- 1 HB88
- 2 135591-1
- 3 By Representative Millican
- 4 RFD: Health
- 5 First Read: 07-FEB-12
- 6 PFD: 02/02/2012

135591-1:n:01/13/2012:JMH/th LRS2011-5952

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8 SYNOPSIS:

May only be sold by prescription. Under existing law, the State Board of Health has the authority to add, delete, or reschedule substances as controlled substances, but the board must exclude a nonnarcotic substance from a schedule if the substance may lawfully be sold over the counter without a prescription pursuant to federal law. Controlled substances are subject to certain storage, record keeping, and security control requirements.

This bill would allow ephedrine,
pseudoephedrine, and phenylpropanolamine to be sold
by prescription by requiring the State Board of
Health to classify the drugs as Schedule III
controlled substances. This bill would give the
board the authority to exempt a product containing
any of these substances from classification as a
controlled substance if the board finds that the
product is effectively formulated to prevent

conversion of the active ingredient into

methamphetamine or its salts or precursors. This

bill would also authorize the board to revoke the

exemption upon notification from the Department of

Public Safety that the product exempted is not

effectively formulated to prevent its conversion to

methamphetamine.

This bill would exempt wholesale drug distributors licensed by the Board of Pharmacy and registered with and regulated by the United States Drug Enforcement Agency from storage, reporting, and record keeping or physical security control requirements related to ephedrine and pseudoephedrine.

16 A BILL

TO BE ENTITLED

18 AN ACT

To amend Sections 20-2-20 and 20-2-181, Code of Alabama 1975; to require the State Board of Health to classify ephedrine, pseudoephedrine, and phenylpropanolamine as controlled substances; to authorize the board to exempt from classification products that are effectively formulated to prevent their conversion to methamphetamine; to authorize the board to revoke the exemption; and to exempt certain wholesale drug distributors from reporting, storage, and security

- 1 requirements for controlled substances classified as such
- because they contain ephedrine, pseudoephedrine, or
- 3 phenylpropanolamine.
- 4 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:
- 5 Section 1. Sections 20-2-20 and 20-2-181, Code of
- Alabama 1975, are amended to read as follows:
- 7 "\$20-2-20.
- 8 "(a) The State Board of Health, unless otherwise 9 specified, shall administer this chapter and may add
- 10 substances to or delete or reschedule all substances
- enumerated in the schedules in Sections 20-2-23, 20-2-25,
- 12 20-2-27, 20-2-29, or 20-2-31 pursuant to the procedures of the
- 13 State Board of Health. In making a determination regarding a
- substance, the State Board of Health shall consider all of the
- 15 following:
- "(1) The actual or relative potential for abuse.
- 17 "(2) The scientific evidence of its pharmacological
- 18 effect, if known.
- "(3) The state of current scientific knowledge
- 20 regarding the substance.
- "(4) The history and current pattern of abuse.
- "(5) The scope, duration, and significance of abuse.
- 23 "(6) The risk to the public health.
- "(7) The potential of the substance to produce
- 25 psychic or physiological dependence liability.
- 26 "(8) Whether the substance is an immediate precursor
- of a substance already controlled under this chapter.

"(b) After considering the factors enumerated in subsection (a), the State Board of Health shall make findings with respect thereto and issue a rule controlling the substance if it finds the substance has a potential for abuse.

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"(c) If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the State Board of Health, the State Board of Health shall similarly control the substance under this chapter after the expiration of 30 days from publication in the federal register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance, unless within that 30-day period, the State Board of Health objects to inclusion, rescheduling, or deletion. In that case, the State Board of Health shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the State Board of Health shall publish its decision, which shall be final unless altered by statute. Upon publication of objection to inclusion, rescheduling, or deletion under this chapter by the State Board of Health, control under this chapter is stayed until the State Board of Health publishes its decision.

- "(d) Authority to control under this section does not extend to distilled spirits, wine, malt, beverages, or tobacco.
- "(e) The State Board of Health shall exclude any nonnarcotic substance from a schedule if such substance, under the federal Food, Drug and Cosmetic Act, the federal

Comprehensive Drug Abuse Prevention and Control Act of 1970, and the law of this state may be lawfully sold over the counter without a prescription.

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"(f)(1) Notwithstanding subsection (e), the State

Board of Health shall classify ephedrine, pseudoephedrine, and

phenylpropanolamine as Schedule III controlled substances

pursuant to this chapter.

Board of Health may exempt from classification as a controlled substance a product containing ephedrine, pseudophedrine, or phenylpropanolamine if the product is effectively formulated to prevent conversion of the active ingredient into methamphetamine or its salts or precursors. Upon notification from the Department of Public Safety that it has probable cause to believe that a product exempted under this subdivision does not effectively prevent conversion of the active ingredient into methamphetamine or its salts or precursors, the State Board of Health may issue an emergency rule revoking the exemption for the product pending a hearing.

"(3) A wholesale drug distributor licensed and regulated by the State Board of Pharmacy and registered and regulated by the United States Drug Enforcement Agency is exempt from the storage, reporting, record keeping, and physical security control requirements for controlled substances containing any material, compound, mixture, or preparation which contains any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine and which is

classified as a controlled substance pursuant to this
subsection.

3 "\$20-2-181.

- "(a) The Board of Pharmacy shall, within one year of July 29, 1991, shall designate by rule listed precursor chemicals.
- "(b) The Board of Pharmacy may subsequently by rule add chemicals as listed precursor chemicals following the criteria set forth in subdivision (2) of Section 20-2-180, and may also by rule delete any substance previously named as a listed precursor chemical. In no event shall a chemical also be designated as a listed precursor chemical if it has been determined to be a controlled substance or an immediate precursor chemical pursuant to the Alabama Uniform Controlled Substances Act, Section 20-2-1 et seq.
- "(c) If any chemical is designated or deleted as a listed precursor chemical under federal law and notice thereof is given to the Board of Pharmacy, the board shall similarly list or delete the substance under this article after the expiration of 30 days from publication in the federal register of a final rule or order designating or deleting such substance as a listed precursor chemical, unless, within 30 days from publication in the federal register of the final rule or order, the board objects to the designation or deletion. In that case, the board shall publish the reasons for objection in the Alabama Administrative Monthly and shall afford all interested parties an opportunity to submit written

Ι	comments and to be heard. At the conclusion of the hearing and
2	the comment period, the State Board of Pharmacy shall publish
3	its decision, which shall be final unless altered by statute.
4	Upon publication of an objection to the designation or
5	deletion by the board, the designation or deletion is stayed
6	until the board publishes its decision. Notwithstanding the
7	provisions of the Alabama Administrative Procedure Act,
8	Sections 41-22-1 through 41-22-27, no further rulemaking or
9	administrative proceedings shall be required of the board with
10	respect to the designation or deletion of substances similarly
11	designated or deleted under federal law.
12	"(d) Until the Board of Pharmacy adopts a rule
13	designating listed precursor chemicals, as required by
14	subsection (a), $\underline{\text{all of}}$ the following chemicals or substances
15	are hereby deemed listed precursor chemicals:
16	"(1) Acetic anhydride; .
17	"(2) Anthranilic acid and its salts; .
18	"(3) Benzyl cyanide ; .
19	"(4) Ephedrine, its salts, optical isomers, and
20	salts of optical isomers;
21	" (5) <u>(4)</u> Ergonovine and its salts ; .
22	" (6) <u>(5)</u> Ergotamine and its salts ; .
23	" (7) <u>(6)</u> Hydriodic acid ; .
24	" (8) <u>(7)</u> Isosafrol ; .
25	" (9) <u>(8)</u> Methylamine ; .
26	" (10) <u>(9)</u> N-Acetylanthranilic acid and its salts ; .

1	" $\frac{(11)}{(10)}$ Norpseudoephedrine, its salts, optical
2	isomers, and salts of optical isomers;.
3	" $\frac{(12)}{(11)}$ Phenylacetic acid and its salts $\frac{1}{7}$.
4	"(13) Phenylpropanolamine, its salts, optical
5	isomers, and salts of optical isomers;
6	" (14) <u>(12)</u> Piperidine and its salts ; .
7	"(15) Pseudoephedrine, its salts, optical isomers,
8	and salts of optical isomers;
9	" (16) <u>(13)</u> Safrole ; and .
10	" $\frac{(17)}{(14)}$ 3,4-Methylenedioxyphenyl-2-propanone."
11	Section 2. This act shall become effective on the
12	first day of the third month following its passage and
13	approval by the Governor, or its otherwise becoming law.