

House Bill 614 (RULES COMMITTEE SUBSTITUTE)

By: Representatives Cooper of the 41st and Stephens of the 164th

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 by the Georgia Drugs and Narcotics Agency; to require dispensers to
6 submit certain information regarding the dispensing of such controlled substances; to provide
7 for the confidentiality of submitted information except under certain circumstances; to
8 authorize the contracting of services relating to the program; to provide for notice and
9 information to prescribers and dispensers; to provide for the establishment of a Prescription
10 Monitoring Program Advisory Committee; to provide for its membership, duties, and
11 organization; to provide for the establishment of rules and regulations; to provide for
12 penalties; to provide for limited liability; to provide for related matters; to provide for an
13 effective date; to repeal conflicting laws; and for other purposes.

14 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

15 style="text-align:center">**SECTION 1.**

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

18 style="text-align:center">"ARTICLE 6

19 16-13-120.

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

22 16-13-121.

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

28 16-13-122.

29 As used in this article, the term:

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

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

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

35 (A) A licensed pharmacy of a hospital that dispenses such substances for the purpose
 36 of inpatient or outpatient hospital care, a licensed pharmacy of a hospital or retail
 37 pharmacy of a hospital that dispenses prescriptions for controlled substances at the time
 38 of dismissal or discharge from such a facility, or a licensed pharmacy of a hospital or
 39 retail pharmacy of a hospital that dispenses or administers such substances for
 40 long-term care patients or inpatient hospice facilities;

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

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

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

52 (E) A licensed veterinarian.

53 A clinic or other health care facility may apply to the agency for an exemption to be
 54 excluded from the definition of this term for purposes of compliance with this article if
 55 compliance would impose an undue hardship on such facility. The agency, in
 56 consultation with the Composite State Board of Medical Examiners and the Georgia State
 57 Board of Pharmacy, shall provide guidelines and criteria for what constitutes an undue

58 hardship which shall include criteria relating to the amount of indigent patients served
59 and the lack of electronic capability of the facility.

60 (4) 'Patient' means the person or animal who is the ultimate user of a drug for whom a
61 prescription is issued or for whom a drug is dispensed.

62 (5) 'Prescriber' means a physician, dentist, optometrist, podiatrist, or other person
63 licensed, registered, or otherwise authorized under the laws of this state to prescribe,
64 distribute, dispense, conduct research with respect to, or administer a controlled substance
65 in the course of professional practice or research in this state. This term shall not include
66 a licensed veterinarian.

67 (6) 'Schedule II, III, IV, or V controlled substance' means a controlled substance that is
68 classified as a Schedule II, III, IV, or V controlled substance under Code Section
69 16-13-26, 16-13-27, 16-13-28, or 16-13-29, respectively, or under the Federal Controlled
70 Substances Act, 21 U.S.C. Section 812.

71 16-13-123.

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

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

84 16-13-124.

85 (a) The agency, in consultation with the Composite State Board of Medical Examiners and
86 the Georgia State Board of Pharmacy, shall establish and maintain a program for the
87 monitoring of prescribing and dispensing of all Schedule II, III, IV, or V controlled
88 substances.

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

- 93 (2) The information submitted for each prescription dispensed for a Schedule II, III, IV,
94 or V controlled substance shall include, but not be limited to:
- 95 (A) United States Drug Enforcement Administration (DEA) permit number or
96 approved dispenser facility identification number;
 - 97 (B) Date prescription filled;
 - 98 (C) Prescription number;
 - 99 (D) Whether prescription is new or a refill;
 - 100 (E) National Drug Code (NDC) for drug dispensed;
 - 101 (F) Quantity and strength dispensed;
 - 102 (G) Number of days' supply of the drug;
 - 103 (H) Patient's name;
 - 104 (I) Patient's address;
 - 105 (J) Patient's date of birth;
 - 106 (K) Approved prescriber identification number;
 - 107 (L) Date prescription issued by prescriber; and
 - 108 (M) Other data elements consistent with standards established by the American Society
109 for Automation in Pharmacy, if designated by regulations of the agency.
- 110 (3) The agency shall not revise the information required to be submitted by dispensers
111 pursuant to paragraph (2) of this subsection more frequently than annually. Any such
112 change to the required information shall neither be effective nor be applicable to
113 dispensers until six months after the adoption of such changes.
- 114 (c) Each dispenser shall weekly submit the information required in subsection (b) of this
115 Code section in accordance with transmission methods and requirements established by the
116 agency and shall report, at a minimum, prescriptions dispensed up to the day prior to data
117 submission.
- 118 (d) Dispensers who do not have the technical capabilities to comply with this article shall
119 not be required to submit prescription information prior to July 1, 2011.
- 120 (e) Beginning July 1, 2011, the agency may issue a waiver to a dispenser that is unable to
121 submit required prescription information by electronic means acceptable to the agency.
122 Such waiver may permit the dispenser to submit required prescription information by paper
123 form or other means, provided that all information required in subsection (b) of this Code
124 section is submitted in this alternative format subject to the frequency requirements of
125 subsection (c) of this Code section. Requests for waivers shall be submitted in writing.

126 16-13-125.

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

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

139 (c) The agency shall review the required prescription information and if there is reasonable
140 cause to believe a violation of law or breach of professional standards may have occurred,
141 the agency shall notify the appropriate law enforcement or professional licensing,
142 certification, or regulatory board or entity and shall provide prescription information to
143 such board or entity which may be necessary for an investigation.

144 (d) The agency shall be authorized to provide data collected pursuant to this article to the
145 following persons or under the following circumstances:

146 (1) Persons authorized to prescribe or dispense controlled substances for the purpose of
147 providing medical or pharmaceutical care for their patients;

148 (2) Upon the request of a person about whom the information requested concerns or
149 upon the request on his or her behalf by his or her attorney;

150 (3) The Composite State Board of Medical Examiners, Georgia State Board of
151 Pharmacy, or any licensing board whose practitioners have the authority to prescribe or
152 dispense controlled substances but only as to the practitioners of such board;

153 (4) Local, state, and federal law enforcement, regulatory, or prosecutorial officials
154 engaged in the administration, investigation, or enforcement of the laws governing licit
155 drugs and who are involved in a bona fide, specific drug related investigation involving
156 a designated case;

157 (5) Upon the lawful order of a court of competent jurisdiction; and

158 (6) Personnel of the agency for purposes of administration and enforcement of this
159 article, Article 2 of this chapter, the 'Georgia Controlled Substances Act,' or any other
160 applicable state law.

161 (e) The agency may provide data to public or private entities for statistical, research, or
162 educational purposes after removing information that could be used to identify prescribers
163 or individual patients or persons who received prescriptions from dispensers.

164 (f) The agency may provide data to a prescription monitoring program of another state if
165 the confidentiality, security, and privacy standards of the requesting state are determined
166 by the agency to be equivalent to those of the agency.

167 (g) Any person who receives data or reports relating to this article from the agency shall
168 not provide such data or reports to any other person except by order of a court of competent
169 jurisdiction or as otherwise permitted pursuant to this article.

170 (h) Prescription information submitted pursuant to this article shall be purged from the
171 data base five years after the prescription was dispensed.

172 (i) Any permissible user identified in this article who directly accesses data electronically
173 shall implement and maintain a comprehensive information security program that contains
174 administrative, technical, and physical safeguards that are appropriate to the user's size and
175 complexity and to the sensitivity of the personal information obtained. The permissible
176 user shall identify reasonably foreseeable internal and external risks to the security,
177 confidentiality, and integrity of personal information that could result in the unauthorized
178 disclosure, misuse, or other compromise of the information and shall assess the sufficiency
179 of any safeguards in place to control the risks.

180 16-13-126.

181 The agency shall be authorized to contract with another state agency or with a private
182 vendor, as necessary, to ensure the effective operation of the prescription monitoring
183 program established pursuant to this article. Any contractor shall be bound to comply with
184 the provisions regarding confidentiality of prescription information in Code Section
185 16-13-125 and shall be subject to the penalties specified in Code Section 16-13-130 for
186 unlawful acts.

187 16-13-127.

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

191 16-13-128.

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

199 (b) The advisory committee shall consist of:

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

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

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

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

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

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

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

207 (8) A representative from the Division of Public Health of the Department of Human
208 Resources;

209 (9) A consumer member; and

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

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

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

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

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

220 16-13-129.

221 The agency shall promulgate rules and regulations setting forth the procedures and methods
222 for implementing this article. Nothing in this article shall be construed to authorize the
223 agency to establish rules or regulations which limit, revise, or expand or purport to limit,
224 revise, or expand any prescription or dispensing authority of any prescriber or dispenser
225 subject to this article.

226 16-13-130.

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

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

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

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

242 16-13-131.

243 Nothing in this article shall require a dispenser or prescriber to obtain information about
244 a patient from the prescription monitoring program established pursuant to this article. A
245 dispenser or prescriber shall not have a duty and shall not be held liable for damages to any
246 person in any civil, criminal, or administrative action for injury, death, or loss to person or
247 property on the basis that the dispenser or prescriber did or did not seek or obtain
248 information from the prescription monitoring program. A dispenser or prescriber acting
249 in good faith shall be immune from any civil, criminal, or administrative liability that might
250 otherwise be incurred or imposed for requesting or receiving information from the
251 prescription monitoring program."

252 **SECTION 2.**

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

254 **SECTION 3.**

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