- 1 SB115
- 2 147751-2
- 3 By Senators Ward, Reed, Allen, Whatley, Scofield, Glover,

4 Waggoner, Marsh, Fielding and Holley

- 5 RFD: Judiciary
- 6 First Read: 05-FEB-13

147751-2:n:02/04/2013:MCS/tan LRS2013-511R1 1 2 3 4 5 6 7 SYNOPSIS: This bill would amend various sections of 8 Article 10, Controlled Substances Prescription 9 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 further for teleconferencing and video conferencing 14 15 for the committee meetings; provide further for transmitting information on controlled substance 16 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 To amend Sections 20-2-212, 20-2-213, 20-2-214, 25 20-2-215, and 20-2-219 of the Code of Alabama 1975, relating 26 27 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:

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:

"(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

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 No monies shall be 3 4 withdrawn or expended from the fund for any purpose unless the monies have been appropriated by the Legislature and allocated 5 pursuant to this article.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

"(4) To create a Controlled Substances Prescription 19 Database Advisory Committee. The mission of the advisory 20 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 information contained in the database. The committee shall 25 consist of one representative designated by each of the 26 27 following organizations:

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

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

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

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

22

"§20-2-213.

"(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.

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 III, Class IV, and Class V controlled substances directly to 15 patients, or in the case of veterinarians, for administration 16 17 to animals, but excluding sample medications. For the purposes of this article, sample medications are defined as those drugs 18 labeled as a sample, not for resale under the laws and 19 regulations of the Federal Food and Drug Administration. 20 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.

"(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 1 2 transmitting controlled substance prescription information: "(1) Name or other identifying designation of the 3 4 prescribing practitioner. "(2) Date prescription was filled or medications 5 6 dispensed. 7 "(3) Name of person and full address for whom the prescription was written or to whom the medications were 8 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 dispensing pharmacy or practitioner. 14 15 "(7) Other data elements consistent with standards established by the American Society for Automation in Pharmacy 16 17 as may be designated by regulations adopted by the department. "(8) Method of payment and third-party payor 18 identification of the controlled substance dispensed. 19 "(e) In addition to any other applicable law or 20 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 against the license of the pharmacy, pharmacist, or licensed 24 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

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

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"§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 <u>inquiries information</u> concerning the licensees of the 15 certifying board.

"(2) A licensed practitioner approved by the 16 17 department who has authority to prescribe, dispense, or administer controlled substances, provided, however, that 18 such. The licensed practitioner's access shall be limited to 19 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

controlled substances database prior to prescribing,
 dispensing, or administering medications or as part of their
 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.

"(3) (4) A licensed assistant to physician approved 8 by the department who is authorized to prescribe, administer, 9 10 or dispense pursuant to a Qualified Alabama Controlled Substances Registration Certificate; provided, however, that 11 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.

"(4) (5) A licensed pharmacist approved by the 16 17 department, provided, however, that such access is limited to information related to the patient or prescribing practitioner 18 designated on a controlled substance prescription that a 19 pharmacist has been asked to fill. Pharmacists shall have no 20 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.

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

1 information upon application to the department accompanied by 2 an affidavit stating <u>a declaration that</u> probable cause <u>exists</u> 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, if recognized by the Alliance for Prescription Drug Monitoring 8 Programs under procedures developed, certified, or approved by 9 10 the United States Department of Justice or the Integrated Justice Information Systems Institute or successor entity 11 12 subject to or consistent with limitations for access 13 prescribed by this chapter for the Alabama Prescription Drug 14 Monitoring Program.

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

19 "§20-2-215.

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"<u>Database Funding.</u>

"(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 6 7 created or maintained in the regular course of business of a pharmacy, medical, dental, optometric, or veterinary 8 practitioner, or other entity covered by this article and all 9 10 information, documents, or records otherwise available from original sources are not to be construed as immune from 11 12 discovery or use in any civil proceedings merely because such information contained in those records was reported to the 13 14 controlled substances prescription database in accordance with 15 the provisions of this article.

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"§20-2-219.

17 "The controlled substances prescription database shall become operational within 12 months after the State 18 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 source, public or private, including grants or contributions 23 of money or other items of value, which it determines 24 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.