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

1 2 ENROLLED, An Act, To amend Sections 20-2-212, 20-2-213, 20-2-214, 3 20-2-215, and 20-2-219 of the Code of Alabama 1975, relating 4 5 to the Controlled Substances Prescription Database and the 6 Controlled Substances Prescription Database Advisory Committee; to provide further for the membership and meetings 7 of the committee; to provide further for information used in transmitting information on controlled substances 9 10 prescriptions; and to provide further for access to, 11 confidentiality of records of, and funding of the database. 12 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA: 13 Section 1. Sections 20-2-212, 20-2-213, 20-2-214, 14 20-2-215, and 20-2-219 of the Code of Alabama 1975, are 15 amended to read as follows: "\$20-2-212. 16 17 "The department is hereby authorized to establish, 18

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"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.

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withdrawn or expended from the fund for any purpose unless the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

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

Τ	"k. The Alabama independent brug Store Association
2	Medicaid Agency.
3	"1. 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.

"\$20-2-213. 9

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- "(a) Each of the entities designated in subsection (b) shall report to the department, or to an entity designated by the department, controlled substances prescription information as designated by regulation pertaining to all Class II, Class III, Class IV, and Class V controlled substances in such manner as may be prescribed by the department by regulation.
- "(b) The following entities or practitioners are subject to the reporting requirements of subsection (a):
- "(1) Licensed pharmacies, not including pharmacies of general and specialized hospitals, nursing homes, and any other healthcare facilities which provide inpatient care, so long as the controlled substance is administered and used by a patient on the premises of the facility.

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

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- "(3) Licensed physicians, dentists, podiatrists, optometrists, or veterinarians who dispense Class II, Class III, Class IV, and Class V controlled substances directly to patients, or in the case of veterinarians, for administration to animals, but excluding sample medications. For the purposes of this article, sample medications are defined as those drugs labeled as a sample, not for resale under the laws and regulations of the Federal Food and Drug Administration.

 Controlled substances administered to patients by injection, topical application, suppository administration, or oral administration during the course of treatment are excluded from the reporting requirement.
- "(c) The manner of reporting controlled substance prescription information shall be in such manner and format as designated in the regulations of the department.
- "(d) The following data elements shall be used in transmitting controlled substance prescription information:
- "(1) Name or other identifying designation of the prescribing practitioner.
- "(2) Date prescription was filled or medications 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) National Drug Code (NDC) of controlled substance dispensed.

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- "(5) Quantity of controlled substance dispensed.
- "(6) Name or other identifying designation of dispensing pharmacy or practitioner.
- "(7) Other data elements consistent with standards established by the American Society for Automation in Pharmacy as may be designated by regulations adopted by the department.
- "(8) Method of payment and third-party payor identification of the controlled substance dispensed.

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

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2	investigate	d and	apr	propriat	:e	action	taken t	ther	eon.		

3 "\$20-2-214.

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

- "(1) Authorized representatives of the certifying boards, provided, however, that access shall be limited to inquiries information concerning the licensees of the certifying board.
- "(2) A licensed practitioner approved by the department who has authority to prescribe, dispense, or administer controlled substances, provided, however, that such. The licensed practitioner's access shall be limited to information concerning an assistant to physician with himself or herself, registrants who possess a Qualified Alabama Controlled Substances Registration Certificate over whom the practitioner exercises physician supervision and or with whom they have a joint practice agreement, a current or prospective patient of the practitioner, and individuals seeking treatment from the practitioner. Practitioners shall have no requirement or obligation to access or check the information in the controlled substances database prior to prescribing, dispensing, or administering medications or as part of their

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

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

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

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

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requirement or obligation to access or check the information in the controlled substances database prior to dispensing or administering medications or as part of their professional practices. pharmacists has been asked to fill. Pharmacists shall have no requirement or obligation to access or check the information in the controlled substances database prior to dispensing or administering medications or as part of their professional practices.

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

" $\frac{(6)}{(7)}$ Employees of the department and consultants engaged by the department for operational and review purposes.

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

"(9) Authorized representatives of the Alabama

Medicaid Agency; provided, however, that access shall be

limited to inquiries concerning possible misuse or abuse of

controlled substances by Medicaid recipients.

"\$20-2-215.

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"Database Funding.

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

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

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

"\$20-2-219.

"The controlled substances prescription database shall become operational within 12 months after the State

Health Officer certifies to the certifying boards in writing that the department has sufficient funds to finance the development, implementation, and operation of the database.

The department may make deposits into the fund from any source, public or private, including grants or contributions of money or other items of value, which it determines necessary to carry out the purpose of the program.

Notwithstanding amounts contained in the fund that remain unencumbered or unobligated at the close of the fiscal year shall not revert but shall remain available for expenditure for the purposes designated in future years."

Section 2. This act shall become effective on the

first day of the third month following its passage and

approval by the Governor, or its otherwise becoming law.

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4		Speaker of the House of Representatives	
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6		President and Presiding Officer of the Sena	ite
7		House of Representatives	
8 9		hereby certify that the within Act originat seed by the House 09-APR-13, as amended.	ed in
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11		Jeff Woodard	
12		Clerk	
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16	Senate	02-MAY-13	Passed
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