

1 HB150
2 147751-2
3 By Representative McClendon
4 RFD: Health
5 First Read: 06-FEB-13

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8 SYNOPSIS: This bill would amend various sections of
9 Article 10, Controlled Substances Prescription
10 Database, of Chapter 2, Title 20 of the Code of
11 Alabama 1975, to: Provide further for the
12 membership of the Controlled Substances
13 Prescription Database Advisory Committee; provide
14 further for teleconferencing and video conferencing
15 for the committee meetings; provide further for
16 transmitting information on controlled substance
17 prescriptions; provide further for access to the
18 database and confidentiality of records in the
19 database; and provide further for database funding.

20
21 A BILL
22 TO BE ENTITLED
23 AN ACT
24

25 To amend Sections 20-2-212, 20-2-213, 20-2-214,
26 20-2-215, and 20-2-219 of the Code of Alabama 1975, relating
27 to the Controlled Substances Prescription Database and the

1 Controlled Substances Prescription Database Advisory
2 Committee; to provide further for the membership and meetings
3 of the committee; to provide further for information used in
4 transmitting information on controlled substances
5 prescriptions; and to provide further for access to,
6 confidentiality of records of, and funding of the database.

7 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

8 Section 1. Sections 20-2-212, 20-2-213, 20-2-214,
9 20-2-215, and 20-2-219 of the Code of Alabama 1975, are
10 amended to read as follows:

11 "§20-2-212.

12 "The department is hereby authorized to establish,
13 create, and maintain a controlled substances prescription
14 database program. In order to carry out its responsibilities
15 under this article, the department is hereby granted the
16 following powers and authority:

17 "(1) To adopt regulations, in accordance with the
18 Alabama Administrative Procedure Act, governing the
19 establishment and operation of a controlled substances
20 prescription database program.

21 "(2) To receive and to expend for the purposes
22 stated in this article funds in the form of grants, donations,
23 federal matching funds, interagency transfers, and
24 appropriated funds designated for the development,
25 implementation, operation, and maintenance of the controlled
26 substances prescription database. The funds received pursuant
27 to this subdivision shall be deposited in a new fund that is

1 hereby established as a separate special revolving trust fund
2 in the State Treasury to be known as the Alabama State
3 Controlled Substance Database Trust Fund. No monies shall be
4 withdrawn or expended from the fund for any purpose unless the
5 monies have been appropriated by the Legislature and allocated
6 pursuant to this article. Any monies appropriated shall be
7 budgeted and allocated pursuant to the Budget Management Act
8 in accordance with Article 4 (commencing with Section 41-4-80)
9 of Chapter 4 of Title 41, and only in the amounts provided by
10 the Legislature in the general appropriations act or other
11 appropriations act.

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

19 "(4) To create a Controlled Substances Prescription
20 Database Advisory Committee. The mission of the advisory
21 committee is to consult with and advise the State Health
22 Officer on matters related to the establishment, maintenance,
23 and operation of the database, access to the database
24 information, how access is to be regulated, and security of
25 information contained in the database. The committee shall
26 consist of one representative designated by each of the
27 following organizations:

- 1 "a. The Medical Association of the State of Alabama.
- 2 "b. The Alabama Dental Association.
- 3 "c. The Alabama Pharmacy Association.
- 4 "d. The Alabama Veterinary Medicine Association.
- 5 "e. The State Health Officer, or his or her
6 designee.
- 7 "f. The Alabama Hospital Association.
- 8 "g. The Executive Director of the Alabama State
9 Board of Pharmacy.
- 10 "h. The Executive Director of the Board of Medical
11 Examiners.
- 12 "i. The Alabama Optometric Association.
- 13 "j. One representative from each of the certifying
14 boards established under the Alabama Uniform Controlled
15 Substances Act.
- 16 "k. The Alabama ~~Independent Drug Store Association~~
17 Medicaid Agency.
- 18 "l. The Alabama Podiatry Association.
- 19 "m. The Alabama Department of Mental Health.
- 20 "(5) If a member of the Controlled Substances
21 Prescription Database Advisory Committee is unable to attend a
22 meeting, the organization which appointed that member may
23 designate one of its employees or agents as a proxy. A proxy
24 may participate in all deliberations of the committee and vote
25 on all questions considered by the advisory committee.
26 Designations of a proxy must be in writing, must specify by
27 name the individual who will serve as proxy, and must specify

1 the date of the meeting at which the proxy is authorized to
2 serve. There must be a separate written proxy designation for
3 each meeting at which a proxy will serve.

4 "(6) The membership of the committee shall be
5 inclusive and reflect the racial, gender, geographic,
6 urban/rural and economic diversity of the state. The committee
7 shall annually report to the Legislature by the second
8 legislative day of each regular session the extent to which
9 the committee has complied with the diversity provisions
10 provided for in this subdivision.

11 "(7) Members of the Controlled Substances
12 Prescription Database Advisory Committee may participate in a
13 meeting by means of conference telephone, video conference, or
14 similar communications equipment by means of which all persons
15 participating in the meeting may hear each other at the same
16 time. Participation by such means shall constitute presence in
17 person at a meeting for all purposes, including the
18 establishment of a quorum. Telephone or video conference or
19 similar communications equipment shall also allow members of
20 the public the opportunity to simultaneously listen to or
21 observe the meetings.

22 "§20-2-213.

23 "(a) Each of the entities designated in subsection
24 (b) shall report to the department, or to an entity designated
25 by the department, controlled substances prescription
26 information as designated by regulation pertaining to all
27 Class II, Class III, Class IV, and Class V controlled

1 substances in such manner as may be prescribed by the
2 department by regulation.

3 "(b) The following entities or practitioners are
4 subject to the reporting requirements of subsection (a):

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

10 "(2) Mail order pharmacies or pharmacy benefit
11 programs filling prescriptions for or dispensing controlled
12 substances to residents of this state.

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

25 "(c) The manner of reporting controlled substance
26 prescription information shall be in such manner and format as
27 designated in the regulations of the department.

1 "(d) The following data elements shall be used in
2 transmitting controlled substance prescription information:

3 "(1) Name or other identifying designation of the
4 prescribing practitioner.

5 "(2) Date prescription was filled or medications
6 dispensed.

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

10 "(4) National Drug Code (NDC) of controlled
11 substance dispensed.

12 "(5) Quantity of controlled substance dispensed.

13 "(6) Name or other identifying designation of
14 dispensing pharmacy or practitioner.

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

18 "(8) Method of payment and third-party payor
19 identification of the controlled substance dispensed.

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

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

7 "§20-2-214.

8 "The following persons or entities shall be
9 permitted access to the information in the controlled
10 substances database, subject to the limitations indicated
11 below:

12 "(1) Authorized representatives of the certifying
13 boards, provided, however, that access shall be limited to
14 ~~inquiries~~ information concerning the licensees of the
15 certifying board.

16 "(2) A licensed practitioner approved by the
17 department who has authority to prescribe, dispense, or
18 administer controlled substances, ~~provided, however, that~~
19 ~~such.~~ The licensed practitioner's access shall be limited to
20 information concerning ~~an assistant to physician with himself~~
21 or herself, registrants who possess a Qualified Alabama
22 Controlled Substances Registration Certificate over whom the
23 practitioner exercises physician supervision and or with whom
24 they have a joint practice agreement, a current ~~or prospective~~
25 patient of the practitioner, and individuals seeking treatment
26 from the practitioner. ~~Practitioners shall have no requirement~~
27 ~~or obligation to access or check the information in the~~

1 ~~controlled substances database prior to prescribing,~~
2 ~~dispensing, or administering medications or as part of their~~
3 ~~professional practice.~~

4 "(3) A licensed physician approved by the department
5 who has authority to prescribe, dispense, or administer
6 controlled substances may designate up to two employees who
7 may access the database on the physician's behalf.

8 ~~"(3) (4)~~ A licensed assistant to physician approved
9 by the department who is authorized to prescribe, administer,
10 or dispense pursuant to a Qualified Alabama Controlled
11 Substances Registration Certificate; provided, however, that
12 such access shall be limited to information concerning a
13 ~~current or prospective~~ patient of the assistant to the
14 physician or an individual seeking treatment from the
15 assistant to physician.

16 ~~"(4) (5)~~ A licensed pharmacist approved by the
17 department, provided, however, that such access is limited to
18 information related to the patient or prescribing practitioner
19 designated on a controlled substance prescription that a
20 pharmacist has been asked to fill. ~~Pharmacists shall have no~~
21 ~~requirement or obligation to access or check the information~~
22 ~~in the controlled substances database prior to dispensing or~~
23 ~~administering medications or as part of their professional~~
24 ~~practices.~~

25 ~~"(5) (6)~~ State and local law enforcement authorities
26 as authorized under Section 20-2-91, and federal law
27 enforcement authorities authorized to access prescription

1 information upon application to the department accompanied by
2 ~~an affidavit stating~~ a declaration that probable cause exists
3 for the use of the requested information.

4 "~~(6)~~ (7) Employees of the department and consultants
5 engaged by the department for operational and review purposes.

6 "~~(7)~~ (8) The prescription drug monitoring program of
7 any of the other states or territories of the United States,
8 if recognized by the Alliance for Prescription Drug Monitoring
9 Programs under procedures developed, certified, or approved by
10 the United States Department of Justice or the Integrated
11 Justice Information Systems Institute or successor entity
12 subject to or consistent with limitations for access
13 prescribed by this chapter for the Alabama Prescription Drug
14 Monitoring Program.

15 "(9) Authorized representatives of the Alabama
16 Medicaid Agency; provided, however, that access shall be
17 limited to inquiries concerning possible misuse or abuse of
18 controlled substances by Medicaid recipients.

19 "\$20-2-215.

20 "Database Funding.

21 "(a) The controlled substances database and all
22 information contained therein and any records maintained by
23 the department or by any entity contracting with the
24 department which is submitted to, maintained, or stored as a
25 part of the controlled substances prescription database, and
26 any reproduction or copy of that information is hereby
27 declared privileged and confidential, is not a public record,

1 is not subject to subpoena or discovery in civil proceedings
2 and may only be used for investigatory or evidentiary purposes
3 related to violations of state or federal law and regulatory
4 activities of licensing or regulatory boards of practitioners
5 authorized to prescribe or dispense controlled substances.

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

16 "§20-2-219.

17 ~~"The controlled substances prescription database~~
18 ~~shall become operational within 12 months after the State~~
19 ~~Health Officer certifies to the certifying boards in writing~~
20 ~~that the department has sufficient funds to finance the~~
21 ~~development, implementation, and operation of the database.~~
22 The department may make deposits into the fund from any
23 source, public or private, including grants or contributions
24 of money or other items of value, which it determines
25 necessary to carry out the purpose of the program.
26 Notwithstanding amounts contained in the fund that remain
27 unencumbered or unobligated at the close of the fiscal year

1 shall not revert but shall remain available for expenditure
2 for the purposes designated in future years."

3 Section 2. This act shall become effective on the
4 first day of the third month following its passage and
5 approval by the Governor, or its otherwise becoming law.