

ACT No. 2004-443

1 SB35
2 66287-6
3 By Senator Means
4 RFD: Health
5 First Read: 03-FEB-04
6 PFD: 01/13/2004



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3 ENROLLED, An Act,

4 To state the legislative intent; to define terms; to
5 authorize the Alabama Department of Public Health to
6 establish, create, and maintain a controlled substances
7 prescription database program with authority to create a
8 controlled substances prescription database advisory
9 committee; to require the reporting of controlled substance
10 prescription data to the Department of Public Health by
11 pharmacies, physicians, and other practitioners authorized to
12 prescribe controlled substances and to enumerate the data
13 elements to be reported; to specify those persons or entities
14 permitted access to information in the controlled substances
15 database; to provide that all information maintained in the
16 controlled substances prescription database is confidential
17 and not a public record and is not subject to subpoena or
18 discovery in civil proceedings; to prescribe penalties for the
19 unauthorized disclosure of information contained in the
20 controlled substances prescription database; to assess a
21 surcharge in the amount of \$10 per year on the controlled
22 substance registration certificate of each licensed medical,
23 dental, podiatric, optometric, and veterinary medicine
24 practitioner to be used by the Department of Public Health for
25 the development, implementation, operation, and maintenance of

1 the controlled substances prescription database; to provide
2 that the database shall become operational within 12 months
3 after the State Health Officer certifies that sufficient funds
4 are available to implement and operate the database; to
5 provide that persons or entities required to report
6 information to the database are not liable for any claim of
7 damages as a result of such report; and to provide for the
8 effective date of this act.

9 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

10 Section 1. The Alabama Legislature hereby finds that
11 the diversion, abuse, and misuse of prescription medications
12 classified as controlled substances under the Alabama Uniform
13 Controlled Substances Act constitutes a serious threat to the
14 health and welfare of the citizens of the State of Alabama.
15 The Legislature further finds that establishment of a
16 controlled substances prescription database to monitor the
17 prescribing and dispensing of controlled substances will
18 materially assist state regulators and practitioners
19 authorized to prescribe and dispense controlled substances in
20 the prevention of diversion, abuse, and misuse of controlled
21 substances prescription medication through the provision of
22 education and information, early intervention, and prevention
23 of diversion, and investigation and enforcement of existing
24 laws governing the use of controlled substances.

1 Section 2. For the purposes of this act, the
2 following terms shall have the respective meanings ascribed by
3 this section:

4 (1) CERTIFYING BOARDS. Those boards designated in
5 Section 20-2-2(4), Code of Alabama 1975.

6 (2) CONTROLLED SUBSTANCE. Any drug or medication
7 defined as a controlled substance within the meaning of
8 Section 20-2-2(5), Code of Alabama 1975.

9 (3) DEPARTMENT. The Alabama Department of Public
10 Health.

11 (4) LICENSING BOARD or COMMISSION. The board,
12 commission, or other entity that is authorized to issue a
13 professional license to a pharmacist or an authorized
14 practitioner.

15 (5) PHARMACY. A retail establishment, as defined in
16 Section 34-23-1(4), Code of Alabama 1975, licensed by the
17 Alabama State Board of Pharmacy.

18 (6) PRACTITIONER or AUTHORIZED PRACTITIONER. A
19 medical, dental, podiatric, optometric, or veterinary medical
20 practitioner licensed to practice in this state and authorized
21 to prescribe, dispense, or furnish controlled substances under
22 the Alabama Uniform Controlled Substances Act.

23 (7) STATE HEALTH OFFICER. The executive officer of
24 the Alabama Department of Public Health as designated in
25 Section 22-2-8, Code of Alabama 1975.

1 Section 3. The Alabama Department of Public Health
2 is hereby authorized to establish, create, and maintain a
3 controlled substances prescription database program. In order
4 to carry out its responsibilities under this act, the
5 department is hereby granted the following powers and
6 authority:

7 (1) To adopt regulations, in accordance with the
8 Alabama Administrative Procedure Act, governing the
9 establishment and operation of a controlled substances
10 prescription database program.

11 (2) To receive and to expend for the purposes stated
12 in this act funds in the form of grants, donations, federal
13 matching funds, inter-agency transfers, and appropriated funds
14 designated for the development, implementation, operation, and
15 maintenance of the controlled substances prescription
16 database. The funds received pursuant to subdivision (2) of
17 Section 3 shall be deposited in a new fund that is hereby
18 established as a separate special revolving trust fund in the
19 State Treasury to be known as the Alabama State Controlled
20 Substance Database Trust Fund. No monies shall be withdrawn or
21 expended from the fund for any purpose unless the monies have
22 been appropriated by the Legislature and allocated pursuant to
23 this chapter. Any monies appropriated shall be budgeted and
24 allocated pursuant to the Budget Management Act in accordance
25 with Article 4 (commencing with Section 41-4-80) of Chapter 4

1 of Title 41, and only in the amounts provided by the
2 Legislature in the general appropriations act or other
3 appropriations act.

4 There is hereby appropriated to the Alabama
5 Department of Public Health the sum of \$200,000 from the
6 Alabama State Controlled Substance Database Trust Fund for the
7 controlled substances prescription database program for the
8 fiscal year ending September 30, 2005.

9 (3) To enter into one or more contracts with the
10 State Board of Pharmacy for the performance of designated
11 operational functions for the controlled substances
12 prescription database, including, but not limited to, the
13 receipt, collection, input, and transmission of controlled
14 substances prescription data and such other operational
15 functions as the department may elect.

16 (4) To create a controlled substances prescription
17 database advisory committee. The mission of the advisory
18 committee is to consult with and advise the State Health
19 Officer on matters related to the establishment, maintenance,
20 and operation of the database, access to the database
21 information, how access is to be regulated, and security of
22 information contained in the database. The committee shall
23 consist of one representative designated by each of the
24 following organizations:

25 a. The Medical Association of the State of Alabama.

- 1 b. The Alabama Dental Association.
- 2 c. The Alabama Pharmacy Association.
- 3 d. The Alabama Veterinary Medicine Association.
- 4 e. The State Health Officer, or his or her designee.
- 5 f. The Alabama Hospital Association.
- 6 g. The Executive Director of the Alabama State Board
- 7 of Pharmacy
- 8 h. The Executive Director of the Board of Medical
- 9 Examiners.
- 10 i. The Alabama Optometric Association.
- 11 j. One representative from each of the certifying
- 12 boards established under the Alabama Uniform Controlled
- 13 Substances Act.
- 14 k. Alabama Independent Drug Store Association.
- 15 l. Alabama Podiatry Association.

16 Section 4. (a) Each of the entities designated in
17 subsection (b) shall report to the department, or to an entity
18 designated by the department, controlled substances
19 prescription information as designated by regulation
20 pertaining to all Class II, Class III, Class IV, and Class V
21 controlled substances in such manner as may be prescribed by
22 the department by regulation.

23 (b) The following entities or practitioners are
24 subject to the reporting requirements of subsection (a):

1 (1) Licensed pharmacies, not including pharmacies of
2 general and specialized hospitals, nursing homes, and any
3 other healthcare facilities which provide inpatient care, so
4 long as the controlled substance is administered and used by a
5 patient on the premises of the facility.

6 (2) Mail order pharmacies or pharmacy benefit
7 programs filling prescriptions for or dispensing controlled
8 substances to residents of this state.

9 (3) Licensed physicians, dentists, podiatrists,
10 optometrists, or veterinarians who dispense Class II, Class
11 III, Class IV, and Class V controlled substances directly to
12 patients, or in the case of veterinarians, for administration
13 to animals, but excluding sample medications. For the purposes
14 of this act, sample medications are defined as those drugs
15 labeled as a sample, not for resale under the laws and
16 regulations of the Federal Food and Drug Administration.
17 Controlled substances administered to patients by injection,
18 topical application, suppository administration, or oral
19 administration during the course of treatment are excluded
20 from the reporting requirement.

21 (c) The manner of reporting controlled substance
22 prescription information shall be in such manner and format as
23 designated in the regulations of the department.

24 (d) The following data elements shall be used in
25 transmitting controlled substance prescription information:

1 (1) Name or other identifying designation of the
2 prescribing practitioner.

3 (2) Date prescription was filled or medications
4 dispensed.

5 (3) Name of person and full address for whom the
6 prescription was written or to whom the medications were
7 dispensed.

8 (4) National Drug Code (NDC) of controlled substance
9 dispensed.

10 (5) Quantity of controlled substance dispensed.

11 (6) Name or other identifying designation of
12 dispensing pharmacy or practitioner.

13 (7) Other data elements consistent with standards
14 established by the American Society for Automation in Pharmacy
15 may be designated by regulations adopted by the department.

16 (e) In addition to any other applicable law or
17 regulation, the failure of a licensed pharmacy or pharmacist
18 or a licensed practitioner to comply with the requirements of
19 this section shall constitute grounds for disciplinary action
20 against the license of the pharmacy, pharmacist, or licensed
21 practitioner by the appropriate licensing board or commission,
22 and the imposition of such penalties as the licensing board or
23 commission may prescribe. The department shall report to the
24 appropriate licensing board, agency, or commission the failure
25 of a licensed pharmacist or a licensed practitioner to comply

1 with the reporting requirements of this section. Any report
2 made by the department to a licensing board, agency, or
3 commission shall be deemed a formal complaint and shall be
4 investigated and appropriate action taken thereon.

5 Section 5. The following persons or entities shall
6 be permitted access to the information in the controlled
7 substances database, subject to the limitations indicated
8 below:

9 (1) Authorized representatives of the certifying
10 boards, provided, however, that access shall be limited to
11 inquiries concerning the licensees of the certifying board.

12 (2) A licensed practitioner approved by the
13 department who has authority to prescribe, dispense, or
14 administer controlled substances, provided, however, that such
15 access shall be limited to information concerning a current or
16 prospective patient of the practitioner.

17 Practitioners shall have no requirement or
18 obligation to access or check the information in the
19 controlled substances database prior to prescribing,
20 dispensing, or administering medications or as part of their
21 professional practice.

22 (3) A licensed pharmacist approved by the
23 department, provided, however, that such access is limited to
24 information related to the patient or prescribing practitioner

1 designated on a controlled substance prescription that a
2 pharmacist has been asked to fill.

3 Pharmacists shall have no requirement or obligation
4 to access or check the information in the controlled
5 substances database prior to dispensing or administering
6 medications or as part of their professional practices.

7 (4) State and local law enforcement authorities as
8 authorized under Section 20-2-91, Code of Alabama 1975, and
9 federal law enforcement authorities authorized to access
10 prescription information upon application to the department
11 accompanied by an affidavit stating probable cause for the use
12 of the requested information.

13 (5) Employees of the department and consultants
14 engaged by the department for operational and review purposes.

15 Section 6. The controlled substances database and
16 all information contained therein and any records maintained
17 by the department or by any entity contracting with the
18 department which is submitted to, maintained, or stored as a
19 part of the controlled substances prescription database is
20 hereby declared privileged and confidential, is not a public
21 record, is not subject to subpoena or discovery in civil
22 proceedings and may only be used for investigatory or
23 evidentiary purposes related to violations of state or federal
24 law and regulatory activities of licensing or regulatory
25 boards of practitioners authorized to prescribe or dispense

1 controlled substances. Nothing in this section shall apply to
2 records created or maintained in the regular course of
3 business of a pharmacy, medical, dental, optometric, or
4 veterinary practitioner, or other entity covered by this act
5 and all information, documents, or records otherwise available
6 from original sources are not to be construed as immune from
7 discovery or use in any civil proceedings merely because such
8 information contained in those records was reported to the
9 controlled substances prescription database in accordance with
10 the provisions of this act.

11 Section 7. Any person who intentionally makes an
12 unauthorized disclosure of information contained in the
13 controlled substances prescription database shall be guilty of
14 a Class A misdemeanor. Any person or entity who intentionally
15 obtains unauthorized access to or who alters or destroys
16 information contained in the controlled substances
17 prescription database shall be guilty of a Class C felony.

18 Section 8. There is hereby assessed a surcharge in
19 the amount of ten dollars (\$10) per year on the controlled
20 substance registration certificate of each licensed medical,
21 dental, podiatric, optometric, and veterinary medicine
22 practitioner authorized to prescribe or dispense controlled
23 substances. This surcharge shall be effective for every
24 certificate issued or renewed on or after the effective date
25 of this act, shall be in addition to any other fees collected

1 by the certifying boards, and shall be collected by each of
2 the certifying boards and remitted to the department at such
3 times and in such manner as designated in the regulations of
4 the department. The proceeds of the surcharge assessed herein
5 shall be used exclusively for the development, implementation,
6 operation, and maintenance of the controlled substances
7 prescription database.

8 At the end of the first fiscal year after the
9 controlled substances database becomes operational, and at the
10 end of each succeeding fiscal year thereafter, the State
11 Health Officer shall determine the actual operating costs for
12 the database, to include an allocation of costs for the
13 services of employees of the department. If at the end of the
14 fiscal year the State Health Officer determines that the funds
15 received by the department for operation of the database
16 exceed the operational costs incurred by at least twenty-five
17 thousand dollars (\$25,000), then the department shall refund a
18 portion of such excess to the certifying boards which made
19 payments to the department under this section in an amount
20 proportional to the boards' payment, provided, however, that
21 no payment of less than five thousand dollars (\$5,000) to a
22 certifying board shall be made.

23 Section 9. The department is authorized to grant
24 funds to participating pharmacies for the purpose of
25 reimbursing reasonable costs for dedicated equipment and

1 software incurred by pharmacies in complying with the
2 reporting requirements of this act. Such grants shall be
3 funded by gifts, grants, donations, or other funds
4 appropriated for the operation of the controlled substances
5 prescription database. The department is authorized to
6 determine standards and specifications for any equipment and
7 software purchased by the authority of this section.

8 Section 10. The controlled substances prescription
9 database shall become operational within 12 months after the
10 State Health Officer certifies to the certifying boards in
11 writing that the department has sufficient funds to finance
12 the development, implementation, and operation of the
13 database.

14 Section 11. Any person or entity required to report
15 information concerning controlled substance prescriptions to
16 the department, or to its designated agent, pursuant to the
17 requirements of this act shall not be liable to any person for
18 any claim of damages as a result of the act of reporting the
19 information and no lawsuit may be predicated thereon.

20 Section 12. This act shall become effective on the
21 first day of the third month following its passage and
22 approval by the Governor, or its otherwise becoming law.

Lucy Baxley

President and Presiding Officer of the Senate

Art. / Hunt

Speaker of the House of Representatives

SB35

Senate 11-MAR-04

I hereby certify that the within Act originated in and passed the Senate, as amended.

McDowell Lee
Secretary

House of Representatives
Amended and passed 27-APR-04

Senate concurred in House amendment 04-MAY-04

By: Senator Means

APPROVED 5-13-04
TIME 8:17 am
[Signature]
GOVERNOR

Alabama Secretary Of State