TITLE 44. HEALTH

CHAPTER 53. Poisons, Drugs and Other Controlled Substances

ARTICLE 15. Prescription Monitoring Program

SECTION 44-53-1610. Citation of article.

This article may be cited as the "South Carolina Prescription Monitoring Act".

HISTORY: 2006 Act No. 396, § 1, eff June 14, 2006.

SECTION 44-53-1620. Purpose.

This article is intended to improve the state's ability to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

HISTORY: 2006 Act No. 396, § 1, eff June 14, 2006.

SECTION 44-53-1630. Definitions.

As used in this section:

(1) "Controlled substances" means those substances listed in Schedules II, III, and IV of the schedules provided for in Sections 44-53-210, 44-53-230, 44-53-250, and 44-53-270.

(2) "Dispenser" means a person who delivers a Schedule II-IV controlled substance to the ultimate user, but does not include:

(a) a licensed hospital pharmacy that distributes controlled substances for the purpose of inpatient hospital care or dispenses prescriptions for controlled substances at the time of discharge from the hospital;

(b) a practitioner or other authorized person who administers these controlled substances; or

(c) a wholesale distributor of a Schedule II-IV controlled substance.

(3) "Drug control" means the Department of Health and Environmental Control, Bureau of Drug Control.

(4) "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed, or both.

(5) "Authorized delegate" means an individual who is approved as having access to the prescription **monitoring program** and who is directly supervised by an authorized practitioner or

pharmacist.

HISTORY: 2006 Act No. 396, § 1, eff June 14, 2006; 2014 Act No. 244 (S.840), § 1, eff June 6, 2014.

Effect of Amendment

2014 Act No. 244, § 1, added paragraph (5), defining "authorized delegate".

SECTION 44-53-1640. Authority to establish and maintain prescription **monitoring program**; electronic submission of information by dispensers; exemptions.

(A) The Department of Health and Environmental Control, Bureau of Drug Control may establish and maintain a program to monitor the prescribing and dispensing of all Schedule II, III, and IV controlled substances by professionals licensed to prescribe or dispense these substances in this State.

(B)(1) A dispenser shall submit to drug control, by electronic means, information regarding each prescription dispensed for a controlled substance. The following information must be submitted for each prescription:

(a) dispenser DEA registration number;

(b) date drug was dispensed;

(c) prescription number;

(d) whether prescription is new or a refill;

(e) NDC code for drug dispensed;

(f) quantity dispensed;

(g) approximate number of days supplied;

(h) patient name;

(i) patient address;

(j) patient date of birth;

(k) prescriber DEA registration number;

(l) date prescription issued by prescriber.

(2) A dispenser shall submit daily to the department the information required pursuant to subsection

(B)(1) in accordance with transmission methods and protocols provided in the latest edition of the "ASAP Telecommunications Format for Controlled Substances", developed by the American Society for Automation in Pharmacy.

(3) Drug control may issue a waiver to a dispenser who is unable to submit prescription information by electronic means. The waiver may permit the dispenser to submit prescription information by paper form or other means if all information required pursuant to subsection (B)(1) is submitted in this alternative format.

HISTORY: 2006 Act No. 396, § 1, eff June 14, 2006; 2014 Act No. 244 (S.840), § 2, eff June 6, 2014.

Effect of Amendment

2014 Act No. 244, § 2, rewrote subsection (B)(2).

SECTION 44-53-1650. Confidentiality; persons to whom data may be released.

(A) Prescription information submitted to drug control is confidential and not subject to public disclosure under the Freedom of Information Act or any other provision of law, except as provided in subsections (C) and (D).

(B) Drug control shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed, except as provided for in subsections (C) and (D).

(C) If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, drug control shall notify the appropriate law enforcement or professional licensure, certification, or regulatory agency or entity and shall provide prescription information required for an investigation.

(D) Drug control may provide data in the prescription **monitoring program** to the following persons:

(1) a practitioner or pharmacist or authorized delegate who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide patient;

(2) an individual who requests the individual's own prescription monitoring information in accordance with procedures established pursuant to state law;

(3) a designated representative of the South Carolina Department of Labor, Licensing and Regulation responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(4) a local, state, or federal law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of the laws governing licit drugs and who is involved in a bona fide specific drug related investigation involving a designated person;

(5) the South Carolina Department of Health and Human Services regarding Medicaid program recipients;

(6) a properly convened grand jury pursuant to a subpoena properly issued for the records;

(7) personnel of drug control for purposes of administration and enforcement of this article;

(8) qualified personnel for the purpose of bona fide research or education; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser must be deleted or redacted from such information prior to disclosure. Further, release of the information only may be made pursuant to a written agreement between qualified personnel and the department in order to ensure compliance with this subsection.

HISTORY: 2006 Act No. 396, § 1, eff June 14, 2006; 2014 Act No. 244 (S.840), § 3, eff June 6, 2014.

Effect of Amendment

2014 Act No. 244, § 3, in subsection (D)(1), inserted "or authorized delegate", and made nonsubstantive changes in subsection (D)(8).

SECTION 44-53-1660. Contract for administration by other State agency or private vendor.

Drug control may contract with another agency of this State or with a private vendor, as necessary, to ensure the effective operation of the prescription **monitoring program**. A contractor shall comply with the provisions regarding confidentiality of prescription information in Section 44-53-1650 and is subject to the penalties specified in Section 44-53-1680 for unlawful acts.

HISTORY: 2006 Act No. 396, § 1, eff June 14, 2006.

SECTION 44-53-1670. Promulgation of regulations.

Drug control may promulgate regulations setting forth the procedures and methods for implementing this article.

HISTORY: 2006 Act No. 396, § 1, eff June 14, 2006.

SECTION 44-53-1680. Violations and penalties.

(A) A dispenser or authorized delegate who knowingly fails to submit prescription monitoring information to drug control as required by this article, or who knowingly submits incorrect prescription

information, is guilty of a misdemeanor and, upon conviction, must be fined not more than two thousand dollars or imprisoned not more than two years, or both.

(B) A person or persons authorized to have prescription monitoring information pursuant to this article who knowingly discloses this information in violation of this article is guilty of a felony and, upon conviction, must be fined not more than ten thousand dollars or imprisoned not more than ten years, or both.

(C) A person or persons authorized to have prescription monitoring information pursuant to this article who uses this information in a manner or for a purpose in violation of this article is guilty of a felony and, upon conviction, must be fined not more than ten thousand dollars or imprisoned not more than ten years, or both.

(D) A pharmacist or practitioner, licensed in Title 40, who knowingly discloses prescription monitoring information in a manner or for a purpose in violation of this article shall be reported to his respective board for disciplinary action.

(E) Nothing in this chapter requires a pharmacist or practitioner to obtain information about a patient from the prescription **monitoring program**. A pharmacist or practitioner does not have a duty and must not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or practitioner did or did not seek or obtain information from the prescription **monitoring program**. A pharmacist or practitioner acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the prescription **monitoring program**.

HISTORY: 2006 Act No. 396, § 1, eff June 14, 2006; 2014 Act No. 244 (S.840), § 4, eff June 6, 2014.

Effect of Amendment

2014 Act No. 244, § 4, in subsection (A), inserted "or authorized delegate", and substituted "misdemeanor and," for "misdemeanor, and"; added subsection (D); and redesignated former subsection (D) as (E).

ARTICLE 18. Julian's Law

SECTION 44-53-1810. Definitions.

As used in this article:

(1) "Academic medical center" means a research hospital that operates a medical residency program for physicians and conducts research that involves human subjects, and other hospital research programs conducting research as a subrecipient with the academic medical center as the prime awardee.

(2) "Approved source" means a provider approved by the United States Food and Drug Administration which produces cannabidiol that:

(a) has been manufactured and tested in a facility approved or certified by the United States Food and Drug Administration or similar national regulatory agency in another country which has been approved by the United States Food and Drug Administration; and

(b) has been tested in animals to demonstrate preliminary effectiveness and to ensure that it is safe to administer to humans.

(3) "Cannabidiol" means a finished preparation containing, of its total cannabinoid content, at least 98 percent cannabidiol and not more than 0.90 percent tetrahydrocannabinol by volume that has been extracted from marijuana or synthesized in a laboratory.

(4) "Designated caregiver" means a person who provides informal or formal care to a qualifying patient, with or without compensation, on a temporary or permanent or full-time or part-time basis and includes a relative, household member, day care personnel, and personnel of a public or private institution or facility.

(5) "Pharmacist" means an individual health care provider licensed by this State to engage in the practice of pharmacy.

(6) "Physician" means a doctor of medicine or doctor of osteopathic medicine licensed by the South Carolina Board of Medical Examiners.

(7) "Qualifying patient" means anyone who suffers from Lennox-Gastaut Syndrome, Dravet Syndrome, also known as severe myoclonic epilepsy of infancy, or any other form of refractory epilepsy that is not adequately treated by traditional medical therapies.

HISTORY: 2014 Act No. 221 (S.1035), § 2, eff June 2, 2014.

SECTION 44-53-1820. FDA approved clinical trials to treat patients who have certain forms of epilepsy with cannabidiol; principal investigators; subinvestigators.

(A) A statewide investigational new drug application may be established in this State, if approved by the United States Food and Drug Administration to conduct expanded access clinical trials using cannabidiol on qualifying patients with severe forms of epilepsy.

(B) Any physician who is board certified and practicing in an academic medical center in this State and treating patients with severe forms of epilepsy may serve as the principal investigator for such clinical trials if such physician:

(1) applies to and is approved by the United States Food and Drug Administration as the principal

investigator in a statewide investigational new drug application; and

(2) receives a license from the United States Drug Enforcement Administration.

(C) Such physician, acting as principal investigator, may include subinvestigators who are also board certified and who practice in an academic medical center in this State and treat patients with severe forms of epilepsy. Such subinvestigators shall comply with subsection (B)(2) of this section.

(D) The principal investigator and all subinvestigators shall adhere to the rules and regulations established by the relevant institutional review board for each participating academic medical center and by the United States Food and Drug Administration, the United States Drug Enforcement Administration, and the National Institute on Drug Abuse.

(E) Nothing in this article prohibits a physician licensed in South Carolina from applying for Investigational New Drug authorization from the United States Food and Drug Administration.

HISTORY: 2014 Act No. 221 (S.1035), § 2, eff June 2, 2014.

SECTION 44-53-1830. Cannabidiol for use in clinical trials.

(A) Expanded access clinical trials conducted pursuant to a statewide investigational new drug application established pursuant to this chapter only shall utilize cannabidiol which is:

(1) from an approved source; and

(2) approved by the United States Food and Drug Administration to be used for treatment of a condition specified in an investigational new drug application.

(B) The principal investigator and any subinvestigator may receive cannabidiol directly from an approved source or authorized distributor for an approved source for use in the expanded access clinical trials.

HISTORY: 2014 Act No. 221 (S.1035), § 2, eff June 2, 2014.

SECTION 44-53-1840. Immunity.

(A) A person acting in compliance with the provisions of this article must not be subject to arrest, prosecution, or any civil or administrative penalty, including a civil penalty or disciplinary action by a professional licensing board, or be denied any right or privilege, for the use, prescription, administration, possession, manufacture, or distribution of medical cannabis.

(B) The State must defend a state employee against a federal claim or suit that arises or by virtue of their good faith performance of official duties pursuant to this article.

HISTORY: 2014 Act No. 221 (S.1035), § 2, eff June 2, 2014.