Senate Bill 241

By: Senators Unterman of the 45th, Burke of the 11th, Miller of the 49th, Watson of the 1st and Hufstetler of the 52nd

AS PASSED SENATE

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 change certain provisions of the electronic data base of prescription information; to transfer responsibilities for the electronic data base of prescription information of the Georgia Drugs and Narcotics Agency to the Department of Public Health; to provide for the department's authority to continue the maintenance and development of the electronic data base of prescription information; to provide for definitions; to change the frequency of reporting provision; to amend Article 1 of Chapter 2A of Title 31 of the Official Code of Georgia Annotated, relating to the Department of Public Health, so as to provide for the department to maintain and administer the electronic data base of prescription information; to amend Article 9 of Chapter 7 of Title 31 of the Official Code of Georgia Annotated, relating to hospice care, so as to provide for the disposal of controlled substances upon the death of a hospice patient; to provide for a definition; to provide for persons authorized to dispose of controlled substances; to provide for a time frame; to provide for related matters; 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 adding new paragraphs to Code Section 16-13-21, relating to definitions, to read as follows:

"(6.3) 'De-identified' means data that has been processed to remove personal identifiers from the health information in compliance with the standard and implementation rules of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996, P.L. 104-191."

"(7.1) 'Department' means the Department of Public Health."

SECTION 2.

Said chapter is further amended by revising Code Section 16-13-57, relating to program to record prescription information into electronic data base, administration, and oversight, as follows:

"16-13-57.

~~(a)~~ Subject to funds as may be appropriated by the General Assembly or otherwise available for such purpose, the ~~agency~~ department shall, in consultation with members of the Georgia Composite Medical Board, the State Board of Pharmacy, and the agency, establish and maintain a program to electronically record into an electronic data base prescription information resulting from the dispensing of Schedule II, III, IV, or V controlled substances 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~~.~~, for health oversight purposes; and to gather data for epidemiological research.

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

SECTION 3.

Said chapter is further amended by revising Code Section 16-13-58, relating to funds for development and maintenance of program and granting of funds to dispensers, as follows:

"16-13-58.

(a) The ~~agency~~ department shall be authorized to apply for available grants and may accept any gifts, grants, donations, and other funds to assist in developing and maintaining the program established pursuant to Code Section 16-13-57; provided, however, that neither the ~~board, agency,~~ department 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~~ department 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 received by the ~~agency~~ department for the operation of the program established pursuant to Code Section 16-13-57. The ~~agency~~ department 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."

SECTION 4.

Said chapter is further amended by revising Code Section 16-13-59, relating to information to include for each Schedule II, III, IV, or V controlled substance prescription and compliance, as follows:

"16-13-59.

(a) For purposes of the program established pursuant to Code Section 16-13-57, each dispenser shall submit to the ~~agency~~ department by electronic means information regarding each prescription dispensed for a Schedule II, III, IV, or V controlled substance. 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~~ department.

(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~~ department ~~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~~ ~~the~~ department.

(c) The ~~agency~~ department may issue a waiver to a dispenser that is unable to submit prescription information by electronic means acceptable to the ~~agency~~ department. Such waiver may permit the dispenser to submit prescription information to the ~~agency~~ department 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~~ department.

(d) The ~~agency~~ department 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~~ department shall not access or allow others to access any identifying prescription information from the electronic data base after two years from the date such information was originally received by the ~~agency~~ department. The ~~agency~~ department may retain ~~aggregated~~ de-identified prescription information for ~~a period of two years from the date the information is received~~ more than two years but shall promulgate regulations and procedures that will ensure that any identifying information the ~~agency~~ department receives from any dispenser or reporting entity that is two years 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~~ department for an exemption to be excluded from compliance with this Code section if compliance would impose an undue hardship on such dispenser. The ~~agency~~ department shall provide guidelines and criteria for what constitutes an undue hardship.

(g) For purposes of this Code section, the term 'dispenser' shall include any pharmacy or facility physically located in another state or foreign country that in any manner ships, mails, or delivers a dispensed controlled substance into this state.″

SECTION 5.

Said chapter is further amended by revising Code Section 16-13-60, relating to privacy and confidentiality, use of data, and security program, 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.

(b) The ~~agency~~ department, 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. Nothing in this subsection shall be construed to prohibit the agency from accessing prescription information as a part of an investigation into suspected or reported abuses or regarding illegal access of the data. Such information may be used in the prosecution of an offender who has illegally obtained prescription information.

(c) The ~~agency~~ department 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 delegates are licensed, registered, or certified by the state regulatory board governing the delegating prescriber or dispenser, and the delegating prescriber or dispenser shall be held responsible for the use of the information and data by their delegates; and

(C) 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, for health oversight purposes, or 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~~ and

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

(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, including the Georgia Bureau of Investigation, for further investigation and potential prosecution; or

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

(d) The ~~board~~ department may provide ~~statistical~~ de-identified data to government entities and other entities for statistical, research, educational, instructional, drug abuse prevention, or grant application purposes after removing information that could be used to identify prescribers ~~or individual patients or persons who received prescriptions from dispensers; the board may provide nonpatient specific data to the agency for instructional, drug abuse prevention, and research purposes~~.

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

(f) Any permissible user identified in this part who directly accesses electronic data 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~~ department. 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.

(g) No provision in this part shall be construed to modify, limit, diminish, or impliedly repeal any authority ~~existing on June 30, 2011,~~ of a licensing or regulatory board or any other entity so authorized to obtain prescription information from sources other than the data base maintained pursuant to this part; provided, however, that the ~~agency~~ department shall be authorized to release information from the data base only in accordance with the provisions of this part."

SECTION 6.

Said chapter is further amended by revising Code Section 16-13-61, relating to the Electronic Database Review Advisory Committee, members, terms, officers, procedure, and compensation, as follows:

"16-13-61.

(a) There is established an Electronic Database Review Advisory Committee for the purposes of consulting with and advising the ~~agency~~ department 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 ~~ten~~ eleven members as follows:

(1) A representative from the ~~agency~~ department;

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

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

(4) A representative with expertise in personal privacy matters, appointed by the president of the State Bar of Georgia;

(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;

(9) A representative from the State Board of Optometry; ~~and~~

(10) The consumer member appointed by the Governor to the State Board of Pharmacy pursuant to subsection (b) of Code Section 26-4-21.; and

(11) A representative from the agency.

(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."

SECTION 7.

Said chapter is further amended by revising Code Section 16-13-62, relating to rules and regulations, as follows:

"16-13-62.

The ~~agency~~ department shall establish rules and regulations to implement the requirements of this part. Nothing in this part shall be construed to authorize the ~~agency~~ department 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. Nothing in this part shall be construed to impede, impair, or limit a prescriber from prescribing pain medication in accordance with the pain management guidelines developed and adopted by the Georgia Composite Medical Board."

SECTION 8.

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

"(a) A dispenser who knowingly and intentionally fails to submit prescription information to the ~~agency~~ department 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."

SECTION 9.

Article 1 of Chapter 2A of Title 31, relating to the Department of Public Health, is amended in Code Section 31-2A-4, relating to the obligation to safeguard and promote health of people of the state, by revising paragraphs (13) and (14) and adding a new paragraph to read as follows:

"(13) Exchange data with the Department of Community Health for purposes of health improvement and fraud prevention for programs operated by the Department of Community Health pursuant to mutually agreed upon data sharing agreements and in accordance with federal confidentiality laws relating to health care; ~~and~~

(14) Provide The Council of Superior Court Clerks of Georgia the data set forth in Code Section 15-12-40.1, without charge and in the electronic format requested~~.~~ and

(15) Maintain and administer the electronic data base of prescription information established under Code Section 16-13-57."

SECTION 10.

Article 9 of Chapter 7 of Title 31 of the Official Code of Georgia Annotated, relating to hospice care, is amended by adding a new Code section to read as follows:

"31-7-180.

(a) As used in this Code section, the term 'controlled substance' means a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29.

(b) When a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided for ultimate users pursuant to 21 U.S.C. 822(g) (4). An ultimate user includes a person who has lawfully obtained and possesses a controlled substance for his or her own use or for use by a member of his or her household pursuant to 21 U.S.C. 802(27). A member of the hospice patient family unit or the hospice care team as such terms are defined in this article shall be authorized to dispose of the deceased patient's controlled substances under this Code section. Such controlled substances shall be disposed of in accordance with the federal Controlled Substances Act. Such disposal shall be conducted within 72 hours of the death of the patient."

SECTION 11.

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