

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

ENGROSSED

A BILL
TO BE ENTITLED
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 "(1) To adopt regulations, in accordance with the
2 Alabama Administrative Procedure Act, governing the
3 establishment and operation of a controlled substances
4 prescription database program.

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15 withdrawn or expended from the fund for any purpose unless the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

23 "(3) To enter into one or more contracts with the
24 State Board of Pharmacy for the performance of designated
25 operational functions for the controlled substances
26 prescription database, including, but not limited to, the
27 receipt, collection, input, and transmission of controlled

1 substances prescription data and such other operational
2 functions as the department may elect.

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

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

13 "b. The Alabama Dental Association.

14 "c. The Alabama Pharmacy Association.

15 "d. The Alabama Veterinary Medicine Association.

16 "e. The State Health Officer, or his or her
17 designee.

18 "f. The Alabama Hospital Association.

19 "g. The Executive Director of the Alabama State
20 Board of Pharmacy.

21 "h. The Executive Director of the Board of Medical
22 Examiners.

23 "i. The Alabama Optometric Association.

24 "j. One representative from each of the certifying
25 boards established under the Alabama Uniform Controlled
26 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
26 similar communications equipment by means of which all persons
27 participating in the meeting may hear each other at the same

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

7 "§20-2-213.

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

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

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

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

25 "(3) Licensed physicians, dentists, podiatrists,
26 optometrists, or veterinarians who dispense Class II, Class
27 III, Class IV, and Class V controlled substances directly to

1 patients, or in the case of veterinarians, for administration
2 to animals, but excluding sample medications. For the purposes
3 of this article, sample medications are defined as those drugs
4 labeled as a sample, not for resale under the laws and
5 regulations of the Federal Food and Drug Administration.
6 Controlled substances administered to patients by injection,
7 topical application, suppository administration, or oral
8 administration during the course of treatment are excluded
9 from the reporting requirement.

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

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

15 "(1) Name or other identifying designation of the
16 prescribing practitioner.

17 "(2) Date prescription was filled or medications
18 dispensed.

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

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

24 "(5) Quantity of controlled substance dispensed.

25 "(6) Name or other identifying designation of
26 dispensing pharmacy or practitioner.

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

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

6 "(e) In addition to any other applicable law or
7 regulation, the failure of a licensed pharmacy or pharmacist
8 or a licensed practitioner to comply with the requirements of
9 this section shall constitute grounds for disciplinary action
10 against the license of the pharmacy, pharmacist, or licensed
11 practitioner by the appropriate licensing board or commission,
12 and the imposition of such penalties as the licensing board or
13 commission may prescribe. The department shall report to the
14 appropriate licensing board, agency, or commission the failure
15 of a licensed pharmacist or a licensed practitioner to comply
16 with the reporting requirements of this section. Any report
17 made by the department to a licensing board, agency, or
18 commission shall be deemed a formal complaint and shall be
19 investigated and appropriate action taken thereon.

20 "§20-2-214.

21 "The following persons or entities shall be
22 permitted access to the information in the controlled
23 substances database, subject to the limitations indicated
24 below:

25 "(1) Authorized representatives of the certifying
26 boards, provided, however, that access shall be limited to

1 ~~inquiries~~ information concerning the licensees of the
2 certifying board.

3 "(2) A licensed practitioner approved by the
4 department who has authority to prescribe, dispense, or
5 administer controlled substances, ~~provided, however, that~~
6 ~~such.~~ The licensed practitioner's access shall be limited to
7 information concerning ~~an assistant to physician with himself~~
8 or herself, registrants who possess a Qualified Alabama
9 Controlled Substances Registration Certificate over whom the
10 practitioner exercises physician supervision and or with whom
11 they have a joint practice agreement, a current ~~or prospective~~
12 patient of the practitioner, and individuals seeking treatment
13 ~~from the practitioner. Practitioners shall have no requirement~~
14 ~~or obligation to access or check the information in the~~
15 ~~controlled substances database prior to prescribing,~~
16 ~~dispensing, or administering medications or as part of their~~
17 ~~professional practice.~~ from the practitioner. Practitioners
18 shall have no requirement or obligation, under this article,
19 to access or check the information in the controlled
20 substances database prior to prescribing, dispensing, or
21 administering medications or as part of their professional
22 practice. However, the applicable licensing boards, in their
23 discretion, may impose such a requirement or obligation by
24 regulations.

25 "(3) A licensed physician approved by the department
26 who has authority to prescribe, dispense, or administer

1 controlled substances may designate up to two employees who
2 may access the database on the physician's behalf.

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

11 ~~"(4)~~ (5) A licensed pharmacist approved by the
12 department, provided, however, that such access is limited to
13 information related to the patient or prescribing practitioner
14 designated on a controlled substance prescription that a
15 ~~pharmacist has been asked to fill. Pharmacists shall have no~~
16 ~~requirement or obligation to access or check the information~~
17 ~~in the controlled substances database prior to dispensing or~~
18 ~~administering medications or as part of their professional~~
19 ~~practices.~~ pharmacists has been asked to fill. Pharmacists
20 shall have no requirement or obligation to access or check the
21 information in the controlled substances database prior to
22 dispensing or administering medications or as part of their
23 professional practices.

24 ~~"(5)~~ (6) State and local law enforcement authorities
25 as authorized under Section 20-2-91, and federal law
26 enforcement authorities authorized to access prescription
27 information upon application to the department accompanied by

1 ~~an affidavit stating~~ a declaration that probable cause exists
2 for the use of the requested information.

3 ~~"(6)~~ (7) Employees of the department and consultants
4 engaged by the department for operational and review purposes.

5 ~~"(7)~~ (8) The prescription drug monitoring program of
6 any of the other states or territories of the United States,
7 if recognized by the Alliance for Prescription Drug Monitoring
8 Programs under procedures developed, certified, or approved by
9 the United States Department of Justice or the Integrated
10 Justice Information Systems Institute or successor entity
11 subject to or consistent with limitations for access
12 prescribed by this chapter for the Alabama Prescription Drug
13 Monitoring Program.

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

18 "\$20-2-215.

19 "Database Funding.

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

1 and may only be used for investigatory or evidentiary purposes
2 related to violations of state or federal law and regulatory
3 activities of licensing or regulatory boards of practitioners
4 authorized to prescribe or dispense controlled substances.

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

15 "§20-2-219.

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

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House of Representatives

Read for the first time and re-
ferred to the House of Representa-
tives committee on Health 06-FEB-13

Read for the second time and placed
on the calendar 1 amendment 14-FEB-13

Read for the third time and passed
as amended..... 09-APR-13

Yeas 91, Nays 0, Abstains 0

Jeff Woodard
Clerk