

The House Committee on Health and Human Services offers the following substitute to HB 614:

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 enact the "Georgia Prescription Monitoring Program Act"; to
3 provide for legislative intent; to provide for definitions; to provide for the establishment of
4 a program for the monitoring of prescribing and dispensing Schedule II, III, IV, or V
5 controlled substances and of selling over-the-counter Schedule V controlled substances by
6 the Georgia Drugs and Narcotics Agency; to require dispensers to submit certain information
7 regarding the dispensing and sale of such controlled substances; to provide for the
8 confidentiality of submitted information except under certain circumstances; to authorize the
9 contracting of services relating to the program; to provide for notice and information to
10 prescribers and dispensers; to provide for the establishment of a Prescription Monitoring
11 Program Advisory Committee; to provide for its membership, duties, and organization; to
12 provide for the establishment of rules and regulations; to provide for penalties; to provide for
13 limited liability; to include pseudoephedrine as a Schedule V controlled substance; to remove
14 pseudoephedrine from the definition of "dangerous drug"; to provide for related matters; to
15 provide for an effective date; to repeal conflicting laws; and for other purposes.

16 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

17 **SECTION 1.**

18 Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled
19 substances, is amended by adding a new article to read as follows:

20 "ARTICLE 6

21 16-13-120.

22 This article shall be known and may be cited as the 'Georgia Prescription Monitoring
23 Program Act.'

24 16-13-121.

25 This article is intended to improve health care quality and effectiveness by reducing abuse
26 of controlled substances, reducing duplicative prescribing and overprescribing of controlled
27 substances, and improving controlled substance prescribing practices with the intent of
28 establishing an electronic data base available to dispensers and prescribers of controlled
29 substances.

30 16-13-122.

31 As used in this article, the term:

32 (1) 'Agency' means the Georgia Drugs and Narcotics Agency.

33 (2) 'Controlled substance' has the same meaning given such term in paragraph (4) of
34 Code Section 16-13-21.

35 (3) 'Dispenser' means a person that delivers a Schedule II, III, IV, or V controlled
36 substance or an OTC Schedule V controlled substance to the ultimate user but shall not
37 include:

38 (A) A licensed pharmacy of a hospital that dispenses or sells such substances for the
39 purpose of inpatient or outpatient hospital care, a licensed pharmacy of a hospital or
40 retail pharmacy of a hospital that dispenses prescriptions for controlled substances or
41 sells OTC Schedule V controlled substances at the time of dismissal or discharge from
42 such a facility, or a licensed pharmacy of a hospital or retail pharmacy of a hospital that
43 dispenses, sells, or administers such substances for long-term care patients or inpatient
44 hospice facilities;

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

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

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

56 (E) A licensed veterinarian.

57 A clinic or other health care facility may apply to the agency for an exemption to be
58 excluded from the definition of this term for purposes of compliance with this article if
59 compliance would impose an undue hardship on such facility. The agency, in

60 consultation with the Composite State Board of Medical Examiners and the Georgia State
61 Board of Pharmacy, shall provide guidelines and criteria for what constitutes an undue
62 hardship which shall include criteria relating to the amount of indigent patients served
63 and the lack of electronic capability of the facility.

64 (4) 'OTC Schedule V controlled substance' means any drug that is classified as a
65 Schedule V controlled substance but that can be sold without a prescription in accordance
66 with state and federal laws and regulations.

67 (5) 'Patient' means the person or animal who is the ultimate user of a drug for whom a
68 prescription is issued or for whom a drug is dispensed.

69 (6) 'Prescriber' means a physician, dentist, optometrist, podiatrist, or other person
70 licensed, registered, or otherwise authorized under the laws of this state to prescribe,
71 distribute, dispense, conduct research with respect to, or administer a controlled substance
72 in the course of professional practice or research in this state. This term shall not include
73 a licensed veterinarian.

74 (7) 'Purchaser' means a person who purchases an OTC Schedule V controlled substance
75 as authorized by law.

76 (8) 'Schedule II, III, IV, or V controlled substance' means a controlled substance that is
77 classified as a Schedule II, III, IV, or V controlled substance under Code Section
78 16-13-26, 16-13-27, 16-13-28, or 16-13-29, respectively, or under the Federal Controlled
79 Substances Act, 21 U.S.C. Section 812.

80 16-13-123.

81 (a) The agency may apply for available grants and accept any gifts, grants, or donations
82 to assist in developing and maintaining the program established by this article.

83 (b) The agency shall be authorized to grant funds to dispensers for the purpose of covering
84 costs for dedicated equipment and software for dispensers to use in complying with the
85 reporting requirements of this article. Such grants shall be funded by gifts, grants,
86 donations, or other funds appropriated for the operation of the prescription monitoring
87 program established under the provisions of Code Section 16-13-124. The agency shall be
88 authorized to establish standards and specifications for any equipment and software
89 purchased pursuant to a grant received pursuant to this article. Nothing in this article shall
90 be construed to require a dispenser or prescriber to incur costs to purchase equipment and
91 software to comply with this article or to incur ongoing expenses in complying with this
92 article.

93 16-13-124.

94 (a) The agency, in consultation with the Composite State Board of Medical Examiners and
95 the Georgia State Board of Pharmacy, shall establish and maintain a program for the
96 monitoring of prescribing and dispensing of all Schedule II, III, IV, or V controlled
97 substances and the selling of all OTC Schedule V controlled substances.

98 (b)(1) Except as otherwise provided for in this Code section, beginning January 1, 2011,
99 each dispenser shall submit to the agency by electronic means information regarding each
100 prescription dispensed for a Schedule II, III, IV, or V controlled substance in accordance
101 with this subsection.

102 (2) The information submitted for each prescription dispensed for a Schedule II, III, IV,
103 or V controlled substance shall include, but not be limited to:

104 (A) United States Drug Enforcement Administration (DEA) permit number or
105 approved dispenser facility identification number;

106 (B) Date prescription filled;

107 (C) Prescription number;

108 (D) Whether prescription is new or a refill;

109 (E) National Drug Code (NDC) for drug dispensed;

110 (F) Quantity and strength dispensed;

111 (G) Number of days' supply of the drug;

112 (H) Patient's name;

113 (I) Patient's address;

114 (J) Patient's date of birth;

115 (K) Approved prescriber identification number;

116 (L) Date prescription issued by prescriber; and

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

119 (3) The information submitted for each OTC Schedule V controlled substance sold shall
120 include, but not be limited to:

121 (A) United States Drug Enforcement Administration (DEA) permit number or
122 approved dispenser facility identification number;

123 (B) Date of sale;

124 (C) Name and strength of the OTC Schedule V controlled substance;

125 (D) Quantity purchased or attempted to be purchased;

126 (E) Purchaser's name;

127 (F) Purchaser's address;

128 (G) Purchaser's date of birth; and

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

131 (4) The agency shall not revise the information required to be submitted by dispensers
132 pursuant to paragraph (2) or (3) of this subsection more frequently than annually. Any
133 such change to the required information shall neither be effective nor be applicable to
134 dispensers until six months after the adoption of such changes.

135 (c) Each dispenser shall weekly submit the information required in subsection (b) of this
136 Code section in accordance with transmission methods and requirements established by the
137 agency and shall report, at a minimum, prescriptions dispensed and OTC Schedule V
138 controlled substances sold up to the day prior to data submission.

139 (d) Dispensers who do not have the technical capabilities to comply with this article shall
140 not be required to submit prescription information prior to July 1, 2011.

141 (e) Beginning July 1, 2011, the agency may issue a waiver to a dispenser that is unable to
142 submit required prescription and sale information by electronic means acceptable to the
143 agency. Such waiver may permit the dispenser to submit required prescription and sale
144 information by paper form or other means, provided that all information required in
145 subsection (b) of this Code section is submitted in this alternative format subject to the
146 frequency requirements of subsection (c) of this Code section. Requests for waivers shall
147 be submitted in writing.

148 16-13-125.

149 (a) Required prescription and sale information submitted to the agency shall be
150 confidential and shall not be subject to open records requirements, as contained in Article
151 4 of Chapter 18 of Title 50, except as provided in subsections (c) and (d) of this Code
152 section.

153 (b) The agency shall establish and maintain strict procedures to ensure that the privacy and
154 confidentiality of patients, prescribers, and purchasers and patient, prescriber, and
155 purchaser information collected, recorded, transmitted, and maintained pursuant to this
156 article are protected, including verification of the identity of a recipient of information
157 pursuant to this Code section. Such information shall not be disclosed to persons except
158 as otherwise provided in this article and only in a manner which in no way would conflict
159 with the requirements of the federal Health Insurance Portability and Accountability Act
160 of 1996, P.L. 104-191. This may include, but not be limited to, restricting access only to
161 those individuals and entities which clearly demonstrate a need to know such information.

162 (c) The agency shall review the required prescription and sale information and if there is
163 reasonable cause to believe a violation of law or breach of professional standards may have
164 occurred, the agency shall notify the appropriate law enforcement or professional licensing,

165 certification, or regulatory board or entity and shall provide prescription and sale
166 information to such board or entity which may be necessary for an investigation.
167 (d) The agency shall be authorized to provide data collected pursuant to this article to the
168 following persons or under the following circumstances:
169 (1) Persons authorized to prescribe or dispense controlled substances for the purpose of
170 providing medical or pharmaceutical care for their patients;
171 (2) Upon the request of a person about whom the information requested concerns or
172 upon the request on his or her behalf by his or her attorney;
173 (3) The Composite State Board of Medical Examiners, Georgia State Board of
174 Pharmacy, or any licensing board whose practitioners have the authority to prescribe or
175 dispense controlled substances but only as to the practitioners of such board;
176 (4) Local, state, and federal law enforcement, regulatory, or prosecutorial officials
177 engaged in the administration, investigation, or enforcement of the laws governing licit
178 drugs and who are involved in a bona fide, specific drug related investigation involving
179 a designated case;
180 (5) Upon the lawful order of a court of competent jurisdiction; and
181 (6) Personnel of the agency for purposes of administration and enforcement of this
182 article, Article 2 of this chapter, the 'Georgia Controlled Substances Act,' or any other
183 applicable state law.
184 (e) The agency may provide data to public or private entities for statistical, research, or
185 educational purposes after removing information that could be used to identify prescribers,
186 individual patients or persons who received prescriptions from dispensers, or purchasers.
187 (f) The agency may provide data to a prescription monitoring program of another state if
188 the confidentiality, security, and privacy standards of the requesting state are determined
189 by the agency to be equivalent to those of the agency.
190 (g) Any person who receives data or reports relating to this article from the agency shall
191 not provide such data or reports to any other person except by order of a court of competent
192 jurisdiction or as otherwise permitted pursuant to this article.
193 (h) Prescription information submitted pursuant to this article shall be purged from the
194 data base five years after the prescription was dispensed.
195 (i) Any permissible user identified in this article who directly accesses data electronically
196 shall implement and maintain a comprehensive information security program that contains
197 administrative, technical, and physical safeguards that are appropriate to the user's size and
198 complexity and to the sensitivity of the personal information obtained. The permissible
199 user shall identify reasonably foreseeable internal and external risks to the security,
200 confidentiality, and integrity of personal information that could result in the unauthorized

201 disclosure, misuse, or other compromise of the information and shall assess the sufficiency
202 of any safeguards in place to control the risks.

203 16-13-126.

204 The agency shall be authorized to contract with another state agency or with a private
205 vendor, as necessary, to ensure the effective operation of the prescription monitoring
206 program established pursuant to this article. Any contractor shall be bound to comply with
207 the provisions regarding confidentiality of prescription information in Code Section
208 16-13-125 and shall be subject to the penalties specified in Code Section 16-13-130 for
209 unlawful acts.

210 16-13-127.

211 The agency shall provide notice and information to all prescribers and dispensers in this
212 state as to the intent of this article, the program established pursuant to this article, and
213 instructions on how to submit prescription information to the agency via electronic means.

214 16-13-128.

215 (a) There is established a Prescription Monitoring Program Advisory Committee for the
216 purposes of consulting with and advising the agency on matters related to the
217 establishment, maintenance, and operation of the prescription monitoring program
218 established pursuant to this article. This shall include, but not be limited to, data collection,
219 regulation of access to data, evaluation of data to identify benefits and outcomes of the
220 program, communication to prescribers and dispensers as to the intent of the program and
221 how to use the data base, and security of data collected.

222 (b) The advisory committee shall consist of:

223 (1) A representative from the Composite State Board of Medical Examiners;

224 (2) A representative from the Georgia State Board of Pharmacy;

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

226 (4) A board certified oncologist appointed by the agency;

227 (5) A pain management specialist appointed by the agency;

228 (6) A representative from a licensed hospice appointed by the agency;

229 (7) An addictive disorders specialist appointed by the agency;

230 (8) A representative from the Division of Public Health of the Department of Human
231 Resources;

232 (9) A consumer member; and

233 (10) A representative from the State Board of Optometry.

234 Each member of the advisory committee shall serve a two-year term and until the
235 appointment and qualification of such member's successor.

236 (c) The advisory committee shall elect a chairperson and vice chairperson from among its
237 membership to serve a term of one year.

238 (d) The advisory committee shall meet at the call of the chairperson or upon request by at
239 least three of the members and shall meet at least one time per year. A majority of the
240 committee shall constitute a quorum.

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

243 16-13-129.

244 The agency shall promulgate rules and regulations setting forth the procedures and methods
245 for implementing this article. Nothing in this article shall be construed to authorize the
246 agency to establish rules or regulations which limit, revise, or expand or purport to limit,
247 revise, or expand any prescription or dispensing authority of any prescriber or dispenser
248 subject to this article.

249 16-13-130.

250 (a) A dispenser who willfully and intentionally fails to submit prescription monitoring
251 information to the agency as required by this article or willfully and intentionally submits
252 incorrect prescription information shall be guilty of a misdemeanor and punished by
253 imprisonment for a period not to exceed 12 months or a fine not to exceed \$1,000.00, or
254 both.

255 (b) An individual authorized to have prescription monitoring information pursuant to this
256 article who willfully and intentionally discloses such information in violation of this article
257 shall be guilty of a felony and punished by imprisonment for a period not to exceed ten
258 years or a fine not to exceed \$10,000.00, or both.

259 (c) An individual authorized to have prescription monitoring information pursuant to this
260 article who willfully and intentionally uses such information in a manner or for a purpose
261 in violation of this article shall be guilty of a felony and punished by imprisonment for a
262 period not to exceed ten years or a fine not to exceed \$10,000.00, or both.

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

265 16-13-131.

266 Nothing in this article shall require a dispenser or prescriber to obtain information about
267 a patient or purchaser from the prescription monitoring program established pursuant to

268 this article. A dispenser or prescriber shall not have a duty and shall not be held liable for
 269 damages to any person in any civil, criminal, or administrative action for injury, death, or
 270 loss to person or property on the basis that the dispenser or prescriber did or did not seek
 271 or obtain information from the prescription monitoring program. A dispenser or prescriber
 272 acting in good faith shall be immune from any civil, criminal, or administrative liability
 273 that might otherwise be incurred or imposed for requesting or receiving information from
 274 the prescription monitoring program."

275 **SECTION 2.**

276 Said chapter is further amended by revising Code Section 16-13-29, relating to Schedule V
 277 controlled substances, as follows:

278 "16-13-29.

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

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

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

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

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

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

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

294 ~~(2) Reserved;~~

295 ~~(3)(2) Pregabalin; or~~

296 (3) Pseudoephedrine; or

297 (4) Pyrovalerone."

298 **SECTION 3.**

299 Said chapter is further amended in Code Section 16-13-71, relating to the definition of
 300 dangerous drug, by revising paragraph (806) of subsection (b) as follows:

301 "~~(806) Pseudoephedrine—See exceptions~~ Reserved;"

302 **SECTION 4.**

303 Said chapter is further amended in Code Section 16-13-71, relating to the definition of
304 dangerous drug, by revising paragraph (23) of subsection (c) as follows:

305 "~~(23) Pseudoephedrine — when a single dosage unit is 60 mg. or less or when~~
306 ~~manufactured in an extended release form with a dosage unit of 240 mg. or less~~ Reserved;"

307 **SECTION 5.**

308 This Act shall become effective on July 1, 2009.

309 **SECTION 6.**

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