-312. Minimum reporting requirements for wholesalers and manufacturers -- Establishment of rules as to reporting requirements.

(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 board may 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.

HISTORY: Acts 2016, ch. 1002, § 12.