ARKANSAS SENATE

85th General Assembly - Regular Session, 2005

Amendment Form

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Subtitle of House Bill No. 2970

"TO REQUIRE DISCLOSURE OF CERTAIN PHARMACEUTICAL MARKETING PRACTICES."

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Amendment No. 1 to House Bill No. 2970.

Amend House Bill No. 2970 as engrossed, H4/4/05 (version: 04-04-2005 17:18):

Delete the Title of the bill and substitute the following:
"AN ACT TO REPEAL PORTIONS OF ACT 256 OF 2005 WHICH CLASSED CERTAIN PRODUCTS AS SCHEDULE V CONTROLLED SUBSTANCES; AND FOR OTHER PURPOSES."

AND

Delete the subtitle in its entirety and substitute:

"AN ACT TO REPEAL PORTIONS OF ACT 256 OF 2005 WHICH CLASSED CERTAIN PRODUCTS AS SCHEDULE V CONTROLLED SUBSTANCES."

AND

Delete everything after the Enacting Clause and substitute the following:

"SECTION 1. Arkansas Code § 5-64-212, which was added by Section 2 of Act 256 of 2005, is repealed.

~~5-64-212. Substances in Schedule V.~~

~~(a) Ephedrine combination products, pseudoephedrine, and phenylpropanolamine, as defined in § 5-64-1103(g)(1), shall be designated Schedule V controlled substances in addition to the drugs and other substances listed in Schedule V of the List of Controlled Substances for the State of Arkansas promulgated by the Director of the Department of Health.~~

~~(b) The Schedule V classification shall not apply to:~~

~~(1) Exempt products described in § 5-64-1103(b)(1);~~

~~(2) Any ephedrine or pseudoephedrine in liquid, liquid capsule, or liquid gel capsule form described in § 5-64-1103(b)(2); or~~

~~(3) Products that are dispensed pursuant to a valid prescription which is not restricted to five (5) refills within a six (6) month period. These products are regulated in the same manner as any non-scheduled prescription drug and must be kept in a container that is supplied by the pharmacy and labeled in a manner consistent with any other prescription.~~

~~(c) The Director of the Department of Health may reschedule a product described in subdivision (b)(1) or (b)(2) of this section if it is determined that the conversion of the active ingredient in the product into methamphetamine or its salts or precursors is feasible.~~

~~(d) A wholesale distributor with exclusive rights to distribute pseudoephedrine to only licensed pharmacies is exempt from Schedule V requirements for the storage and distribution of pseudoephedrine.~~

SECTION 2. Arkansas Code § 5-64-1005(d), as amended by Section 3 of Act 256 and pertaining to exemptions from recordkeeping requirements, is amended to read as follows:

(d) Any sale, transfer, furnishing, or receipt by a retail distributor of any drug which contains any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act or regulations adopted thereunder, provided that:

(1) The drug is sold in blister packs of not more than three (3) grams of ephedrine, pseudoephedrine, or phenylpropanolamine base, each blister containing not more than two (2) dosage units;

(2) If the use of a blister pack is technically unfeasible, the drug is packaged in unit dose packets or pouches;

(3) ~~The drug is an exempted product described in § 5-64-1103(b)(1), or the product contains ephedrine or pseudoephedrine in liquid, liquid capsule, or liquid gel capsule form described in § 5-64-1103(b)(2), and~~ In the case of liquids, the drug is sold in package sizes of not more than three (3) grams of ephedrine, ~~or~~ pseudoephedrine, or phenylpropanolamine base; and

(4) The total quantity of the sale is not greater than three (3) packages~~,~~ or ~~five (5) grams of ephedrine, or~~ nine (9) grams ~~of pseudoephedrine~~, whichever is smaller.

SECTION 3 . Arkansas Code § 5-64-1103, as amended by Act 256 of 2005, is amended to read as follows:

5-64-1103. ~~Sales limits~~ Retail sales.

(a) It shall be unlawful ~~for any person, other than a person or entity described in § 5-64-1101(a)(3) and (a)(4),~~ for a retail distributor or an employee of a retail distributor to knowingly ~~dispense,~~ sell, transfer, or otherwise furnish in a single transaction: ~~products containing ephedrine, pseudoephedrine, or phenylpropanolamine except in a licensed pharmacy by a licensed pharmacist or a registered pharmacy technician.~~

~~(b) Unless the product has been rescheduled pursuant to § 5-64-212(c), this section shall not apply to retail distributor sales for personal use of:~~

~~(1) Products that the Department of Health, in collaboration with the Arkansas State Board of Pharmacy, upon application of a manufacturer, exempts by rule from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine or its salts or precursors; or~~

~~(2) Products containing ephedrine or pseudoephedrine in liquid, liquid capsule, or liquid gel capsule form if the drug is dispensed, sold, transferred, or otherwise furnished in a single transaction limited to no more than three (3) packages, with any single package containing not more~~

~~than ninety-six (96) liquid capsules or liquid gel capsules or not more than three (3) grams of ephedrine or pseudoephedrine base.~~

~~(c)(1) A pharmacy must maintain a written or electronic log, or receipts of transactions involving the sale of ephedrine, pseudoephedrine, or phenylpropanolamine.~~

~~(2) A person purchasing, receiving, or otherwise acquiring ephedrine, pseudoephedrine, or phenylpropanolamine shall be required to:~~

~~(A) Produce current and valid proof of identity; and~~

~~(B) Sign a written or electronic log or receipt that documents the date of the transaction, the name of the person, and the quantity of pseudoephedrine or ephedrine purchased, received, or otherwise acquired.~~

~~(d) Unless pursuant to a valid prescription, it shall be unlawful for a licensed pharmacist or a registered pharmacy technician to knowingly dispense, sell, transfer or otherwise furnish in a single transaction:~~

(1) More than three (3) packages of one (1) or more products that the distributor or employee knows to contain ephedrine, pseudoephedrine, or phenylpropanolamine, their salts, isomers, or salts of isomers; or

(2) Any single package of any product that the distributor or employee knows to contain ~~contains~~ ephedrine, pseudoephedrine, or phenylpropanolamine, which contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three (3) grams of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts, isomers, or salts of isomers, or a combination of any of these substances, whichever is smaller; or

(3) Any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, unless:

(A) The product is sold in package sizes of not more than three (3) grams of ephedrine, pseudoephedrine, or phenylpropanolamine base and is packaged in blister packs, each blister containing not more than two dosage units; or

(B) Where the use of blister packs is technically infeasible, that is packaged in unit dose packets or pouches; or

(C) In the case of liquids, the drug is sold in package sizes of not more than three (3) grams of ephedrine, pseudoephedrine, or phenylpropanolamine base; or

(4)(A) Any product containing ephedrine, pseudoephedrine, or phenylpropanolamine to any person under the age of eighteen (18) years, unless the person is purchasing ~~an exempt product under subdivision (b)(1) or (2) of this section~~ a pediatric product intended for a child.

(B) The person making the sale shall require proof of age from the purchaser, unless from the purchaser's outward appearance the person would reasonably presume the purchaser to be twenty-five (25) years of age or older.

(C) "Proof of age" means any document issued by a governmental agency which:

(i) Contains a description of the person or a photograph of the person, or both, and gives the person's date of birth; and

(ii) Includes, without being limited to, a passport, military identification card, or driver's license.

~~(c)~~(b)(1) Any ~~person~~ retail distributor or employee of the retail distributor who violates ~~subsections~~ subsection (a) ~~or (d)~~ of this section

shall be guilty of a Class A misdemeanor and may also be subject to a civil fine not to exceed five thousand dollars ($5,000).

(2)(A) The prosecuting attorney may waive any civil penalty under this section if ~~a person~~ the retail distributor or employee of the retail distributor establishes that he or she acted in good faith to prevent violations of this section, and the violations occurred despite the exercise of due diligence.

(B) In making a determination, the prosecuting attorney may consider evidence that an employer trained employees how to sell, transfer, or otherwise furnish substances specified in this subchapter in accordance with applicable laws.

~~(f)~~(c) (1) It shall be unlawful for any person, other than a person or entity described in § 5-64-1101(a)(1)-(4) ~~of this section~~, to knowingly purchase, acquire, or otherwise receive in a single transaction:

(A) More than three (3) packages of one (1) or more products that the person knows to contain ephedrine, pseudoephedrine, or phenylpropanolamine, their salts, isomers, or salts of isomers; or

(B) Any single package of any product that the person knows to contain ephedrine, pseudoephedrine, or phenylpropanolamine, which contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three (3) grams of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts, isomers, or salts of isomers, or a combination of any of these substances, whichever is smaller.

(2) ~~It shall be unlawful for any person, other than a person or entity described in § 5-64-1101(a)(1) – (4), to knowingly purchase, acquire, or otherwise receive more than five (5) grams of ephedrine or nine (9) grams of pseudoephedrine or phenylpropanolamine within any thirty-day period.~~

~~(3)~~ Any person who violates the provisions of ~~subdivisions~~ subdivision (c)(1)~~(f)(1) or (2)~~ of this section shall be guilty of a Class A misdemeanor.

(d) This section shall not apply to:

(1) Pediatric products primarily intended for administration to children under twelve (12) years of age, according to label instructions, either:

(A) In solid dosage form whose individual dosage units to not exceed recommended dosage, according to label instructions, does not exceed fifteen (15) milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine; or

(B) In liquid form whose recommended dosage, according to label instructions, does not exceed fifteen milligrams (15 mg) of ephedrine, pseudoephedrine, or phenylpropanolamine per five milliliters (5 ml) of liquid product;

(2) Pediatric liquid products primarily intended for administration to children under two (2) years of age for which the recommended dosage does not exceed two milliliters (2 ml) and the total package content does not exceed one fluid ounce (1 fl. oz.); or

(3) Products that the State Board of Pharmacy, upon application of a manufacturer, exempts by rule from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine or its salts or precursors.

~~(g)~~(e) For the purposes of this subchapter:

(1) The terms "ephedrine", "pseudoephedrine", and

"phenylpropanolamine" mean any product containing ephedrine, pseudoephedrine, or phenylpropanolamine or any of their salts, isomers, or salts of isomers, alone or in a mixture;

~~(2) "Proof of age" or "proof of identity" means any document issued by a governmental agency that:~~

~~(A) Contains a description of the person or a photograph of the person, or both, and gives the person's date of birth; and~~

~~(B) Includes, without being limited to, a passport, military identification card, or driver's license;~~

~~(3)~~(2) "Retail distributor" means a grocery store, general merchandise store, drugstore, convenience store, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, or phenylpropanolamine products for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales and includes any person or entity that makes a direct sale or has knowledge of the sale, but does not include any manager, supervisor, or owner not present and not otherwise aware of the sale, nor shall it include the parent company of that entity if the company is not involved in direct sales regulated by this subchapter; and

~~(4)~~(3) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine in quantities at or below that specified in subsection (a) of this section, and includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.

~~(h)~~(f) Nothing in this section shall prohibit a person under the age of eighteen (18) years from possessing and selling ephedrine, pseudoephedrine, or phenylpropanolamine ~~products described in subsections (a) and (b) of this section~~ as an agent of the minor's employer acting within the scope of the minor's employment.

SECTION 4. EMERGENCY CLAUSE. It is hereby found and determined by the Eighty-fifth General Assembly that Act 256 of 2005 designated ephedrine combination products, pseudoephedrine, and phenylpropanolamine as Schedule V controlled substances; that the application of this provision places undue restraint on Arkansas businesses; and that this act is immediately necessary to avoid the risk of irreparable harm. Therefore, an emergency is declared to exist and this act being immediately necessary for the preservation of the public peace, health, and safety shall be effective on:

(1) Thirty (30) days from and after the date of its passage and approval;

(2) If the bill is neither approved nor vetoed by the Governor, it shall become effective thirty (30) days from the expiration of the period of time during which the Governor may veto the bill; or

(3) If the bill is vetoed by the Governor and the veto is overridden, it shall become effective thirty (30) days from the date the last house overrides the veto."

The Amendment was read the first time, rules suspended and read the second time and _____

By: Senator Malone

JDF/JDF - 04-12-2005 11:41 _____

JDF489 **Secretary**