Sec Punishment Review
- Remove Criminal Stare 16-13-63

LC 29 4714ERS.

_____ offers the following substitute to HB 184:

A BILL TO BE ENTITLED

AN ACT

To amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, so as to provide for the establishment of a program to monitor the prescribing and dispensing of Schedule II controlled substances and soma and its derivatives; to provide for definitions; to require dispensers to submit certain information regarding the dispensing of such controlled substances; to provide for the confidentiality of submitted information except under certain circumstances; to provide for the establishment of an Electronic Database Review Advisory Committee; to provide for its membership, duties, and organization; to provide for the establishment of rules and regulations; to provide for limited liability; to provide for penalties; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, is amended by revising Code Section 16-13-21, relating to definitions relative to regulation of controlled substances, as follows:

"16-13-21.

As used in this article, the term:

(0.5) 'Addiction' means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

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(1) 'Administer' means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or by any other means, to the body of a patient or research subject by:

(A) A practitioner or, in his or her presence, by his or her authorized agent; or

(B) The patient or research subject at the direction and in the presence of the practitioner.

(1.1) 'Agency' means the Georgia Drugs and Narcotics Agency established pursuant to Code Section 26-4-29.

(2) 'Agent' of a manufacturer, distributor, or dispenser means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

(2.1) 'Board' means the State Board of Pharmacy or its designee, so long as such designee is another state entity.

(3) 'Bureau' means the ~~Drug Enforcement Administration, United States Department of Justice, or its successor agency~~ Georgia Bureau of Investigation.

(4) 'Controlled substance' means a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 21 C.F.R. Part 1308.

(5) 'Conveyance' means any object, including aircraft, vehicle, or vessel, but not including a person, which may be used to carry or transport a substance or object.

(6) 'Counterfeit substance' means:

(A) A controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the controlled substance;

(B) A controlled substance or noncontrolled substance, which is held out to be a controlled substance or marijuana, whether in a container or not which does not bear a label which accurately or truthfully identifies the substance contained therein; or

(C) Any substance, whether in a container or not, which bears a label falsely identifying the contents as a controlled substance.

(6.1) 'Dangerous drug' means any drug, other than a controlled substance, which cannot be dispensed except upon the issuance of a prescription drug order by a practitioner authorized under this chapter.

(6.2) 'DEA' means the United States Drug Enforcement Administration.

(7) 'Deliver' or 'delivery' means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.

(8) 'Dependent,' 'dependency,' 'physical dependency,' 'psychological dependency,' or 'psychic dependency' means and includes the state of ~~dependence by an individual toward or upon a substance, arising from the use of that substance, being characterized by behavioral and other responses which include the loss of self-control with respect to that substance, or a strong compulsion to use that substance on a continuous basis in order to experience some psychic effect resulting from the use of that substance by that individual, or to avoid any discomfort occurring when the individual does not use that substance~~ adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

(9) 'Dispense' means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery, or the delivery of a controlled substance by a practitioner, acting in the normal course of his or her professional practice and in accordance with this article, or to a relative or representative of the person for whom the controlled substance is prescribed.

(10) 'Dispenser' means ~~a practitioner who dispenses~~ a person that delivers a Schedule II, III, IV, or V controlled substance to the ultimate user but shall not include:

(A) A pharmacy licensed as a hospital pharmacy by the Georgia Board of Pharmacy pursuant to Code Section 26-4-110;

(B) An institutional pharmacy that serves only a health care facility, including, but not limited to, a nursing home, an intermediate care home, a personal care home, or a hospice program, which provides patient care and which pharmacy dispenses such substances to be administered and used by a patient on the premises of the facility;

(C) A practitioner or other authorized person who administers such a substance; or

(D) A pharmacy operated by, on behalf of, or under contract with the Department of Corrections for the sole and exclusive purpose of providing services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution. This shall include correctional institutions operated by private entities in this state which house inmates under the Department of Corrections.

(11) 'Distribute' means to deliver a controlled substance, other than by administering or dispensing it.

(12) 'Distributor' means a person who distributes.

(12.05) 'FDA' means the United States Food and Drug Administration.

(12.1) 'Imitation controlled substance' means:

(A) A product specifically designed or manufactured to resemble the physical appearance of a controlled substance, such that a reasonable person of ordinary knowledge would not be able to distinguish the imitation from the controlled substance by outward appearances; or

(B) A product, not a controlled substance, which, by representations made and by dosage unit appearance, including color, shape, size, or markings, would lead a reasonable person to believe that, if ingested, the product would have a stimulant or depressant effect similar to or the same as that of one or more of the controlled substances included in Schedules I through V of Code Sections 16-13-25 through 16-13-29.

(13) 'Immediate precursor' means a substance which the State Board of Pharmacy has found to be and by rule identifies as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used, in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

(14) 'Isomers' means stereoisomers (optical isomers), geometrical isomers, and structural isomers (chain and positional isomers,) but shall not include functional isomers).

(15) 'Manufacture' means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging, or labeling of a controlled substance:

(A) By a practitioner as an incident to his or her administering or dispensing of a controlled substance in the course of his or her professional practice; or

(B) By a practitioner or by his or her authorized agent under his or her supervision for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

(16) 'Marijuana' means all parts of the plant of the genus Cannabis, whether growing or not, the seeds thereof, the resin extracted from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin; but shall not include samples as described in subparagraph (P) of paragraph (3)

of Code Section 16-13-25 and shall not include the completely defoliated mature stalks of such plant, fiber produced from such stalks, oil, or cake, or the completely sterilized samples of seeds of the plant which are incapable of germination.

(17) 'Narcotic drug' means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(B) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical ~~with~~ to any of the substances referred to in subparagraph (A) of this paragraph, but not including the isoquinoline alkaloids of opium;

(C) Opium poppy and poppy straw; or

(D) Coca leaves and any salt, compound, derivative, stereoisomers of cocaine, or preparation of coca leaves, and any salt, compound, stereoisomers of cocaine, derivative, or preparation thereof which is chemically equivalent or identical ~~with~~ to any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(18) 'Opiate' means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Code Section 16-13-22, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

(19) 'Opium poppy' means the plant of the species Papaver somniferum L., except its seeds.

(19.1) 'Patient' means the person who is the intended consumer of a drug for whom a prescription is issued or for whom a drug is dispensed.

(20) 'Person' means an individual, corporation, government, or governmental subdivision or agency, business trust, estate, trust, partnership, or association, or any other legal entity.

(21) 'Poppy straw' means all parts, except the seeds, of the opium poppy after mowing.

(22) 'Potential for abuse' means and includes a substantial potential for a substance to be used by an individual to the extent of creating hazards to the health of the user or the safety of the public, or the substantial potential of a substance to cause an individual using that substance to become dependent upon that substance.

(23) 'Practitioner' means:

(A) A physician, dentist, pharmacist, podiatrist, ~~veterinarian;~~ scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise authorized by law to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

(C) An advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-25. For purposes of this chapter and Code Section 43-34-25, an advanced practice registered nurse is authorized to register with the federal Drug Enforcement Administration and appropriate state authorities; or

(D) A physician assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103. For purposes of this chapter and subsection (e.1) of Code Section 43-34-103, a physician assistant is authorized to register with the federal Drug Enforcement Administration and appropriate state authorities.

(23.1) 'Prescriber' means a physician, dentist, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to prescribe, distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state.

(24) 'Production' includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(25) 'Registered' or 'register' means registration as required by this article.

(26) 'Registrant' means a person who is registered under this article.

(26.1) 'Schedule II controlled substance' means a controlled substance that is classified as a Schedule II controlled substance under Code Section 16-13-26 or under the Federal Controlled Substances Act, 21 U.S.C. Section 812.

(27) 'State,' when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession thereof, or any area subject to the legal authority of the United States.

(27.1) 'Tolerance' means a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(28) 'Ultimate user' means a person who lawfully possesses a controlled substance for his or her own use, for the use of a member of his or her household, or for administering

to an animal owned by him or her or by a member of his or her household or an agent or representative of the person.

(29) 'Noncontrolled substance' means any drug or other substance other than a controlled substance as defined by paragraph (4) of this Code section.

(30) 'Wholesaler' means any person, firm, corporation, association, dealer, or broker selling or offering for sale, in or into this state, any Schedule II, III, IV, or V controlled substance that is classified as a Schedule II, III, IV, or V controlled substance under Code Section 16-13-26, 16-13-27, 16-13-28, or 16-13-29, respectively, or under the Federal Controlled Substances Act, 21 U.S.C. Section 812."

SECTION 2.

Said chapter is further amended by designating Article 2 as Part 1 of Article 2 and by adding a new part to Article 2 to read as follows:

"Part 2

16-13-57.

(a) Subject to funds as may be appropriated by the General Assembly or otherwise available for such purpose, the agency shall, in consultation with members of the Georgia Composite Medical Board, establish and maintain a program to electronically record into an electronic data base prescription information resulting from the dispensing of Schedule II controlled substances and soma and its derivatives and to electronically review such prescription information that has been entered into such data base. The purpose of such program shall be to assist in the reduction of the abuse of controlled substances, to improve, enhance, and encourage a better quality of health care by promoting the proper use of medications to treat pain and terminal illness, and to reduce duplicative prescribing and overprescribing of controlled substance practices.

(b) Such program shall be administered by the agency at the direction and oversight of the board.

16-13-58.

(a) The agency shall be authorized to apply for available grants and may accept any gifts, grants, donations, and other funds, including funds from the disposition of forfeited property, to assist in developing and maintaining the program established pursuant to Code Section 16-13-57: provided, however, that neither the board, agency, nor any other state entity shall accept a grant that requires as a condition of the grant any sharing of information that is inconsistent with this part.

(b) The agency shall be authorized to grant funds to dispensers for the purpose of covering costs for dedicated equipment and software for dispensers to use in complying with the reporting requirements of Code Section 16-13-59. Such grants to dispensers shall be funded by gifts, grants, donations, or other funds, including funds from the disposition of forfeited property, received by the agency for the operation of the program established pursuant to Code Section 16-13-57. The agency shall be authorized to establish standards and specifications for any equipment and software purchased pursuant to a grant received by a dispenser pursuant to this Code section. Nothing in this part shall be construed to require a dispenser to incur costs to purchase equipment or software to comply with this part.

(c) Nothing in this part shall be construed to require any appropriation of state funds.

16-13-59.

(a) For purposes of the program established pursuant to Code Section 16-13-57, each dispenser shall submit to the agency by electronic means information regarding each prescription dispensed for a Schedule II controlled substance and soma and its derivatives. The information submitted for each prescription shall include at a minimum, but shall not be limited to:

(1) DEA permit number or approved dispenser facility controlled substance identification number;

(2) Date the prescription was dispensed;

(3) Prescription serial number;

(4) If the prescription is new or a refill;

(5) National Drug Code (NDC) for drug dispensed;

(6) Quantity and strength dispensed;

(7) Number of days supply of the drug;

(8) Patient's name;

(9) Patient's address;

(10) Patient's date of birth;

(11) Patient gender;

(12) Method of payment;

(13) Approved prescriber identification number or prescriber's DEA permit number;

(14) Date the prescription was issued by the prescriber; and

(15) Other data elements consistent with standards established by the American Society for Automation in Pharmacy, if designated by regulations of the agency.

(b) Each dispenser shall submit the prescription information required in subsection (a) of this Code section in accordance with transmission methods and frequency requirements established by the agency on at least a weekly basis and shall report, at a minimum, such

prescription information no later than ten days after the prescription is dispensed. If a dispenser is temporarily unable to comply with this subsection due to an equipment failure or other circumstances, such dispenser shall notify the board and agency.

(c) The agency may issue a waiver to a dispenser that is unable to submit prescription information by electronic means acceptable to the agency. Such waiver may permit the dispenser to submit prescription information to the agency by paper form or other means, provided all information required in subsection (a) of this Code section is submitted in this alternative format and in accordance with the frequency requirements established pursuant to subsection (b) of this Code section. Requests for waivers shall be submitted in writing to the agency.

(d) The agency shall not revise the information required to be submitted by dispensers pursuant to subsection (a) of this Code section more frequently than annually. Any such change to the required information shall neither be effective nor applicable to dispensers until six months after the adoption of such changes.

(e) The agency shall not access or allow others to access any identifying prescription information from the electronic data base after one year from the date such information was originally received by the agency. The agency may retain aggregated prescription information for a period of one year from the date the information is received but shall promulgate regulations and procedures that will ensure that any identifying information the agency receives from any dispenser or reporting entity that is one year old or older is deleted or destroyed on an ongoing basis in a timely and secure manner.

(f) A dispenser may apply to the agency for an exemption to be excluded from compliance with this Code section if compliance would impose an undue hardship on such dispenser. The agency shall provide guidelines and criteria for what constitutes an undue hardship.

(g) On and after July 1, 2012, on a monthly basis, wholesalers shall provide the agency with the type and quantity of any Schedule II, III, IV, or V controlled substance that is shipped to a dispenser in this state. Such information shall be provided by the tenth day of each month with respect to the previous month's information and shall be in the electronic format required by the board for such information.

16-13-60.

(a) Except as otherwise provided in subsections (c) and (d) of this Code section, prescription information submitted pursuant to Code Section 16-13-59 shall be confidential and shall not be subject to open records requirements, as contained in Article 4 of Chapter 18 of Title 50.

(b) The agency, in conjunction with the board, shall establish and maintain strict procedures to ensure that the privacy and confidentiality of patients, prescribers, and

patient and prescriber information collected, recorded, transmitted, and maintained pursuant to this part are protected. Such information shall not be disclosed to any person or entity except as specifically provided in this part and only in a manner which in no way conflicts with the requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996, P.L. 104-191.

(c) The agency shall be authorized to provide requested prescription information collected pursuant to this part:

(1) To persons authorized to prescribe or dispense controlled substances for the sole purpose of providing medical or pharmaceutical care for their patients;

(2) Upon the request of a patient, prescriber, or dispenser about whom the prescription information requested concerns or upon the request on his or her behalf of his or her attorney;

(3) To local, state, or federal law enforcement or prosecutorial officials pursuant to the issuance of a search warrant pursuant to Article 2 of Chapter 5 of Title 17; and

(4) To the agency or the Georgia Composite Medical Board upon the issuance of an administrative subpoena issued by a Georgia state administrative law judge.

(d) The board may provide data to government entities for statistical, research, educational, or grant application purposes after removing information that could be used to identify prescribers or individual patients or persons who received prescriptions from dispensers.

(e) Any person who receives electronic data base prescription information or related reports relating to this part from the agency shall not provide such information or reports to any other person except by order of a court of competent jurisdiction pursuant to this part.

(f) Any permissible user identified in this part who directly accesses electronic base prescription information shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are substantially equivalent to the security measures of the agency. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, or other compromise of the information and shall assess the sufficiency of any safeguards in place to control the risks.

16-13-61.

(a) There is established an Electronic Database Review Advisory Committee for the purposes of consulting with and advising the agency on matters related to the establishment, maintenance, and operation of how prescriptions are electronically reviewed

pursuant to this part. This shall include, but shall not be limited to, data collection, regulation of access to data, evaluation of data to identify benefits and outcomes of the reviews, communication to prescribers and dispensers as to the intent of the reviews and how to use the data base, and security of data collected.

(b) The advisory committee shall consist of nine members as follows:

(1) A representative from the agency;

(2) A representative from the Georgia Composite Medical Board;

(3) A representative from the Georgia Board of Dentistry;

(4) A consumer representative, appointed by the board;

(5) A representative from a specialty profession that deals in addictive medicine, appointed by the Georgia Composite Medical Board;

(6) A pain management specialist, appointed by the Georgia Composite Medical Board;

(7) An oncologist, appointed by the Georgia Composite Medical Board;

(8) A representative from a hospice or hospice organization, appointed by the Georgia Composite Medical Board; and

(9) A representative from the State Board of Optometry.

(c) Each member of the advisory committee shall serve a three-year term or until the appointment and qualification of such member's successor.

(d) The advisory committee shall elect a chairperson and vice chairperson from among its membership to serve a term of one year. The vice chairperson shall serve as the chairperson at times when the chairperson is absent.

(e) The advisory committee shall meet at the call of the chairperson or upon request by at least three of the members and shall meet at least one time per year. Five members of the committee shall constitute a quorum.

(f) The members shall receive no compensation or reimbursement of expenses from the state for their services as members of the advisory committee.

16-13-62.

The agency shall establish rules and regulations to implement the requirements of this part. Nothing in this part shall be construed to authorize the agency to establish policies, rules, or regulations which limit, revise, or expand or purport to limit, revise, or expand any prescription or dispensing authority of any prescriber or dispenser subject to this part.

16-13-63.

Nothing in this part shall require a dispenser or prescriber to obtain information about a patient from the program established pursuant to this part. A dispenser or prescriber shall not have a duty and shall not be held liable for damages to any person in any civil,

criminal, or administrative action for injury, death, or loss to person or property on the basis that the dispenser or prescriber did or did not seek or obtain information from the electronic data base established pursuant to Code Section 16-13-57.

16-13-64.

(a) A dispenser who knowingly and intentionally fails to submit prescription information to the agency as required by this part or knowingly and intentionally submits incorrect prescription information shall be guilty of a felony and, upon conviction thereof, shall be punished for each such offense by imprisonment for not less than one year nor more than five years, a fine not to exceed $50,000.00, or both, and such actions shall be reported to the licensing board responsible for issuing such dispenser's dispensing license for action to be taken against such dispenser's license.

(b) An individual authorized to access electronic data base prescription information pursuant to this part who negligently uses, releases, or discloses such information in a manner or for a purpose in violation of this part shall be guilty of a misdemeanor. Any person who is convicted of negligently using, releasing, or disclosing such information in violation of this part shall, upon the second or subsequent conviction, be guilty of a felony and shall be punished by imprisonment for not less than one nor more than three years, a fine not to exceed $5,000.00, or both.

(c)(1) An individual authorized to access electronic data base prescription information pursuant to this part who knowingly obtains or discloses such information in a manner or for a purpose in violation of this part shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not less than one year nor more than five years, a fine not to exceed $50,000.00, or both.

(2) Any person who knowingly obtains, attempts to obtain, or discloses electronic data base prescription information pursuant to this part under false pretenses shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not less than one year nor more than five years, a fine not to exceed $100,000.00, or both.

(3) Any person who obtains or discloses electronic data base prescription information not specifically authorized herein with the intent to sell, transfer, or use such information for commercial advantage, personal gain, or malicious harm shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not less than two years nor more than ten years, a fine not to exceed $250,000.00, or both.

(d) Any person who is injured by reason of any violation of this part shall have a cause of action for the actual damages sustained and, where appropriate, punitive damages. Such person may also recover attorney's fees in the trial and appellate courts and the costs of investigation and litigation reasonably incurred.

(e) The penalties provided by this Code section are intended to be cumulative of other penalties which may be applicable and are not intended to repeal such other penalties."

SECTION 3.

This Act shall become effective on July 1, 2011.

SECTION 4.

All laws and parts of laws in conflict with this Act are repealed.