Senate Bill 248

By: Senators Shafer of the 48th, Chance of the 16th and Douglas of the 17th

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 State Board of Pharmacy; 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 Georgia Drugs and Narcotics Agency to contract for services relating to the program; to 9 provide for notice and information to prescribers and dispensers; to provide for the 10 establishment of a Prescription Monitoring Program Advisory Committee; to provide for its membership, duties, and organization; to provide for the establishment of rules and 11 12 regulations; to provide for penalties; to provide for limited liability; to provide for related 13 matters; to provide for an effective date; to repeal conflicting laws; and for other purposes. BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA: 14 **SECTION 1.** 15

16 Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled17 substances, is amended by adding a new article to read as follows:

18

"ARTICLE 6

19 <u>16-13-120.</u>

- 20 This article shall be known and may be cited as the 'Georgia Prescription Monitoring
- 21 <u>Program Act.'</u>

22 16-13-121. 23 This article is intended to improve the state's ability to identify and stop diversion of 24 prescription drugs in an efficient and cost-effective manner that will not impede the 25 appropriate medical utilization of licit controlled substances or other licit drugs with 26 potential for abuse while minimizing impact on pharmacy operations. 27 16-13-122. 28 As used in this article, the term: 29 (1) 'Agency' means the Georgia Drugs and Narcotics Agency. 30 (2) 'Board' means the Georgia State Board of Pharmacy. 31 (3) 'Controlled substance' has the same meaning given such term in paragraph (4) of 32 Code Section 16-13-21. 33 (4) 'Dispenser' means a person that delivers a Schedule II, III, IV, or V controlled substance to the ultimate user but shall not include: 34 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 such substances for long-term care patients 40 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 center, or other secure correctional institution. This shall include correctional 49 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 board for an exemption 53 to be excluded from the definition of this term for purposes of compliance with this article if compliance would impose an undue hardship on such facility. The board shall 54 55 provide guidelines and criteria for what constitutes an undue hardship which shall include 56 criteria relating to the amount of indigent patients served and the lack of electronic 57 capability of the facility.

- (5) 'Patient' means the person or animal who is the ultimate user of a drug for whom a
 prescription is issued or for whom a drug is dispensed.
 (6) 'Prescriber' means a physician, dentist, veterinarian, scientific investigator, or other
- 61 person licensed, registered, or otherwise authorized under the laws of this state to
- 62 prescribe, distribute, dispense, conduct research with respect to, or administer a
 63 controlled substance in the course of professional practice or research in this state.
- 64 (7) 'Schedule II, III, IV, or V controlled substance' means a controlled substance that is
- 65 <u>classified as a Schedule II, III, IV, or V controlled substance under Code Section</u>
- 66 <u>16-13-26, 16-13-27, 16-13-28, or 16-13-29, respectively, or under the Federal Controlled</u>
- 67 <u>Substances Act, 21 U.S.C. Section 812.</u>

68 <u>16-13-123.</u>

- 69 (a) The board and agency may apply for available grants and accept any gifts, grants, or
- donations to assist in developing and maintaining the program established by this article.
 (b) The board shall be authorized to grant funds to dispensers for the purpose of covering
- 72 <u>costs for dedicated equipment and software for dispensers to use in complying with the</u>
- 73 reporting requirements of this article. Such grants shall be funded by gifts, grants,
- 74 donations, or other funds appropriated for the operation of the prescription monitoring
- 75 program established under the provisions of Code Section 16-13-124. The board shall be
- 76 <u>authorized to establish standards and specifications for any equipment and software</u>
- 77 purchased pursuant to a grant received pursuant to this article. Nothing in this article shall
- 78 <u>be construed to require a dispenser to incur costs to purchase equipment and software to</u>
- 79 <u>comply with this article.</u>
- 80 <u>16-13-124.</u>
- 81 (a) The board shall establish and maintain a program for the monitoring of prescribing and
- 82 <u>dispensing of all Schedule II, III, IV, or V controlled substances.</u>
- 83 (b) Each dispenser shall submit to the board by electronic means information regarding
- 84 each prescription dispensed for a Schedule II, III, IV, or V controlled substance. The
- 85 <u>information submitted for each prescription shall include, but not be limited to:</u>
- 86 (1) United States Drug Enforcement Administration (DEA) permit number or approved
- 87 <u>dispenser facility identification number;</u>
- 88 (2) Date prescription filled;
- 89 (<u>3) Prescription number;</u>
- 90 (4) Whether prescription is new or a refill;
- 91 (5) National Drug Code (NDC) for drug dispensed;
- 92 (6) Quantity dispensed;

93	(7) Number of days' supply of the drug;
94	(8) Patient's name;
95	(9) Patient's address;
96	(10) Patient's date of birth;
97	(11) Approved prescriber identification number;
98	(12) Date prescription issued by prescriber; and
99	(13) Other data elements consistent with standards established by the American Society
100	for Automation in Pharmacy, if designated by regulations of the board.
101	(c) Each dispenser shall submit the information in accordance with transmission methods
102	and frequency requirements established by the board but no less often than weekly and
103	shall report, at a minimum, prescriptions dispensed up to the day prior to data submission.
104	(d) The board may issue a waiver to a dispenser that is unable to submit prescription
105	information by electronic means acceptable to the board. Such waiver may permit the
106	dispenser to submit prescription information by paper form or other means, provided all
107	information required in subsection (b) of this Code section is submitted in this alternative
108	format subject to the frequency requirements of subsection (c) of this Code section.
109	Requests for waivers shall be submitted in writing.
110	<u>16-13-125.</u>
111	(a) Prescription information submitted to the board shall be confidential and shall not be
112	subject to open records requirements, as contained in Article 4 of Chapter 18 of Title 50,
113	except as provided in subsections (c) and (d) of this Code section.
114	(b) The board shall establish and maintain strict procedures to ensure that the privacy and
115	confidentiality of patients and prescribers and patient and prescriber information collected,
116	recorded, transmitted, and maintained pursuant to this article are protected. Such
117	information shall not be disclosed to persons except as otherwise provided in this article
118	and only in a manner which in no way would conflict with the requirements of the federal
119	Health Insurance Portability and Accountability Act of 1996, P.L. 104-191. This may
120	include, but not be limited to, restricting access only to those individuals and entities which
121	clearly demonstrate a need to know such information.
122	(c) The board shall review the prescription information and if there is reasonable cause to
123	believe a violation of law or breach of professional standards may have occurred, the board
124	shall notify the appropriate law enforcement or professional licensing, certification, or
125	regulatory agency or entity and shall provide prescription information to such agency or
126	entity which may be necessary for an investigation.
127	(d) The board shall be authorized to provide data collected pursuant to this article to the
128	following persons or under the following circumstances:

129	(1) Persons authorized to prescribe or dispense controlled substances for the purpose of
130	providing medical or pharmaceutical care for their patients;
131	(2) Upon the request of a person about whom the information requested concerns or
132	upon the request on his or her behalf by his or her attorney;
133	(3) The Composite State Board of Medical Examiners or any licensing board whose
134	practitioners have the authority to prescribe or dispense controlled substances;
135	(4) Local, state, and federal law enforcement, regulatory, or prosecutorial officials
136	engaged in the administration, investigation, or enforcement of the laws governing licit
137	drugs and who are involved in a bona fide, specific drug related investigation involving
138	a designated case;
139	(5) Upon the lawful order of a court of competent jurisdiction; and
140	(6) Personnel of the agency for purposes of administration and enforcement of this
141	article, Article 2 of this chapter, the 'Georgia Controlled Substances Act,' or any other
142	applicable state law.
143	(e) The board may provide data to public or private entities for statistical, research, or
144	educational purposes after removing information that could be used to identify prescribers
145	or individual patients or persons who received prescriptions from dispensers.
146	(f) The board may provide data to a prescription monitoring program of another state if the
147	confidentiality, security, and privacy standards of the requesting state are determined by
148	the board to be equivalent to those of the board.
149	(g) Any person who receives data or reports relating to this article from the board shall not
150	provide such data or reports to any other person except by order of a court of competent
151	jurisdiction or as otherwise permitted pursuant to this article.
152	<u>16-13-126.</u>
153	The agency shall be authorized to contract with another state agency or with a private
154	vendor, as necessary, to ensure the effective operation of the prescription monitoring
155	program established pursuant to this article. Any contractor shall be bound to comply with
156	the provisions regarding confidentiality of prescription information in Code Section
157	16-13-125 and shall be subject to the penalties specified in Code Section 16-13-130 for
158	unlawful acts.
159	<u>16-13-127.</u>
160	The board shall provide notice and information to all prescribers and dispensers in this state

- 161 <u>as to the intent of this article, the program established pursuant to this article, and</u>
- 162 <u>instructions on how to submit prescription information to the board via electronic means.</u>

163	<u>16-13-128.</u>
164	(a) There is established a Prescription Monitoring Program Advisory Committee for the
165	purposes of consulting with and advising the board and the agency on matters related to the
166	establishment, maintenance, and operation of the prescription monitoring program
167	established pursuant to this article. This shall include, but not be limited to, data collection,
168	regulation of access to data, evaluation of data to identify benefits and outcomes of the
169	program, communication to prescribers and dispensers as to the intent of the program and
170	how to use the data base, and security of data collected.
171	(b) The advisory committee shall consist of five members, appointed by the board, which
172	may include individuals representing pharmacies, dentistry, and medical professionals.
173	The board shall be authorized, but not required, to make such appointments from
174	recommendations submitted by the Medical Association of Georgia, the Georgia Dental
175	Association, the Georgia Pharmacy Association, and the Georgia Society of Health System
176	Pharmacies. Each member of the advisory committee shall serve a two-year term and until
177	the appointment and qualification of such member's successor.
178	(c) The advisory committee shall elect a chairperson and vice chairperson from among its
179	membership to serve a term of one year.
180	(d) The advisory committee shall meet at the call of the chairperson or upon request by at
181	least three of the members and shall meet at least one time per year. Three members of the
182	committee shall constitute a quorum.
183	(e) The members shall receive no compensation or reimbursement of expenses from the
184	state for their services as members of the advisory committee.

- 185 <u>16-13-129.</u>
- 186 <u>The board shall promulgate rules and regulations setting forth the procedures and methods</u>
- 187 <u>for implementing this article.</u>
- 188 <u>16-13-130.</u>
- 189 (a) A dispenser who willfully and intentionally fails to submit prescription monitoring
- 190 information to the board as required by this article or willfully and intentionally submits
- 191 incorrect prescription information shall be guilty of a misdemeanor and punished by
- 192 imprisonment for a period not to exceed 12 months or a fine not to exceed \$1,000.00, or
- 193 <u>both.</u>
- 194 (b) An individual authorized to have prescription monitoring information pursuant to this
- 195 <u>article who willfully and intentionally discloses such information in violation of this article</u>
- 196 <u>shall be guilty of a felony and punished by imprisonment for a period not to exceed ten</u>
- 197 years or a fine not to exceed \$10,000.00, or both.

- 198 (c) An individual authorized to have prescription monitoring information pursuant to this
- 199 <u>article who willfully and intentionally uses such information in a manner or for a purpose</u>
- 200 in violation of this article shall be guilty of a felony and punished by imprisonment for a
- 201 period not to exceed ten years or a fine not to exceed \$10,000.00, or both.
- 202 (d) The penalties provided by this Code section are intended to be cumulative of other
- 203 penalties which may be applicable and are not intended to repeal such other penalties.

<u>16-13-131.</u>

- 205 Nothing in this article shall require a dispenser or prescriber to obtain information about
- 206 <u>a patient from the prescription monitoring program established pursuant to this article.</u> A
- 207 dispenser or prescriber shall not have a duty and shall not be held liable for damages to any
- 208 person in any civil, criminal, or administrative action for injury, death, or loss to person or
- 209 property on the basis that the dispenser or prescriber did or did not seek or obtain
- 210 information from the prescription monitoring program. A dispenser or prescriber acting
- 211 in good faith shall be immune from any civil, criminal, or administrative liability that might
- 212 <u>otherwise be incurred or imposed for requesting or receiving information from the</u>
- 213 prescription monitoring program."

214 SECTION 2.

- 215 This Act shall become effective on July 1, 2009.
- 216 **SECTION 3.**
- 217 All laws and parts of laws in conflict with this Act are repealed.