

The Senate Committee on Health and Human Services offered the following substitute to SB 241:

A BILL TO BE ENTITLED
AN ACT

1 To amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to
2 controlled substances, so as to change certain provisions of the electronic data base of
3 prescription information; to transfer responsibilities for the electronic data base of
4 prescription information of the Georgia Drugs and Narcotics Agency to the Department of
5 Public Health; to provide for the department's authority to continue the maintenance and
6 development of the electronic data base of prescription information; to provide for
7 definitions; to change the frequency of reporting provision; to amend Article 1 of Chapter 2A
8 of Title 31 of the Official Code of Georgia Annotated, relating to the Department of Public
9 Health, so as to provide for the department to maintain and administer the electronic data
10 base of prescription information; to provide for related matters; to repeal conflicting laws;
11 and for other purposes.

12 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

13 Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled
14 substances, is amended by adding new paragraphs to Code Section 16-13-21, relating to
15 definitions, to read as follows:
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17 "(6.3) 'De-identified' means data that has been processed to remove personal identifiers
18 from the health information in compliance with the standard and implementation rules
19 of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996,
20 P.L. 104-191."

21 "(7.1) 'Department' means the Department of Public Health."

SECTION 2.

22 Said chapter is further amended by revising Code Section 16-13-57, relating to program to
23 record prescription information into electronic data base, administration, and oversight, as
24 follows:
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26 "16-13-57.

27 (a) Subject to funds as may be appropriated by the General Assembly or otherwise
 28 available for such purpose, the ~~agency department~~ shall, in consultation with members of
 29 the Georgia Composite Medical Board, the State Board of Pharmacy, and the agency,
 30 establish and maintain a program to electronically record into an electronic data base
 31 prescription information resulting from the dispensing of Schedule II, III, IV, or V
 32 controlled substances and to electronically review such prescription information that has
 33 been entered into such data base. The purpose of such program shall be to assist in the
 34 reduction of the abuse of controlled substances; to improve, enhance, and encourage a
 35 better quality of health care by promoting the proper use of medications to treat pain and
 36 terminal illness; and to reduce duplicative prescribing and overprescribing of controlled
 37 substance practices; for health oversight purposes; and to gather data for epidemiological
 38 research.

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

41 **SECTION 3.**

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

44 "16-13-58.

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

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

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

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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~~ 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

- 97 department by paper form or other means, provided all information required in subsection
 98 (a) of this Code section is submitted in this alternative format and in accordance with the
 99 frequency requirements established pursuant to subsection (b) of this Code section.
 100 Requests for waivers shall be submitted in writing to the agency department.
- 101 (d) The agency department shall not revise the information required to be submitted by
 102 dispensers pursuant to subsection (a) of this Code section more frequently than annually.
 103 Any such change to the required information shall neither be effective nor applicable to
 104 dispensers until six months after the adoption of such changes.
- 105 (e) The agency department shall not access or allow others to access any identifying
 106 prescription information from the electronic data base after two years from the date such
 107 information was originally received by the agency department. The agency department
 108 may retain aggregated de-identified prescription information for a period of two years from
 109 the date the information is received more than two years but shall promulgate regulations
 110 and procedures that will ensure that any identifying information the agency department
 111 receives from any dispenser or reporting entity that is two years old or older is deleted or
 112 destroyed on an ongoing basis in a timely and secure manner.
- 113 (f) A dispenser may apply to the agency department for an exemption to be excluded from
 114 compliance with this Code section if compliance would impose an undue hardship on such
 115 dispenser. The agency department shall provide guidelines and criteria for what constitutes
 116 an undue hardship.
- 117 (g) For purposes of this Code section, the term 'dispenser' shall include any pharmacy or
 118 facility physically located in another state or foreign country that in any manner ships,
 119 mails, or delivers a dispensed controlled substance into this state."

120 **SECTION 5.**

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

123 "(a) Except as otherwise provided in subsections (c), (c.1), and (d) of this Code section,
 124 prescription information submitted pursuant to Code Section 16-13-59 shall be confidential
 125 and shall not be subject to open records requirements, as contained in Article 4 of
 126 Chapter 18 of Title 50.

127 (b) The agency department, in conjunction with the board, shall establish and maintain
 128 strict procedures to ensure that the privacy and confidentiality of patients, prescribers, and
 129 patient and prescriber information collected, recorded, transmitted, and maintained
 130 pursuant to this part are protected. Such information shall not be disclosed to any person
 131 or entity except as specifically provided in this part and only in a manner which in no way
 132 conflicts with the requirements of the federal Health Insurance Portability and

133 Accountability Act (HIPAA) of 1996, P.L. 104-191. Nothing in this subsection shall be
134 construed to prohibit the agency from accessing prescription information as a part of an
135 investigation into suspected or reported abuses or regarding illegal access of the data. Such
136 information may be used in the prosecution of an offender who has illegally obtained
137 prescription information.

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

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

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

147 (B) Such delegates are licensed, registered, or certified by the state regulatory board
148 governing the delegating prescriber or dispenser, and the delegating prescriber or
149 dispenser shall be held responsible for the use of the information and data by their
150 delegates; and

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

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

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

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

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

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

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

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

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

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

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

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

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

204 (g) No provision in this part shall be construed to modify, limit, diminish, or impliedly
 205 repeal any authority ~~existing on June 30, 2011,~~ of a licensing or regulatory board or any
 206 other entity so authorized to obtain prescription information from sources other than the

207 data base maintained pursuant to this part; provided, however, that the agency department
 208 shall be authorized to release information from the data base only in accordance with the
 209 provisions of this part."

210 SECTION 6.

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

214 "16-13-61.

215 (a) There is established an Electronic Database Review Advisory Committee for the
 216 purposes of consulting with and advising the agency department on matters related to the
 217 establishment, maintenance, and operation of how prescriptions are electronically reviewed
 218 pursuant to this part. This shall include, but shall not be limited to, data collection,
 219 regulation of access to data, evaluation of data to identify benefits and outcomes of the
 220 reviews, communication to prescribers and dispensers as to the intent of the reviews and
 221 how to use the data base, and security of data collected.

222 (b) The advisory committee shall consist of ~~ten~~ eleven members as follows:

223 (1) A representative from the agency department;

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

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

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

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

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

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

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

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

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

237 (11) A representative from the agency.

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

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

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

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

248 **SECTION 7.**

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

251 "16-13-62.

252 The agency department shall establish rules and regulations to implement the requirements
 253 of this part. Nothing in this part shall be construed to authorize the agency department to
 254 establish policies, rules, or regulations which limit, revise, or expand or purport to limit,
 255 revise, or expand any prescription or dispensing authority of any prescriber or dispenser
 256 subject to this part. Nothing in this part shall be construed to impede, impair, or limit a
 257 prescriber from prescribing pain medication in accordance with the pain management
 258 guidelines developed and adopted by the Georgia Composite Medical Board."

259 **SECTION 8.**

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

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

269 **SECTION 9.**

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

274 "(13) Exchange data with the Department of Community Health for purposes of health
 275 improvement and fraud prevention for programs operated by the Department of

276 Community Health pursuant to mutually agreed upon data sharing agreements and in
277 accordance with federal confidentiality laws relating to health care; ~~and~~
278 (14) Provide The Council of Superior Court Clerks of Georgia the data set forth in Code
279 Section 15-12-40.1, without charge and in the electronic format requested; and
280 (15) Maintain and administer the electronic data base of prescription information
281 established under Code Section 16-13-57."

282 **SECTION 10.**
283 All laws and parts of laws in conflict with this Act are repealed.