

1 HB270
2 189650-1
3 By Representative Weaver
4 RFD: Health
5 First Read: 23-JAN-18

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8 SYNOPSIS: This bill would amend laws relating to the
9 Prescription Drug Monitoring Program to revise
10 definitions and to create a review committee that
11 may approve the release or publication of
12 de-identified aggregate statewide and regional
13 health information for statistical, research, or
14 educational purposes.

15
16 A BILL
17 TO BE ENTITLED
18 AN ACT

19
20 Relating to the Prescription Drug Monitoring Program
21 (PDMP); to amend Sections 20-2-211, 20-2-212, 20-2-214, and
22 20-2-215, Code of Alabama 1975; to revise definitions; and to
23 create a review committee that may approve the release or
24 publication of de-identified aggregate statewide and regional
25 health information for statistical, research, or educational
26 purposes.

27 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

1 Section 1. Sections 20-2-211, 20-2-212, 20-2-214,
2 and 20-2-215, Code of Alabama 1975, are amended to read as
3 follows:

4 "§20-2-211.

5 "For the purposes of this article, the following
6 terms shall have the respective meanings ascribed by this
7 section:

8 "(1) CERTIFYING BOARDS. Those boards designated in
9 subdivision (3) of Section 20-2-2.

10 "(2) CONTROLLED SUBSTANCE. Any drug or medication
11 defined as a controlled substance within the meaning of
12 subdivision (4) of Section 20-2-2.

13 "(3) DEPARTMENT. The Alabama Department of Public
14 Health.

15 "(4) LICENSING BOARD OR COMMISSION. The board,
16 commission, or other entity that is authorized to issue a
17 professional license to a pharmacist or an authorized
18 practitioner.

19 "(5) PHARMACIST. Any person, as defined in
20 subdivision (17) of Section 34-23-1, licensed by the Alabama
21 State Board of Pharmacy or otherwise permitted by Alabama or
22 federal law to practice the profession of pharmacy within this
23 State.

24 "~~(5)~~ (6) PHARMACY. A retail establishment, as defined
25 in subdivision (18) of Section 34-23-1, licensed by the
26 Alabama State Board of Pharmacy.

1 "~~(6)~~(7) PRACTITIONER or AUTHORIZED PRACTITIONER. A
2 medical, dental, podiatric, or optometric, ~~or veterinary~~
3 ~~medical~~ practitioner licensed, registered, or otherwise
4 authorized by Alabama or federal law to practice in this state
5 ~~and authorized~~ to prescribe, dispense, or furnish controlled
6 substances ~~under the Alabama Uniform Controlled Substances Act~~
7 within this state.

8 "~~(7)~~(8) STATE HEALTH OFFICER. The executive officer
9 of the Alabama Department of Public Health as designated in
10 Section 22-2-8.

11 "§20-2-212.

12 "(a) The department is hereby authorized to
13 establish, create, and maintain a controlled substances
14 prescription database program. In order to carry out its
15 responsibilities under this article, the department is hereby
16 granted the 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 and an Information Release Review
21 Committee.

22 "(b) (1) The mission of the ~~advisory committee~~
23 Controlled Substance Prescription Database Advisory Committee
24 is to consult with and advise the State Health Officer on
25 matters related to the establishment, maintenance, and
26 operation of the database, access to the database information,

1 how access is to be regulated, and security of information
2 contained in the database.

3 "(2) The advisory committee shall consist of one
4 representative designated by each of the following:
5 organizations:

6 "a. One representative designated by the ~~The~~ Medical
7 Association of the State of Alabama.

8 "b. One representative designated by the ~~The~~ Alabama
9 Dental Association.

10 "c. One representative designated by the ~~The~~ Alabama
11 Pharmacy Association.

12 "d. One representative designated by the ~~The~~ Alabama
13 Veterinary Medicine Association.

14 "e. ~~The State Health Officer, or his or her designee~~
15 director of the controlled substances prescription database
16 program in the department.

17 "f. One representative designated by the ~~The~~ Alabama
18 Hospital Association.

19 "g. The Executive Director of the Alabama State
20 Board of Pharmacy, or his or her designee.

21 "h. The Executive Director of the Board of Medical
22 Examiners, or his or her designee.

23 "i. One representative designated by the ~~The~~ Alabama
24 Optometric Association.

25 "j. One representative from each of the certifying
26 boards established under the Alabama Uniform Controlled
27 Substances Act.

1 "k. One representative designated by the ~~The~~ Alabama
2 Medicaid Agency.

3 "l. One representative designated by the ~~The~~ Alabama
4 Podiatry Association.

5 "m. One representative designated by the ~~The~~ Alabama
6 Department of Mental Health.

7 "n. The Attorney General, or his or her designee.

8 "~~(5)~~ (3) If a member of the Controlled Substances
9 Prescription Database Advisory Committee is unable to attend a
10 meeting, the organization which appointed that member may
11 designate one of its employees or agents as a proxy. A proxy
12 may participate in all deliberations of the committee and vote
13 on all questions considered by the advisory committee.

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

19 "~~(6)~~ (4) ~~The membership of the committee shall be~~ The
20 appointing authorities of the committee shall coordinate their
21 appointments to assure the committee membership is inclusive
22 ~~and reflect~~ reflects the racial, gender, geographic,
23 urban/rural, and economic diversity of the state. ~~The~~
24 ~~committee shall annually report to the Legislature by the~~
25 ~~second legislative day of each regular session the extent to~~
26 ~~which the committee has complied with the diversity provisions~~
27 ~~provided for in this subdivision.~~

1 "~~(7)~~(5) Members of the Controlled Substances
2 Prescription Database Advisory Committee may participate in a
3 meeting by means of conference telephone, video conference, or
4 similar communications equipment by means of which all persons
5 participating in the meeting may hear each other at the same
6 time. Participation by such means shall constitute presence in
7 person at a meeting for all purposes, including the
8 establishment of a quorum. Telephone or video conference or
9 similar communications equipment shall also allow members of
10 the public the opportunity to simultaneously listen to or
11 observe the meetings.

12 "(c) (1) The mission of the Information Release
13 Review Committee is to review statistical, research, or
14 educational requests for information, departmental research
15 requests, or department requests regarding publication of
16 information from the controlled substances database.

17 "(2) The review committee shall consist of one
18 licensed practitioner appointed by the State Board of Medical
19 Examiners, one licensed practitioner appointed by the State
20 Board of Dental Examiners, one licensed pharmacist appointed
21 by the State Board of Pharmacy, one representative experienced
22 in medical informatics or clinical research appointed by the
23 State Health Officer, and one representative experienced in
24 medical informatics or clinical research appointed by the
25 Attorney General.

26 "(3) Members of the Information Release Review
27 Committee may receive electronically from the department,

1 statistical, research, or educational requests for
2 information, departmental research requests, or department
3 requests regarding publication of information, and may respond
4 electronically in order to provide their approval or
5 disapproval of those requests.

6 "§20-2-214.

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

11 "(1) Authorized representatives of the certifying
12 boards; provided, however, that access shall be limited to
13 information concerning the licensees of the certifying board,
14 however, authorized representatives from the Board of Medical
15 Examiners may access the database to inquire about certified
16 registered nurse practitioners (CRNPs), or certified nurse
17 midwives (CNMs) that hold a Qualified Alabama Controlled
18 Substances Registration Certificate (QACSC).

19 "(2) A licensed practitioner approved by the
20 department who has authority to prescribe, dispense, or
21 administer controlled substances. The licensed practitioner's
22 access shall be limited to information concerning himself or
23 herself, registrants who possess a Qualified Alabama
24 Controlled Substances Registration Certificate over whom the
25 practitioner exercises physician supervision or with whom they
26 have a joint practice agreement, a certified registered nurse
27 practitioner and a certified nurse midwife with a Qualified

1 Alabama Controlled Substances Registration Certificate over
2 whom the practitioner exercises professional oversight and
3 direction pursuant to an approved collaborative practice
4 agreement, a current patient of the practitioner, and
5 individuals seeking treatment from the practitioner.
6 Practitioners shall have no requirement or obligation, under
7 this article, to access or check the information in the
8 controlled substances database prior to prescribing,
9 dispensing, or administering medications or as part of their
10 professional practice. However, the applicable licensing
11 boards, in their discretion, may impose such a requirement or
12 obligation by regulations.

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

17 "(4) A licensed certified registered nurse
18 practitioner or a licensed certified nurse midwife approved by
19 the department who is authorized to prescribe, administer, or
20 dispense pursuant to a Qualified Alabama Controlled Substances
21 Registration Certificate; provided, however, that such access
22 shall be limited to information concerning a current or
23 prospective patient of the certified registered nurse
24 practitioner or certified nurse midwife.

25 "(5) A licensed assistant to physician approved by
26 the department who is authorized to prescribe, administer, or
27 dispense pursuant to a Qualified Alabama Controlled Substances

1 Registration Certificate; provided, however, that such access
2 shall be limited to information concerning a current patient
3 of the assistant to the physician or an individual seeking
4 treatment from the assistant to physician.

5 "(6) A licensed pharmacist approved by the
6 department, provided, however, that such access is limited to
7 information related to the patient or prescribing practitioner
8 designated on a controlled substance prescription that a
9 ~~pharmacists~~ pharmacist has been asked to fill. Pharmacists
10 shall have no requirement or obligation to access or check the
11 information in the controlled substances database prior to
12 dispensing or administering medications or as part of their
13 professional practices.

14 "(7) State and local law enforcement authorities as
15 authorized under Section 20-2-91, and federal law enforcement
16 authorities authorized to access prescription information upon
17 application to the department accompanied by a declaration
18 that probable cause exists for the use of the requested
19 information.

20 "(8) Employees of the department and consultants
21 engaged by the department ~~for operational and review purposes~~
22 to operate the controlled substances database; provided,
23 however, that access shall be limited to operating and
24 administering the database, conducting departmental research
25 when approved by the review committee, and implementing a
26 research request authorized under subsection (b).

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

10 "(10) Authorized representatives of the Alabama
11 Medicaid Agency; provided, however, that access shall be
12 limited to inquiries concerning possible misuse or abuse of
13 controlled substances by Medicaid recipients.

14 "(b) Subject to the approval of the review
15 committee, the department may release or publish de-identified
16 aggregate statewide and regional information for statistical,
17 research, or educational purposes.

18 "(1) Prior to being released or published, all
19 information that identifies, or could reasonably be used to
20 identify, a patient, a prescriber, a dispenser, or any other
21 person who is the subject of the information, shall be
22 removed, and at a minimum, such de-identification of the
23 information shall comply with 45 C.F.R. §164.514(b) (2), as
24 amended.

25 "(2) Release of information shall be made pursuant
26 to a written data use agreement between the requesting
27 individual or entity and the department.

1 "§20-2-215.

2 "(a) The controlled substances database and all
3 information contained therein and any records maintained by
4 the department or by any entity contracting with the
5 department which is submitted to, maintained, or stored as a
6 part of the controlled substances prescription database, and
7 any reproduction or copy of that information is hereby
8 declared privileged and confidential, is not a public record,
9 and is not subject to subpoena or discovery in civil
10 proceedings. This information is considered clinical in
11 nature, subject to medical interpretation, and may only be
12 used for any of the following:

13 "(1) ~~investigatory~~ Investigatory or evidentiary
14 purposes related to violations of state or federal law.

15 "(2) ~~and regulatory~~ Regulatory activities of
16 licensing or regulatory boards of practitioners authorized to
17 prescribe or dispense controlled substances.

18 "(3) Informing pharmacists and practitioners in
19 prescribing or dispensing controlled substances.

20 "(4) Bona fide statistical, research, or educational
21 purposes when information is properly de-identified as
22 provided in this chapter.

23 "(b) Nothing in this section shall apply to records
24 not originating from the controlled substances database that
25 are created or maintained in the regular course of business of
26 a pharmacy, medical, dental, optometric, or veterinary
27 practitioner, or other entity covered by this article and all

1 information, documents, or records otherwise available from
2 original sources are not to be construed as immune from
3 discovery or use in any civil proceedings merely because such
4 information contained in those records was reported to the
5 controlled substances prescription database in accordance with
6 the provisions of this article."

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