

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

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ENROLLED, An Act,

To amend Sections 20-2-212, 20-2-213, 20-2-214, 20-2-215, and 20-2-219 of the Code of Alabama 1975, relating to the Controlled Substances Prescription Database and the Controlled Substances Prescription Database Advisory Committee; to provide further for the membership and meetings of the committee; to provide further for information used in transmitting information on controlled substances prescriptions; and to provide further for access to, confidentiality of records of, and funding of the database.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

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

"§20-2-212.

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

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

1 "(2) To receive and to expend for the purposes
2 stated in this article funds in the form of grants, donations,
3 federal matching funds, interagency transfers, and
4 appropriated funds designated for the development,
5 implementation, operation, and maintenance of the controlled
6 substances prescription database. The funds received pursuant
7 to this subdivision shall be deposited in a new fund that is
8 hereby established as a separate special revolving trust fund
9 in the State Treasury to be known as the Alabama State
10 Controlled Substance Database Trust Fund. No monies shall be
11 withdrawn or expended from the fund for any purpose unless the
12 monies have been appropriated by the Legislature and allocated
13 pursuant to this article. Any monies appropriated shall be
14 budgeted and allocated pursuant to the Budget Management Act
15 in accordance with Article 4 (commencing with Section 41-4-80)
16 of Chapter 4 of Title 41, and only in the amounts provided by
17 the Legislature in the general appropriations act or other
18 appropriations act.

19 "(3) To enter into one or more contracts with the
20 State Board of Pharmacy for the performance of designated
21 operational functions for the controlled substances
22 prescription database, including, but not limited to, the
23 receipt, collection, input, and transmission of controlled
24 substances prescription data and such other operational
25 functions as the department may elect.

1 "(4) To create a Controlled Substances Prescription
2 Database Advisory Committee. The mission of the advisory
3 committee is to consult with and advise the State Health
4 Officer on matters related to the establishment, maintenance,
5 and operation of the database, access to the database
6 information, how access is to be regulated, and security of
7 information contained in the database. The committee shall
8 consist of one representative designated by each of the
9 following organizations:

10 "a. The Medical Association of the State of Alabama.

11 "b. The Alabama Dental Association.

12 "c. The Alabama Pharmacy Association.

13 "d. The Alabama Veterinary Medicine Association.

14 "e. The State Health Officer, or his or her
15 designee.

16 "f. The Alabama Hospital Association.

17 "g. The Executive Director of the Alabama State
18 Board of Pharmacy.

19 "h. The Executive Director of the Board of Medical
20 Examiners.

21 "i. The Alabama Optometric Association.

22 "j. One representative from each of the certifying
23 boards established under the Alabama Uniform Controlled
24 Substances Act.

1 "k. ~~The Alabama Independent Drug Store Association~~
2 Medicaid Agency.

3 "l. The Alabama Podiatry Association.

4 "m. The Alabama Department of Mental Health.

5 "(5) If a member of the Controlled Substances
6 Prescription Database Advisory Committee is unable to attend a
7 meeting, the organization which appointed that member may
8 designate one of its employees or agents as a proxy. A proxy
9 may participate in all deliberations of the committee and vote
10 on all questions considered by the advisory committee.

11 Designations of a proxy must be in writing, must specify by
12 name the individual who will serve as proxy, and must specify
13 the date of the meeting at which the proxy is authorized to
14 serve. There must be a separate written proxy designation for
15 each meeting at which a proxy will serve.

16 "(6) The membership of the committee shall be
17 inclusive and reflect the racial, gender, geographic,
18 urban/rural and economic diversity of the state. The committee
19 shall annually report to the Legislature by the second
20 legislative day of each regular session the extent to which
21 the committee has complied with the diversity provisions
22 provided for in this subdivision.

23 "(7) Members of the Controlled Substances
24 Prescription Database Advisory Committee may participate in a
25 meeting by means of conference telephone, video conference, or

1 similar communications equipment by means of which all persons
2 participating in the meeting may hear each other at the same
3 time. Participation by such means shall constitute presence in
4 person at a meeting for all purposes, including the
5 establishment of a quorum. Telephone or video conference or
6 similar communications equipment shall also allow members of
7 the public the opportunity to simultaneously listen to or
8 observe the meetings.

9 "§20-2-213.

10 "(a) Each of the entities designated in subsection
11 (b) shall report to the department, or to an entity designated
12 by the department, controlled substances prescription
13 information as designated by regulation pertaining to all
14 Class II, Class III, Class IV, and Class V controlled
15 substances in such manner as may be prescribed by the
16 department by regulation.

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

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

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

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

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

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

21 "(1) Name or other identifying designation of the
22 prescribing practitioner.

23 "(2) Date prescription was filled or medications
24 dispensed.

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

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

6 "(5) Quantity of controlled substance dispensed.

7 "(6) Name or other identifying designation of
8 dispensing pharmacy or practitioner.

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

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

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

1 commission shall be deemed a formal complaint and shall be
2 investigated and appropriate action taken thereon.

3 "§20-2-214.

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

8 "(1) Authorized representatives of the certifying
9 boards, provided, however, that access shall be limited to
10 ~~inquiries~~ information concerning the licensees of the
11 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~~
15 ~~such.~~ The licensed practitioner's access shall be limited to
16 information concerning ~~an assistant to physician with himself~~
17 or herself, registrants who possess a Qualified Alabama
18 Controlled Substances Registration Certificate over whom the
19 practitioner exercises physician supervision and or with whom
20 they have a joint practice agreement, a current ~~or prospective~~
21 patient of the practitioner, and individuals seeking treatment
22 ~~from the practitioner. Practitioners shall have no requirement~~
23 ~~or obligation to access or check the information in the~~
24 ~~controlled substances database prior to prescribing,~~
25 ~~dispensing, or administering medications or as part of their~~

1 ~~professional practice.~~ from the practitioner. Practitioners
2 shall have no requirement or obligation, under this article,
3 to access or check the information in the controlled
4 substances database prior to prescribing, dispensing, or
5 administering medications or as part of their professional
6 practice. However, the applicable licensing boards, in their
7 discretion, may impose such a requirement or obligation by
8 regulations.

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

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

21 ~~"(4)~~ (5) A licensed pharmacist approved by the
22 department, provided, however, that such access is limited to
23 information related to the patient or prescribing practitioner
24 designated on a controlled substance prescription that a
25 pharmacist has been asked to fill. Pharmacists shall have no

1 ~~requirement or obligation to access or check the information~~
2 ~~in the controlled substances database prior to dispensing or~~
3 ~~administering medications or as part of their professional~~
4 ~~practices.~~ pharmacists has been asked to fill. Pharmacists
5 shall have no requirement or obligation to access or check the
6 information in the controlled substances database prior to
7 dispensing or administering medications or as part of their
8 professional practices.

9 "~~(5)~~ (6) State and local law enforcement authorities
10 as authorized under Section 20-2-91, and federal law
11 enforcement authorities authorized to access prescription
12 information upon application to the department accompanied by
13 ~~an affidavit stating~~ a declaration that probable cause exists
14 for the use of the requested information.

15 "~~(6)~~ (7) Employees of the department and consultants
16 engaged by the department for operational and review purposes.

17 "~~(7)~~ (8) The prescription drug monitoring program of
18 any of the other states or territories of the United States,
19 if recognized by the Alliance for Prescription Drug Monitoring
20 Programs under procedures developed, certified, or approved by
21 the United States Department of Justice or the Integrated
22 Justice Information Systems Institute or successor entity
23 subject to or consistent with limitations for access
24 prescribed by this chapter for the Alabama Prescription Drug
25 Monitoring Program.

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

5 "\$20-2-215.

6 "Database Funding.

7 "(a) The controlled substances database and all
 8 information contained therein and any records maintained by
 9 the department or by any entity contracting with the
 10 department which is submitted to, maintained, or stored as a
 11 part of the controlled substances prescription database, and
 12 any reproduction or copy of that information is hereby
 13 declared privileged and confidential, is not a public record,
 14 is not subject to subpoena or discovery in civil proceedings
 15 and may only be used for investigatory or evidentiary purposes
 16 related to violations of state or federal law and regulatory
 17 activities of licensing or regulatory boards of practitioners
 18 authorized to prescribe or dispense controlled substances.

19 "(b) Nothing in this section shall apply to records
 20 created or maintained in the regular course of business of a
 21 pharmacy, medical, dental, optometric, or veterinary
 22 practitioner, or other entity covered by this article and all
 23 information, documents, or records otherwise available from
 24 original sources are not to be construed as immune from
 25 discovery or use in any civil proceedings merely because such

1 information contained in those records was reported to the
2 controlled substances prescription database in accordance with
3 the provisions of this article.

4 "\$20-2-219.

5 ~~"The controlled substances prescription database~~
6 ~~shall become operational within 12 months after the State~~
7 ~~Health Officer certifies to the certifying boards in writing~~
8 ~~that the department has sufficient funds to finance the~~
9 ~~development, implementation, and operation of the database.~~
10 The department may make deposits into the fund from any
11 source, public or private, including grants or contributions
12 of money or other items of value, which it determines
13 necessary to carry out the purpose of the program.
14 Notwithstanding amounts contained in the fund that remain
15 unencumbered or unobligated at the close of the fiscal year
16 shall not revert but shall remain available for expenditure
17 for the purposes designated in future years."

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

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Speaker of the House of Representatives

President and Presiding Officer of the Senate

House of Representatives

I hereby certify that the within Act originated in
and was passed by the House 09-APR-13, as amended.

Jeff Woodard
Clerk

Senate

02-MAY-13

Passed