Senate Bill 81

By: Senators Unterman of the 45th, Miller of the 49th, Mullis of the 53rd, Burke of the 11th and Hufstetler of the 52nd

A BILL TO BE ENTITLED

AN ACT

To amend Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacies, so as to provide that the state health officer may issue a standing order permitting certain persons and entities to obtain opioid antagonists under the conditions the state health officer may impose; to provide for immunity; to amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, so as to change the definition of a dangerous drug; to add a drug to Schedule V; to change certain provisions of the electronic data base of prescription information; to change the dispenser prescription information transmission frequency; to provide for prescriber requirements; to provide for exemptions; to provide for prescription limitations; to provide for penalties; to amend Code Section 31-12-2 of the Official Code of Georgia Annotated, relating to reporting disease, confidentiality, reporting required by pharmacists, immunity from liability as to information supplied, and notification of potential bioterrorism, so as to add neonatal abstinence syndrome reporting; to amend Chapter 5 of Title 26 of the Official Code of Georgia Annotated, relating to drug abuse treatment and education programs, so as to provide for annual inspection; to provide for monthly reporting of certain data; to provide for short titles; to provide for legislative findings; provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

PART I

SECTION 1-1.

This part shall be known and may be cited as the "Jeffrey Dallas Gay, Jr., Act."

SECTION 1-2.

WHEREAS, according to the Centers for Disease Control and Prevention's National Center for Health Statistics, the number of overdose deaths involving opioids rose from 28,647 in 2014 to 33,091 in 2015; and

WHEREAS, according to the Centers for Disease Control and Prevention, two distinct but interconnected trends are driving America's opioid overdose epidemic:

(1) A 15 year increase in deaths from prescription opioid overdoses; and

(2) A recent surge in illicit opioid overdoses driven mainly by heroin and illegally made fentanyl; and

WHEREAS, Naloxone is an overdose reversal and life-saving opioid antagonist that the Food and Drug Administration designates as a prescription only drug; and

WHEREAS, forty-seven states, including Georgia, have passed laws providing immunity to medical professionals who prescribe or dispense Naloxone or persons who administer Naloxone, a life-saving opioid antagonist; and

WHEREAS, Emergency Rule 480-34-0.31-.11 (Naloxone) was signed by the Governor on December 14, 2016, to allow pharmacists to dispense Naloxone to individuals pursuant to a state-wide standing order issued by the state health officer; and

WHEREAS, other states have passed laws to allow the similar sale of Naloxone at pharmacies without a traditional patient-specific prescription, including: Alabama, Alaska, Arkansas, Arizona, California, Colorado, Connecticut, District of Columbia, Florida, Idaho, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

SECTION 1-3.

The General Assembly finds that it is imperative that Emergency Rule 480-34-0.31-.11 be codified to prevent against accidental overdoses and combat the opioid epidemic. The General Assembly further finds that this effort to permanently increase access to Naloxone in Georgia shall be dedicated to Jeffrey Dallas Gay, Jr., and his family in Gainesville, Georgia.

SECTION 1-4.

Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacies, is amended by revising Code Section 26-4-116.2, relating to authority of licensed health practitioners to prescribe opioid antagonists and immunity from liability, as follows:

"26-4-116.2.

(a) As used in this Code section, the term:

(1) 'First responder' means any person or agency who provides on-site care until the arrival of a duly licensed ambulance service. This shall include, but not be limited to, persons who routinely respond to calls for assistance through an affiliation with law enforcement agencies, fire departments, and rescue agencies.

(2) 'Harm reduction organization' means an organization which provides direct assistance and services, such as syringe exchanges, counseling, homeless services, advocacy, drug treatment, and screening, to individuals at risk of experiencing an opioid related overdose.

(3) 'Opioid antagonist' means any drug that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors and that is approved by the federal Food and Drug Administration for the treatment of an opioid related overdose.

(4) 'Opioid related overdose' means an acute condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, mania, or death, resulting from the consumption or use of an opioid or another substance with which an opioid was combined or that a layperson would reasonably believe to be resulting from the consumption or use of an opioid or another substance with which an opioid was combined for which medical assistance is required.

(5) 'Pain management clinic' means a clinic licensed pursuant to Article 10 of Chapter 34 of Title 43.

(6) 'Practitioner' means a physician licensed to practice medicine in this state.

(b) The following persons may prescribe an opioid antagonist:

(1) A practitioner acting in good faith and in compliance with the standard of care applicable to that practitioner may prescribe an opioid antagonist for use in accordance with a protocol specified by such practitioner to a person at risk of experiencing an opioid related overdose or to a pain management clinic, first responder, harm reduction organization, family member, friend, or other person in a position to assist a person at risk of experiencing an opioid related overdose.; or

(2) The state health officer may issue a standing order permitting certain persons and entities, or categories of persons or entities, to obtain opioid antagonists under such

conditions as the state health officer may impose. Such an order shall have state-wide effect.

(c) A pharmacist acting in good faith and in compliance with the standard of care applicable to pharmacists may dispense opioid antagonists pursuant to a prescription issued in accordance with subsection (b) of this Code section.

(d) A person acting in good faith and with reasonable care to another person whom he or she believes to be experiencing an opioid related overdose may administer an opioid antagonist that was prescribed pursuant to subsection (b) of this Code section in accordance with the protocol specified by the practitioner or state health officer.

(e) The following individuals are immune from any civil or criminal liability or professional licensing sanctions for the following actions authorized by this Code section:

(1) Any practitioner acting in good faith and in compliance with the standard of care applicable to that practitioner who prescribes an opioid antagonist pursuant to subsection (b) of this Code section;

(2) Any practitioner or pharmacist acting in good faith and in compliance with the standard of care applicable to that practitioner or pharmacist who dispenses an opioid antagonist pursuant to a prescription issued in accordance with paragraph (1) of subsection (b) of this Code section; ~~and~~

(3) The state health officer acting pursuant to paragraph (2) of subsection (b) of this Code section; and

~~(3)~~(4) Any person acting in good faith, other than a practitioner, who administers an opioid antagonist pursuant to subsection (d) of this Code section.

(f) Pursuant to any standing order issued under paragraph (2) of subsection (b) of this Code section, every pharmacy operating in this state shall keep a copy of the standing order issued by the state health officer and shall keep a record of every opioid antagonist dispensed pursuant to such standing order. Each record shall include the name of the purchaser, and the personal information of such purchaser shall include such purchaser's name and address, including the city, state, and ZIP Code. Such record shall be maintained by the pharmacy for two years. Nothing in this subsection shall prevent such record from being maintained electronically. Pharmacists shall not be required to submit this information to the Prescription Drug Monitoring Program. Such standing order shall not require pharmacies in this state to maintain opioid antagonists in their biennial inventories."

SECTION 1-5.

Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, is amended by revising Code Section 16-13-29, relating to Schedule V, as follows:

"16-13-29.

The controlled substances listed in this Code section are included in Schedule V:

(1) Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or salts thereof, which also contains one or more nonnarcotic, active, medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(A) Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

(B) Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

(C) Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

(D) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(E) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(2) Lacosamide;

(3) Pregabalin;

(4) Pyrovalerone;

(5) Pseudoephedrine as an exempt over-the-counter Schedule V controlled substance distributed in the same manner as set forth in Code Section 16-13-29.2; provided, however, that such exemption shall take effect immediately and shall not require ~~rulemaking~~ rule making by the State Board of Pharmacy; provided, further, that wholesale drug distributors located within this state and licensed by the State Board of Pharmacy and which are registered and regulated by the DEA shall not be subject to any board requirements for controlled substances for the storage, reporting, record keeping, or physical security of drug products containing pseudoephedrine which are more stringent than those included in DEA regulations; ~~or~~

(6) Ezogabine; or

(7) Naloxone as an exempt Schedule V controlled substance, which shall require rule making by the State Board of Pharmacy and such rule shall require such substance to be sold only in a pharmacy. Such rule shall further authorize pharmacists and pharmacy interns and externs under the supervision of a licensed pharmacist to dispense Naloxone only with a prescription by a licensed practitioner or under a standing order issued pursuant to Code Section 26-4-116.2."

SECTION 1-6.

Said chapter is further amended by revising paragraph (635) of subsection (b) of Code Section 16-13-71, relating to the definition of a dangerous drug, as follows:

"(635) ~~Naloxone~~ Reserved;"

PART II

SECTION 2-1.

This part shall be known and may be cited as the "Substance Abuse Treatment and Overdose Prevention Act" or the "STOP Act."

SECTION 2-2.

The General Assembly finds that it is important to understand the needs of its residents with serious substance abuse disorders and the state's ability to provide appropriate and necessary programs and services to Georgia's citizens. Overdose deaths result from a variety of substances, including prescription painkillers, heroin, and synthetic designer drugs. Further, addressing the opioid epidemic will require a state-wide approach that is coordinated and focused on improving addiction and recovery services, overdose prevention resources, disease reporting, and prescription drug policies and monitoring programs. Therefore, the General Assembly has determined it is in the best interests of the state and its citizenry to address these issues through the STOP Act.

SECTION 2-3.

Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, is amended in Code Section 16-13-59, relating to information to include for each Schedule II, III, IV, or V controlled substance prescription and compliance, by revising subsection (b) as follows:

"(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~~ every 24 hours and shall report, at a minimum, such prescription information no later than ~~ten days~~ 24 hours 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."

SECTION 2-4.

Said chapter is further amended in Code Section 16-13-60, relating to privacy and confidentiality, use of data, and security program, by revising subsections (a), (c), and (c.1) as follows:

"(a) Except as otherwise provided in subsections (c), (c.1), 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."

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

(1) To persons authorized to prescribe or dispense controlled substances for the sole purpose of providing medical or pharmaceutical care to a specific patient or to delegates of such persons authorized to prescribe or dispense controlled substances in accordance with the following:

(A) Such delegates are members of the prescriber or dispenser's staff and retrieve and review information and reports strictly for purposes of determining usage, misuse, abuse, or underutilization of prescribed medication;

(B) Such dispenser's delegates are licensed~~, registered, or certified by the state regulatory board governing the delegating prescriber or dispenser, and~~ or registered under Title 26, provided that the delegating ~~prescriber or~~ dispenser shall be held responsible for the use of the information and data by ~~their~~ his or her delegates; ~~and~~

(C) Such prescriber's delegates may include any member of the prescriber's staff, provided that the delegating prescriber shall be held responsible for the use of the information and data by his or her delegates; and

~~(C)~~(D) All information and reports retrieved and reviewed by delegates shall be maintained in a secure and confidential manner in accordance with the requirements of subsection (f) of this Code section;

(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 or state law enforcement or prosecutorial officials pursuant to the issuance of a search warrant from an appropriate court or official in the county in which the office of such law enforcement or prosecutorial officials are located pursuant to Article 2 of Chapter 5 of Title 17 or to federal law enforcement or prosecutorial officials pursuant to the issuance of a search warrant pursuant to 21 U.S.C. or a grand jury subpoena pursuant to 18 U.S.C.; and

(4) To the agency, the Georgia Composite Medical Board or any other state regulatory board governing prescribers or dispensers in this state, or the Department of Community Health for purposes of the state Medicaid program upon the issuance of a subpoena by such agency, board, or department pursuant to their existing subpoena power or to the federal Centers for Medicare and Medicaid Services upon the issuance of a subpoena by the federal government pursuant to its existing subpoena powers.

(c.1) An individual authorized to access electronic data base prescription information pursuant to this part may:

(1) Communicate concerns about a patient's potential usage, misuse, abuse, or underutilization of a controlled substance with ~~other~~ prescribers and dispensers that are involved in the patient's health care; or

(2) Report potential violations of this article to the agency for review or investigation. Following such review or investigation, the agency may:

(A) Refer instances of a patient's possible personal misuse or abuse of controlled substances to the patient's primary prescriber to allow for potential intervention and impairment treatment;

(B) Refer probable violations of controlled substances being acquired for illegal distribution, and not solely for a patient's personal use, to the appropriate authorities for further investigation and potential prosecution; or

(C) Refer probable regulatory violations by prescribers or dispensers to the regulatory board governing such person.″

SECTION 2-5.

Said chapter is further amended by revising Code Section 16-13-63, relating to liability, as follows:

″16-13-63.

(a)(1) 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 civilly liable for damages to any person in any civil or administrative action or criminally responsible 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. ~~Nothing in this part shall create a private cause of action against a prescriber or dispenser~~.

(2) A prescriber or his or her delegate shall seek and review information from the electronic data base established pursuant to Code Section 16-13-57 whenever he or she is prescribing a Schedule II, III, IV, or V controlled substance to a patient for the first

time and at least once every 90 days thereafter if such prescriber continues to prescribe a controlled substance to such patient. A prescriber or delegate shall be exempt from the duty to seek and review information from the electronic data base pursuant to this paragraph if:

(A) The patient is terminally ill and under the supervised care of a hospice program;

(B) The patient is in a long-term care facility that has an on-site pharmacy or the controlled substances under this paragraph are dispensed by a hospital pharmacy;

(C) The patient is undergoing addiction treatment in a program that is administering methadone or buprenorphine;

(D) The prescription is for a supply of three days or less with no refills permitted; or

(E) The electronic data base is not operational due to a systematic technological interruption or widespread electrical failure as a result of a natural disaster, provided the prescriber notifies the board and agency of such incident.

(3)(A) When prescribing a Schedule II, III, IV, or V controlled substance to an adult patient for the first time, a prescriber shall not issue a prescription for more than a five-day supply of such controlled substance, as recommended in the *Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain*.

(B) A prescriber shall not issue a prescription for a Schedule II, III, IV, or V controlled substance for a minor for more than a five-day supply of such controlled substance at any time. The prescriber shall discuss the risks associated with the use of such controlled substance, including the risk of addiction and overdose associated with such controlled substance and the dangers of taking it with alcohol, benzodiazepines, and other central nervous system depressants. Such consultation with a minor and the custodial parent, guardian, person having legal custody of the minor, or other person present at the time of such consultation shall include the medical need for the prescription.

(C) Nothing in this paragraph shall limit a prescriber who, in his or her professional medical judgment, determines that more than a five-day supply of a Schedule II, III, IV, or V controlled substance is medically necessary for palliative care or to treat a patient's acute medical condition, chronic pain, or pain associated with a cancer diagnosis. Such condition shall be documented in the patient's medical record and the prescriber shall indicate that an alternative to such controlled substance was not appropriate to treat such medical condition.

(D) Nothing in this paragraph shall apply to controlled substances specifically designated for treatment of abuse of or dependence on a Schedule II, III, IV, or V controlled substance.

(b) A dispenser or prescriber acting in good faith shall not be held civilly liable for damages to any person in any civil or administrative action or criminally responsible for injury, death, or loss to person or property for receiving or using information from the electronic data base established pursuant to Code Section 16-13-57.″

SECTION 2-6.

Said chapter is further amended by revising Code Section 16-13-64, relating to violations, criminal penalties, and civil damages, by adding a new subsection to read as follows:

″(c.1) A prescriber or his or her delegate who knowingly and intentionally fails to seek and review information as required by this part or who knowingly and intentionally disregards the 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 prescriber's or delegate's license for action to be taken against such prescriber's or delegate's license.″

PART III

SECTION 3-1.

Code Section 31-12-2 of the Official Code of Georgia Annotated, relating to reporting disease, confidentiality, reporting required by pharmacists, immunity from liability as to information supplied, and notification of potential bioterrorism, is amended by adding a new subsection to read as follows:

″(a.1)(1) As used in this subsection, the term 'neonatal abstinence syndrome' means a group of physical problems that occur in a newborn infant who was exposed to addictive illegal or prescription drugs while in the mother's womb.

(2) The department shall require notice and reporting of incidents of neonatal abstinence syndrome. The department shall require the reporting thereof to the department from a health care provider, coroner, or medical examiner, or any other person or entity the department determines has knowledge of diagnosis or health outcomes related, directly or indirectly, to neonatal abstinence syndrome. The department shall provide an annual report to the President of the Senate, the Speaker of the House of Representatives, the chairperson of the House Committee on Health and Human Services, and the chairperson of the Senate Health and Human Services Committee. Such annual report shall include any department findings and recommendations on how to reduce the number of infants born with neonatal abstinence syndrome.″

PART IV.

SECTION 4-1.

Chapter 5 of Title 26 of the Official Code of Georgia Annotated, relating to drug abuse treatment and education programs, is amended by adding new Code sections to read as follows:

"26-5-22.

The authorized department shall conduct an annual onsite inspection of each narcotic treatment program licensed in this state. Such inspection shall include, but not be limited to, the premises, staff, persons in care, and documents pertinent to the continued licensing of such narcotic treatment program so that the department may determine whether a provider is operating in compliance with licensing requirements.

26-5-23.

Patient outcome data for narcotic treatment programs in Georgia shall be reported to the Department of Community Health on a monthly basis. The department shall provide for the establishment of such reporting for the purpose of providing a method of tracking patient outcome data that will assist in determining the number of patients, the length of time in each program, the number of patients discharged from each program, and any other data the department determines that will assist in tracking such patient outcomes."

PART V.

SECTION 5-1.

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