

Senate Bill 418

By: Senators Carter of the 1st, Hawkins of the 49th, Harp of the 29th, Thomas of the 54th, Goggans of the 7th and others

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 provide for the establishment of a program for the monitoring
3 of prescribing and dispensing Schedule II, III, IV, or V controlled substances by the Georgia
4 Drugs and Narcotics Agency; to provide for definitions; to require dispensers to submit
5 certain information regarding the dispensing of such controlled substances; to provide for the
6 confidentiality of submitted information except under certain circumstances; to provide for
7 the establishment of an Electronic Database Review Advisory Committee; to provide for its
8 membership, duties, and organization; to provide for the establishment of rules and
9 regulations; to provide for limited liability; to provide for penalties; to provide for related
10 matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

11 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

12 **SECTION 1.**

13 Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled
14 substances, is amended by revising Code Section 16-13-21, relating to definitions relative
15 to regulation of controlled substances, as follows:

16 "16-13-21.

17 As used in this article, the term:

18 (1) 'Administer' means the direct application of a controlled substance, whether by
19 injection, inhalation, ingestion, or by any other means, to the body of a patient or research
20 subject by:

21 (A) A practitioner or, in his or her presence, by his or her authorized agent; or

22 (B) The patient or research subject at the direction and in the presence of the
23 practitioner.

24 (1.1) 'Agency' means the Georgia Drugs and Narcotics Agency.

25 (2) 'Agent' of a manufacturer, distributor, or dispenser means an authorized person who
26 acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does

27 not include a common or contract carrier, public warehouseman, or employee of the
28 carrier or warehouseman.

29 (2.1) 'Board' means the State Board of Pharmacy.

30 (3) 'Bureau' means the ~~Drug Enforcement Administration, United States Department of~~
31 ~~Justice, or its successor agency~~ Georgia Bureau of Investigation.

32 (4) 'Controlled substance' means a drug, substance, or immediate precursor in Schedules
33 I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of
34 21 C.F.R. Part 1308.

35 (5) 'Conveyance' means any object, including aircraft, vehicle, or vessel, but not
36 including a person, which may be used to carry or transport a substance or object.

37 (6) 'Counterfeit substance' means:

38 (A) A controlled substance which, or the container or labeling of which, without
39 authorization, bears the trademark, trade name, or other identifying mark, imprint,
40 number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser
41 other than the person who in fact manufactured, distributed, or dispensed the controlled
42 substance;

43 (B) A controlled substance or noncontrolled substance, which is held out to be a
44 controlled substance or marijuana, whether in a container or not which does not bear
45 a label which accurately or truthfully identifies the substance contained therein; or

46 (C) Any substance, whether in a container or not, which bears a label falsely
47 identifying the contents as a controlled substance.

48 (6.1) 'Dangerous drug' means any drug, other than a controlled substance, which cannot
49 be dispensed except upon the issuance of a prescription drug order by a practitioner
50 authorized under this chapter.

51 (6.2) 'DEA' means the United States Drug Enforcement Administration.

52 (7) 'Deliver' or 'delivery' means the actual, constructive, or attempted transfer from one
53 person to another of a controlled substance, whether or not there is an agency
54 relationship.

55 (8) 'Dependent,' 'dependency,' 'physical dependency,' 'psychological dependency,' or
56 'psychic dependency' means and includes the state of dependence by an individual toward
57 or upon a substance, arising from the use of that substance, being characterized by
58 behavioral and other responses which include the loss of self-control with respect to that
59 substance, or a strong compulsion to use that substance on a continuous basis in order to
60 experience some psychic effect resulting from the use of that substance by that individual,
61 or to avoid any discomfort occurring when the individual does not use that substance.

62 (9) 'Dispense' means to deliver a controlled substance to an ultimate user or research
63 subject by or pursuant to the lawful order of a practitioner, including the prescribing,

64 administering, packaging, labeling, or compounding necessary to prepare the substance
65 for that delivery, or the delivery of a controlled substance by a practitioner, acting in the
66 normal course of his or her professional practice and in accordance with this article, or
67 to a relative or representative of the person for whom the controlled substance is
68 prescribed.

69 (10) 'Dispenser' means a practitioner who dispenses.

70 (11) 'Distribute' means to deliver a controlled substance, other than by administering or
71 dispensing it.

72 (12) 'Distributor' means a person who distributes.

73 (12.05) 'FDA' means the United States Food and Drug Administration.

74 (12.1) 'Imitation controlled substance' means:

75 (A) A product specifically designed or manufactured to resemble the physical
76 appearance of a controlled substance; such that a reasonable person of ordinary
77 knowledge would not be able to distinguish the imitation from the controlled substance
78 by outward appearances; or

79 (B) A product, not a controlled substance, which, by representations made and by
80 dosage unit appearance, including color, shape, size, or markings, would lead a
81 reasonable person to believe that, if ingested, the product would have a stimulant or
82 depressant effect similar to or the same as that of one or more of the controlled
83 substances included in Schedules I through V of Code Sections 16-13-25 through
84 16-13-29.

85 (13) 'Immediate precursor' means a substance which the State Board of Pharmacy has
86 found to be and by rule identifies as being the principal compound commonly used or
87 produced primarily for use, and which is an immediate chemical intermediary used or
88 likely to be used in the manufacture of a controlled substance, the control of which is
89 necessary to prevent, curtail, or limit manufacture.

90 (14) 'Isomers' means stereoisomers (optical isomers), geometrical isomers, and structural
91 isomers (chain and positional isomers; but shall not include functional isomers).

92 (15) 'Manufacture' means the production, preparation, propagation, compounding,
93 conversion, or processing of a controlled substance, either directly or indirectly by
94 extraction from substances of natural origin, or independently by means of chemical
95 synthesis, and includes any packaging or repackaging of the substance or labeling or
96 relabeling of its container, except that this term does not include the preparation,
97 compounding, packaging, or labeling of a controlled substance:

98 (A) By a practitioner as an incident to his or her administering or dispensing of a
99 controlled substance in the course of his or her professional practice; or

100 (B) By a practitioner or by his or her authorized agent under his or her supervision for
101 the purpose of, or as an incident to, research, teaching, or chemical analysis and not for
102 sale.

103 (16) 'Marijuana' means all parts of the plant of the genus Cannabis, whether growing or
104 not, the seeds thereof, the resin extracted from any part of such plant, and every
105 compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds,
106 or resin; but shall not include samples as described in subparagraph (P) of paragraph (3)
107 of Code Section 16-13-25 and shall not include the completely defoliated mature stalks
108 of such plant, fiber produced from such stalks, oil, or cake, or the completely sterilized
109 samples of seeds of the plant which are incapable of germination.

110 (17) 'Narcotic drug' means any of the following, whether produced directly or indirectly
111 by extraction from substances of vegetable origin, or independently by means of chemical
112 synthesis, or by a combination of extraction and chemical synthesis:

113 (A) Opium and opiate, and any salt, compound, derivative, or preparation of opium or
114 opiate;

115 (B) Any salt, compound, isomer, derivative, or preparation thereof which is chemically
116 equivalent or identical with to any of the substances referred to in subparagraph (A) of
117 this paragraph, but not including the isoquinoline alkaloids of opium;

118 (C) Opium poppy and poppy straw;

119 (D) Coca leaves and any salt, compound, derivative, stereoisomers of cocaine, or
120 preparation of coca leaves, and any salt, compound, stereoisomers of cocaine,
121 derivative, or preparation thereof which is chemically equivalent or identical with any
122 of these substances, but not including decocainized coca leaves or extractions of coca
123 leaves which do not contain cocaine or ecgonine.

124 (18) 'Opiate' means any substance having an addiction-forming or addiction-sustaining
125 liability similar to morphine or being capable of conversion into a drug having
126 addiction-forming or addiction-sustaining liability. It does not include, unless
127 specifically designated as controlled under Code Section 16-13-22, the dextrorotatory
128 isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does
129 include its racemic and levorotatory forms.

130 (19) 'Opium poppy' means the plant of the species *Papaver somniferum* L., except its
131 seeds.

132 (19.1) 'Patient' means the person who is the ultimate user of a drug for whom a
133 prescription is issued or for whom a drug is dispensed.

134 (20) 'Person' means an individual, corporation, government, or governmental subdivision
135 or agency, business trust, estate, trust, partnership, or association, or any other legal
136 entity.

- 137 (21) 'Poppy straw' means all parts, except the seeds, of the opium poppy after mowing.
- 138 (22) 'Potential for abuse' means and includes a substantial potential for a substance to be
139 used by an individual to the extent of creating hazards to the health of the user or the
140 safety of the public, or the substantial potential of a substance to cause an individual
141 using that substance to become dependent upon that substance.
- 142 (23) 'Practitioner' means:
- 143 (A) A physician, dentist, pharmacist, podiatrist, veterinarian, scientific investigator, or
144 other person licensed, registered, or otherwise authorized under the laws of this state
145 to distribute, dispense, conduct research with respect to, or to administer a controlled
146 substance in the course of professional practice or research in this state;
- 147 (B) A pharmacy, hospital, or other institution licensed, registered, or otherwise
148 authorized by law to distribute, dispense, conduct research with respect to, or to
149 administer a controlled substance in the course of professional practice or research in
150 this state;
- 151 (C) An advanced practice registered nurse acting pursuant to the authority of Code
152 Section 43-34-25. For purposes of this chapter and Code Section 43-34-25, an
153 advanced practice registered nurse is authorized to register with the federal Drug
154 Enforcement Administration and appropriate state authorities; or
- 155 (D) A physician assistant acting pursuant to the authority of subsection (e.1) of Code
156 Section 43-34-103. For purposes of this chapter and subsection (e.1) of Code Section
157 43-34-103, a physician assistant is authorized to register with the federal Drug
158 Enforcement Administration and appropriate state authorities.
- 159 (23.1) 'Prescriber' means a physician, dentist, scientific investigator, or other person
160 licensed, registered, or otherwise authorized under the laws of this state to prescribe,
161 distribute, dispense, conduct research with respect to, or administer a controlled substance
162 in the course of professional practice or research in this state.
- 163 (24) 'Production' includes the manufacture, planting, cultivation, growing, or harvesting
164 of a controlled substance.
- 165 (25) 'Registered' or 'register' means registration as required by this article.
- 166 (26) 'Registrant' means a person who is registered under this article.
- 167 (26.1) 'Schedule II, III, IV, or V controlled substance' means a controlled substance that
168 is classified as a Schedule II, III, IV, or V controlled substance under Code Section
169 16-13-26, 16-13-27, 16-13-28, or 16-13-29, respectively, or under the Federal Controlled
170 Substances Act, 21 U.S.C. Section 812.
- 171 (27) 'State,' when applied to a part of the United States, includes any state, district,
172 commonwealth, territory, insular possession thereof, or any area subject to the legal
173 authority of the United States.

174 (28) 'Ultimate user' means a person who lawfully possesses a controlled substance for
 175 his or her own use, for the use of a member of his or her household, or for administering
 176 to an animal owned by him or her or by a member of his or her household or an agent or
 177 representative of the person.

178 (29) 'Noncontrolled substance' means any drug or other substance other than a controlled
 179 substance as defined by paragraph (4) of this Code section."

180 **SECTION 2.**

181 Said chapter is further revised by adding new Code sections to read as follows:

182 "16-13-57.

183 (a) In order to assist in the reduction of the abuse of controlled substances, to improve,
 184 enhance, and encourage a better quality of health care by promoting the proper use of
 185 medications to treat pain and terminal illness, and to reduce duplicative prescribing and
 186 overprescribing of controlled substance prescribing practices, the agency shall establish an
 187 electronic data base to enhance and supplement the state's preexisting ability to review
 188 dispensed controlled substance prescriptions, thereby making it possible to minimize the
 189 impact the current labor intensive review process has on pharmacy and medical practices
 190 which dispense controlled substances.

191 (b) The agency, in consultation with members of both the Georgia Composite Medical
 192 Board and the Georgia State Board of Pharmacy, shall establish and maintain a method to
 193 electronically review prescriptions which result in the dispensing of Schedule II, III, IV,
 194 or V controlled substances.

195 (c) Such electronic data base and review process shall be administered by the agency at
 196 the direction and oversight of the board.

197 16-13-58.

198 (a) The agency may apply for available grants and accept any gifts, grants, donations, and
 199 other funds to assist in developing and maintaining the electronic data base established
 200 pursuant to Code Section 16-13-57.

201 (b) The agency shall be authorized to grant funds to dispensers for the purpose of covering
 202 costs for dedicated equipment and software for dispensers to use in complying with the
 203 reporting requirements of Code Section 16-13-59. Such grants shall be funded by gifts,
 204 grants, donations, or other funds received by the agency for the operation of the electronic
 205 data base established pursuant to Code Section 16-13-57. The agency shall be authorized
 206 to establish standards and specifications for any equipment and software purchased
 207 pursuant to a grant received by a dispenser pursuant to this Code section. Nothing in Code

208 Sections 16-13-57 through 16-13-64 shall be construed to require a dispenser to incur costs
209 to purchase equipment and software to comply with such Code sections.

210 16-13-59.

211 (a) For purposes of the electronic data base and review process established pursuant to
212 Code Section 16-13-57, each dispenser shall submit to the agency by electronic means
213 information regarding each prescription dispensed for a Schedule II, III, IV, or V controlled
214 substance. The information submitted for each prescription shall include at a minimum, but
215 shall not be limited to:

216 (1) United States Drug Enforcement Administration (DEA) permit number or approved
217 dispenser facility controlled substance identification number;

218 (2) Date prescription dispensed;

219 (3) Prescription serial number;

220 (4) If the prescription is new or a refill;

221 (5) National Drug Code (NDC) for drug dispensed;

222 (6) Quantity and strength dispensed;

223 (7) Number of days supply of the drug;

224 (8) Patient's name;

225 (9) Patient's address;

226 (10) Patient's date of birth;

227 (11) Approved prescriber identification number;

228 (12) Date prescription issued by prescriber; and

229 (13) Other data elements consistent with standards established by the American Society
230 for Automation in Pharmacy, if designated by regulations of the board.

231 (b) Each dispenser shall submit the information in accordance with transmission methods
232 and frequency requirements established by the agency but no less often than weekly and
233 shall report, at a minimum, prescriptions dispensed up to the day prior to data submission.

234 (c) The agency may issue a waiver to a dispenser that is unable to submit prescription
235 information by electronic means acceptable to the agency. Such waiver may permit the
236 dispenser to submit prescription information to the agency by paper form or other means,
237 provided all information required in subsection (a) of this Code section is submitted in this
238 alternative format subject to the frequency requirements of subsection (b) of this Code
239 section. Requests for waivers shall be submitted in writing to the agency.

240 (d) The agency shall not revise the information required to be submitted by dispensers
241 pursuant to subsection (a) of this Code section more frequently than annually. Any such
242 change to the required information shall neither be effective nor be applicable to dispensers
243 until six months after the adoption of such changes;

244 (e) The agency shall not access electronic data base prescription information for more than
245 two years after the date it was originally received, and after two years, all such information
246 shall be deleted or destroyed in a timely and secure manner.

247 (f) A hospital, clinic, or other health care facility may apply to the agency for an
248 exemption to be excluded from compliance with this Code section if compliance would
249 impose an undue hardship on such facility. The agency shall provide guidelines and criteria
250 for what constitutes an undue hardship which shall include criteria relating to the number
251 of indigent patients served and the lack of electronic capabilities of the facility.

252 16-13-60.

253 (a) Prescription information submitted to the agency pursuant to Code Section 16-13-59
254 shall be confidential and shall not be subject to open records requirements, as contained in
255 Article 4 of Chapter 18 of Title 50, except as provided in subsections (c) and (d) of this
256 Code section.

257 (b) The agency shall establish and maintain strict procedures to ensure that the privacy and
258 confidentiality of patients and prescribers and patient and prescriber information collected,
259 recorded, transmitted, and maintained pursuant to Code Sections 16-13-57 through
260 16-13-64 are protected. Such information shall not be disclosed to persons except as
261 otherwise provided in Code Sections 16-13-57 through 16-13-64 and only in a manner
262 which in no way would conflict with the requirements of the federal Health Insurance
263 Portability and Accountability Act (HIPAA) of 1996, P.L. 104-191. This may include, but
264 shall not be limited to, restricting access only to those individuals and entities which clearly
265 demonstrate a need to know such information.

266 (c) The agency shall review the prescription information, and if there is reasonable cause
267 to believe a violation of law or breach of professional standards may have occurred, the
268 board shall notify the appropriate professional licensing, certification, or regulatory agency
269 or entity or appropriate law enforcement agency and shall provide prescription information
270 to such entity or agency which may be necessary for an investigation. In no event shall the
271 agency be authorized to analyze prescription information of any individual patient or
272 physician unless there is reasonable cause to believe that an impropriety may have
273 occurred.

274 (d) The agency shall be authorized to provide data collected pursuant to Code Sections
275 16-13-57 through 16-13-64 to the following persons or under the following circumstances:

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

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

280 (3) The Georgia State Board of Pharmacy, the Georgia Composite Medical Board, or any
281 licensing board whose practitioners have the authority to prescribe or dispense controlled
282 substances;

283 (4) Local, state, and federal law enforcement, regulatory, or prosecutorial officials
284 engaged in the administration, investigation, or enforcement of the laws governing licit
285 drugs and whose request meets HIPAA guidelines and who are actively conducting an
286 authorized drug related investigation regarding specific individuals; provided, however
287 that before such information can be disseminated, the official shall include in the request
288 an agency or department complaint or case number in the same manner as required by the
289 Georgia Crime Information Center (GCIC);

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

291 (6) Personnel of the agency for purposes of administration and enforcement of Code
292 Sections 16-13-57 through 16-13-64 or any other applicable state law.

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

296 (f) The agency may provide data to a prescription review program in another state if the
297 confidentiality, security, and privacy standards of the requesting state are determined to be
298 equivalent to those of the agency.

299 (g) Any person who receives data or reports relating to Code Sections 16-13-57 through
300 16-13-64 from the board shall not provide such data or reports to any other person except
301 by order of a court of competent jurisdiction or as otherwise permitted pursuant to Code
302 Sections 16-13-57 through 16-13-64.

303 (h) Any permissible user identified in Code Sections 16-13-57 through 16-13-64 who
304 directly accesses electronic data shall implement and maintain a comprehensive
305 information security program that contains administrative, technical, and physical
306 safeguards that are appropriate to the user's size and complexity and to the sensitivity of
307 the personal information obtained. The permissible user shall identify reasonably
308 foreseeable internal and external risks to the security, confidentiality, and integrity of
309 personal information that could result in the unauthorized disclosure, misuse, or other
310 compromise of the information and shall assess the sufficiency of any safeguards in place
311 to control the risks.

312 16-13-61.

313 (a) There is established an Electronic Database Review Advisory Committee for the
314 purposes of consulting with and advising the agency on matters related to the
315 establishment, maintenance, and operation of how prescriptions are electronically reviewed

316 pursuant to Code Sections 16-13-57 through 16-13-64. This shall include, but shall not be
317 limited to, data collection, regulation of access to data, evaluation of data to identify
318 benefits and outcomes of the reviews, communication to prescribers and dispensers as to
319 the intent of the reviews and how to use the data base, and security of data collected.

320 (b) The advisory committee shall consist of five members as follows:

321 (1) A representative from the Georgia Composite Medical Board;

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

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

324 (4) A consumer representative, appointed by the agency; and

325 (5) A representative from a specialty profession that deals in addictive medicine,
326 oncology or hospice, or other such profession whose duties relate to controlled
327 substances, appointed by the agency.

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

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

333 (e) The advisory committee shall meet at the call of the chairperson or upon request by at
334 least three of the members and shall meet at least one time per year. Three members of the
335 committee shall constitute a quorum.

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

338 16-13-62.

339 The board shall establish rules and regulations to implement the requirements of Code
340 Sections 16-13-57 through 16-13-64. Nothing in Code Sections 16-13-57 through
341 16-13-64 shall be construed to authorize the agency to establish policies, rules, or
342 regulations which limit, revise, or expand or purport to limit, revise, or expand any
343 prescription or dispensing authority of any prescriber or dispenser subject to Code Sections
344 16-13-57 through 16-13-64.

345 16-13-63.

346 Nothing in Code Sections 16-13-57 through 16-13-64 shall require a dispenser or
347 prescriber to obtain information about a patient from the prescription monitoring program
348 established pursuant to Code Sections 16-13-57 through 16-13-64. A dispenser or
349 prescriber shall not have a duty and shall not be held liable for damages to any person in
350 any civil, criminal, or administrative action for injury, death, or loss to person or property

351 on the basis that the dispenser or prescriber did or did not seek or obtain information from
352 the electronic prescriptions data base. A dispenser or prescriber acting in good faith shall
353 be immune from any civil, criminal, or administrative liability that might otherwise be
354 incurred or imposed for requesting or receiving information maintained in the electronic
355 prescription data base established pursuant to Code Section 16-13-57.

356 16-13-64.

357 (a) A dispenser who willfully and intentionally fails to submit electronic data base
358 prescription information to the agency as required by Code Sections 16-13-57 through
359 16-13-64 or willfully and intentionally submits incorrect prescription information shall be
360 guilty of a misdemeanor and punished by imprisonment for a period not to exceed 12
361 months or a fine not to exceed \$1,000.00 or both, and such actions shall be reported to the
362 board responsible for issuing such dispenser's dispensing license for action to be taken
363 against such dispenser's license.

364 (b) An individual authorized to have electronic data base prescription information pursuant
365 to Code Sections 16-13-57 through 16-13-64 who willfully and intentionally uses or
366 discloses such information in violation of Code Sections 16-13-57 through 16-13-64 shall
367 be guilty of a felony and punished by imprisonment for a period not to exceed ten years or
368 a fine not to exceed \$10,000.00 or both.

369 (c) An individual authorized to have electronic data base prescription information pursuant
370 to Code Sections 16-13-57 through 16-13-64 who willfully and intentionally uses or
371 releases such information in a manner or for a purpose in violation of Code Sections
372 16-13-57 through 16-13-64 shall be guilty of a felony and punished by imprisonment for
373 a period not to exceed ten years or a fine not to exceed \$10,000.00 or both.

374 (d) Any person who knowingly requests, obtains, or attempts to obtain electronic data base
375 prescription information pursuant to Code Sections 16-13-57 through 16-13-64 under false
376 pretenses, or who knowingly communicates or attempts to communicate electronic data
377 base prescription information to any agency or person except in accordance with Code
378 Sections 16-13-57 through 16-13-64, or any member, officer, employee, or agent of the
379 agency or the advisory council, or any person who knowingly falsifies electronic data base
380 prescription information or any records relating thereto shall for each such offense, upon
381 conviction thereof, be fined not more than \$5,000.00 or imprisoned for not more than two
382 years or both.

383 (e) The penalties provided by this Code section are intended to be cumulative of other
384 penalties which may be applicable and are not intended to repeal such other penalties."

385 **SECTION 3.**

386 This Act shall become effective on July 1, 2010.

387 **SECTION 4.**

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