

House Bill 614

By: Representative Cooper of the 41<sup>st</sup>

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 certain drugs; to provide for the  
7 confidentiality of submitted information except under certain circumstances; to authorize the  
8 contracting of services relating to the program; to provide for notice and information to  
9 prescribers and dispensers; to provide for the establishment of a Prescription Monitoring  
10 Program Advisory Committee; to provide for its membership, duties, and organization; to  
11 provide for the establishment of rules and regulations; to provide for penalties; to provide for  
12 limited liability; to provide for related matters; to provide for an effective date; to repeal  
13 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 in real time to dispensers and prescribers of  
27 controlled 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; or

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.

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

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

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

61 (5) 'Prescriber' means a physician, dentist, veterinarian, scientific investigator, or other  
62 person licensed, registered, or otherwise authorized under the laws of this state to  
63 prescribe, distribute, dispense, conduct research with respect to, or administer a  
64 controlled substance in the course of professional practice or research in this state.

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

69 16-13-123.

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

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

81 (C) Dispensers who do not have the technical capabilities to comply with this article shall  
82 not be required to submit prescription information prior to January 1, 2011.

83 16-13-124.

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

88 (b) Each dispenser shall submit to the agency by electronic means information regarding  
89 each prescription dispensed for a Schedule II, III, IV, or V controlled substance. The  
90 information submitted for each prescription shall include, but not be limited to:

- 91 (1) United States Drug Enforcement Administration (DEA) permit number or approved  
92 dispenser facility identification number;  
93 (2) Date prescription filled;  
94 (3) Prescription number;  
95 (4) Whether prescription is new or a refill;  
96 (5) National Drug Code (NDC) for drug dispensed;  
97 (6) Quantity and strength dispensed;  
98 (7) Number of days' supply of the drug;  
99 (8) Patient's name;  
100 (9) Patient's address;  
101 (10) Patient's date of birth;  
102 (11) If the prescription is for an animal, the name and address of the owner of the animal  
103 for whom the prescription is written;  
104 (12) Approved prescriber identification number;  
105 (13) Date prescription issued by prescriber; and  
106 (14) Other data elements consistent with standards established by the American Society  
107 for Automation in Pharmacy, if designated by regulations of the agency.  
108 (c) Each dispenser shall submit the information in accordance with transmission methods  
109 and frequency requirements established by the agency but no less often than monthly and  
110 shall report, at a minimum, prescriptions dispensed up to the day prior to data submission.  
111 (d) Beginning January 1, 2011, the agency may issue a waiver to a dispenser that is unable  
112 to submit prescription information by electronic means acceptable to the agency. Such  
113 waiver may permit the dispenser to submit prescription information by paper form or other  
114 means, provided all information required in subsection (b) of this Code section is submitted  
115 in this alternative format subject to the frequency requirements of subsection (c) of this  
116 Code section. Requests for waivers shall be submitted in writing.

117 16-13-125.

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

121 (b) The agency shall establish and maintain strict procedures to ensure that the privacy and  
122 confidentiality of patients and prescribers and patient and prescriber information collected,  
123 recorded, transmitted, and maintained pursuant to this article are protected. Such  
124 information shall not be disclosed to persons except as otherwise provided in this article  
125 and only in a manner which in no way would conflict with the requirements of the federal  
126 Health Insurance Portability and Accountability Act of 1996, P.L. 104-191. This may

127 include, but not be limited to, restricting access only to those individuals and entities which  
128 clearly demonstrate a need to know such information.

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

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

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

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

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

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

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

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

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

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

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

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

162 (i) Any permissible user identified in this article who directly accesses data electronically  
163 shall implement and maintain a comprehensive information security program that contains

164 administrative, technical, and physical safeguards that are appropriate to the user's size and  
165 complexity and to the sensitivity of the personal information obtained. The permissible  
166 user shall identify reasonably foreseeable internal and external risks to the security,  
167 confidentiality, and integrity of personal information that could result in the unauthorized  
168 disclosure, misuse, or other compromise of the information and shall assess the sufficiency  
169 of any safeguards in place to control the risks.

170 16-13-126.

171 The agency shall be authorized to contract with another state agency or with a private  
172 vendor, as necessary, to ensure the effective operation of the prescription monitoring  
173 program established pursuant to this article. Any contractor shall be bound to comply with  
174 the provisions regarding confidentiality of prescription information in Code Section  
175 16-13-125 and shall be subject to the penalties specified in Code Section 16-13-130 for  
176 unlawful acts.

177 16-13-127.

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

181 16-13-128.

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

189 (b) The advisory committee shall consist of:

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

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

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

193 (4) A representative from the State Board of Veterinary Medicine;

194 (5) A board certified oncologist appointed by the agency;

195 (6) A pain management specialist appointed by the agency;

196 (7) A representative from a licensed hospice appointed by the agency;

197 (8) An addictive disorders specialist appointed by the agency;

198 (9) A representative from the Division of Public Health of the Department of Human  
199 Resources; and

200 (10) Other members as appointed by the agency in its discretion from recommendations  
201 submitted by the Medical Association of Georgia, the Georgia Dental Association, the  
202 Georgia Pharmacy Association, and the Georgia Society of Health System Pharmacies.

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

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

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

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

212 16-13-129.

213 The agency shall promulgate rules and regulations setting forth the procedures and methods  
214 for implementing this article. Nothing in this article shall be construed to authorize the  
215 agency to establish rules or regulations which limit, revise, or expand or purport to limit,  
216 revise, or expand any prescription or dispensing authority of any prescriber or dispenser  
217 subject to this article.

218 16-13-130.

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

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

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

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

234 16-13-131.

235 Nothing in this article shall require a dispenser or prescriber to obtain information about  
236 a patient from the prescription monitoring program established pursuant to this article. A  
237 dispenser or prescriber shall not have a duty and shall not be held liable for damages to any  
238 person in any civil, criminal, or administrative action for injury, death, or loss to person or  
239 property on the basis that the dispenser or prescriber did or did not seek or obtain  
240 information from the prescription monitoring program. A dispenser or prescriber acting  
241 in good faith shall be immune from any civil, criminal, or administrative liability that might  
242 otherwise be incurred or imposed for requesting or receiving information from the  
243 prescription monitoring program."

244 **SECTION 2.**

245 This Act shall become effective on January 1, 2010.

246 **SECTION 3.**

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