

House Bill 455 (COMMITTEE SUBSTITUTE)

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

13 **BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:**

14 **SECTION 1.**

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

17 **"ARTICLE 6**

18 16-13-120.

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

21 16-13-121.

22 This article is intended to improve the state's ability to identify and stop diversion of
23 prescription drugs in an efficient and cost-effective manner that will not impede the

1 appropriate medical utilization of licit controlled substances or other licit drugs with
2 potential for abuse while minimizing impact on pharmacy operations.

3 16-13-122.

4 (a) As used in this article, the term:

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

6 (2) 'Board' means the Georgia State Board of Pharmacy.

7 (3) 'Controlled substance' has the same meaning given such term in paragraph (4) of
8 Code Section 16-13-21.

9 (4) 'Dispenser' means a person who delivers a Schedule II, III, or IV controlled substance
10 to the ultimate user but shall not include:

11 (A) A licensed pharmacy of a hospital that dispenses such substances for the purpose
12 of inpatient or outpatient hospital care, a licensed pharmacy of a hospital or retail
13 pharmacy of a hospital which dispenses prescriptions for controlled substances at the
14 time of dismissal or discharge from such a facility, or a licensed pharmacy of a hospital
15 or retail pharmacy of a hospital which dispenses such substances for long-term care
16 patients or inpatient hospice facilities;

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

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

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

28 A hospital, clinic, or other health care facility may apply to the board for an exemption
29 to be excluded from the definition of this term for purposes of compliance with this
30 article if compliance would impose an undue hardship on such facility. The board shall
31 provide guidelines and criteria for what constitutes an undue hardship which shall include
32 criteria relating to the amount of indigent patients served and the lack of electronic
33 capability of the facility.

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

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

5 (7) 'Schedule II, III, or IV controlled substance' means a controlled substance that is
6 classified as a Schedule II, III, or IV controlled substance under Code Section 16-13-26,
7 16-13-27, or 16-13-28, respectively, or under the Federal Controlled Substances Act, 21
8 U.S.C. Section 812.

9 16-13-123.

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

12 (b) The board shall be authorized to grant funds to dispensers for the purpose of covering
13 costs for dedicated equipment and software for dispensers to use in complying with the
14 reporting requirements of this article. Such grants shall be funded by gifts, grants,
15 donations, or other funds appropriated for the operation of the prescription monitoring
16 program. The board shall be authorized to establish standards and specifications for any
17 equipment and software purchased pursuant to a grant received pursuant to this article.
18 Nothing in this article shall be construed to require a dispenser to incur costs to purchase
19 equipment and software used to comply with this article.

20 16-13-124.

21 (a) The board shall establish and maintain a program for the monitoring of prescribing and
22 dispensing of all Schedule II, III or IV controlled substances.

23 (b) Each dispenser shall submit to the board by electronic means information regarding
24 each prescription dispensed for a drug included under subsection (a) of this Code section.

25 The information submitted for each prescription shall include, but not be limited to:

- 26 (1) United States Drug Enforcement Administration (DEA) permit number or approved
27 dispenser facility identification number;
- 28 (2) Date prescription filled;
- 29 (3) Prescription number;
- 30 (4) Whether prescription is new or a refill;
- 31 (5) National Drug Code (NDC) for drug dispensed;
- 32 (6) Quantity dispensed;
- 33 (7) Number of days' supply of the drug;
- 34 (8) Patient's name;
- 35 (9) Patient's address;

1 (10) Patient's date of birth;

2 (11) Approved prescriber identification number;

3 (12) Date prescription issued by prescriber; and

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

6 (c) Each dispenser shall submit the information in accordance with transmission methods
7 and frequency requirements established by the board but no less often than weekly and
8 shall report, at a minimum, prescriptions dispensed up to the day prior to data submission.

9 (d) The board may issue a waiver to a dispenser that is unable to submit prescription
10 information by electronic means acceptable to the board. Such waiver may permit the
11 dispenser to submit prescription information by paper form or other means, provided all
12 information required in subsection (b) of this Code section is submitted in this alternative
13 format subject to the frequency requirements of subsection (c) of this Code section.
14 Requests for waivers shall be submitted in writing.

15 16-13-125.

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

19 (b) The board shall establish and maintain strict procedures to ensure that the privacy and
20 confidentiality of patients and prescribers and patient and prescriber information collected,
21 recorded, transmitted, and maintained pursuant to this article are protected. Such
22 information shall not be disclosed to persons except as otherwise provided in this Code
23 section and only in a manner which in no way would conflict with the requirements of the
24 federal Health Insurance Portability and Accountability Act of 1996, P.L. 104-191. This
25 may include, but not be limited to, restricting access only to those individuals and entities
26 which clearly demonstrate a need to know such information.

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

32 (d) The board shall be authorized to provide data collected pursuant to this article to the
33 following persons or under the following circumstances:

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

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

3 (3) The Composite State Board of Medical Examiners or any licensing board whose
4 practitioners have the authority to prescribe or dispense controlled substances;

5 (4) Local, state, and federal law enforcement or prosecutorial officials engaged in the
6 administration, investigation, or enforcement of the laws governing licit drugs;

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

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

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

14 (f) Any person who receives data or reports from the board shall not provide such data or
15 reports to any other person or entity except by order of a court of competent jurisdiction
16 or as otherwise permitted pursuant to this article.

17 16-13-126.

18 The agency shall be authorized to contract with another state agency or with a private
19 vendor, as necessary, to ensure the effective operation of the prescription monitoring
20 program established pursuant to this article. Any contractor shall be bound to comply with
21 the provisions regarding confidentiality of prescription information in Code Section
22 16-13-125 and shall be subject to the penalties specified in Code Section 16-13-129 for
23 unlawful acts.

24 16-13-127.

25 (a) There is established a Prescription Monitoring Program Advisory Committee for the
26 purposes of consulting with and advising the board and the agency on matters related to the
27 establishment, maintenance, and operation of the prescription monitoring program
28 established pursuant to this article. This shall include, but not be limited to, data collection,
29 regulation of access to data, and security of data collected.

30 (b) The advisory committee shall consist of five members, appointed by the board, which
31 may include individuals representing pharmacies, dentistry, and medical professionals.
32 The board shall be authorized, but not required, to make such appointments from
33 recommendations submitted by the Medical Association of Georgia, the Georgia Dental
34 Association, the Georgia Pharmacy Association, and the Georgia Society of Health System

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

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

5 (d) The advisory committee shall meet at the call of the chairperson or upon request by at
6 least three of the members and shall meet at least one time per year. Three members of the
7 committee shall constitute a quorum.

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

10 16-13-128.

11 The board shall promulgate rules and regulations setting forth the procedures and methods
12 for implementing this article.

13 16-13-129.

14 (a) A dispenser who willfully and intentionally fails to submit prescription monitoring
15 information to the board as required by this article or willfully and intentionally submits
16 incorrect prescription information shall be guilty of a misdemeanor and punished by
17 imprisonment for a period not to exceed 12 months or a fine not to exceed \$1,000.00, or
18 both.

19 (b) A person authorized to have prescription monitoring information pursuant to this
20 article who willfully and intentionally discloses such information in violation of this article
21 shall be guilty of a felony and punished by imprisonment for a period not to exceed ten
22 years or a fine not to exceed \$10,000.00, or both.

23 (c) A person authorized to have prescription monitoring information pursuant to this article
24 who willfully and intentionally uses such information in a manner or for a purpose in
25 violation of this article shall be guilty of a felony and punished by imprisonment for a
26 period not to exceed ten years or a fine not to exceed \$10,000.00, or both.

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

29 16-13-130.

30 Nothing in this article shall require a dispenser or prescriber to obtain information about
31 a patient from the prescription monitoring program established pursuant to this article. A
32 dispenser or prescriber shall not have a duty and shall not be held liable for damages to any
33 person in any civil, criminal, or administrative action for injury, death, or loss to person or
34 property on the basis that the dispenser or prescriber did or did not seek or obtain

1 information from the prescription monitoring program. A dispenser or prescriber acting
2 in good faith shall be immune from any civil, criminal, or administrative liability that might
3 otherwise be incurred or imposed for requesting or receiving information from the
4 prescription monitoring program."

5 **SECTION 2.**

6 This Act shall be effective on July 1, 2008.

7 **SECTION 3.**

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