~~Indicates Matter Stricken~~

Indicates New Matter

HOUSE AMENDMENTS AMENDED

May 26, 2010

**S. 1137**

Introduced by Senators Fair and L. Martin

S. Printed 5/26/10--S.

Read the first time February 3, 2010.

**A** **BILL**

TO AMEND SECTION 44‑53‑398, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO MONITORING THE SALE OF PRODUCTS CONTAINING EPHEDRINE OR PSEUDOEPHEDRINE, SO AS TO ALSO MONITOR PHENYLPROPANOLAMINE AND THE SALE AND PURCHASE OF THESE PRODUCTS, TO MAKE IT ILLEGAL TO PURCHASE THESE PRODUCTS, TO PROVIDE THAT INFORMATION GATHERED FROM THE PURCHASER AT THE TIME OF THE SALE OF THESE PRODUCTS MUST BE ENTERED IN AN ELECTRONIC LOG, RATHER THAN A WRITTEN LOG, TO PROVIDE THAT THE INFORMATION MUST BE TRANSMITTED TO A CENTRAL DATA COLLECTION SYSTEM THAT WILL SUBMIT THIS INFORMATION TO SLED WHICH WILL MAINTAIN THIS INFORMATION TO ASSIST LAW ENFORCEMENT IN MONITORING THESE SALES AND PURCHASES, AND TO PROVIDE THAT A RETAILER OF THESE PRODUCTS MAY APPLY TO THE BOARD OF PHARMACY FOR AN EXEMPTION FROM THE ELECTRONIC LOG REQUIREMENT; AND BY ADDING CHAPTER 14 TO TITLE 23 SO AS TO PROVIDE THAT THE STATE LAW ENFORCEMENT DIVISION SHALL SERVE AS THE REPOSITORY FOR INFORMATION THE CENTRAL DATA COLLECTION GATHERS AND TRANSFERS TO SLED PERTAINING TO THE SALE AND PURCHASE OF PRODUCTS CONTAINING EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE.

Amend Title To Conform

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Section 44‑53‑398 of the 1976 Code, as added by Act 275 of 2006, is amended to read:

“Section 44‑53‑398. (A) Nonprescription products whose sole active ingredient is ephedrine ~~or~~, pseudoephedrine, or phenylpropanolamine may be offered for retail sale only if sold in blister packaging. The retailer shall ensure that such products are not offered for retail sale by self‑service~~,~~ but only from behind a counter or other barrier so that such products are not directly accessible by the public but only by an employee or agent of the retailer.

(B)(1) A retailer may not ~~in any single over the counter sale~~ sell ~~more than three packages of any~~ to an individual in any single day a nonprescription product or a combination of nonprescription products containing more than 3.6 grams of ephedrine ~~or~~, pseudoephedrine ~~as the sole active ingredient or in combination with other active ingredients or any number of packages that contain a combined total of more than nine grams of ephedrine or pseudoephedrine base and shall ensure that the product is delivered directly into the custody of the purchaser~~ , or phenylpropanolamine; and a retailer may not sell to an individual in a thirty‑day period a nonprescription product or a combination of nonprescription products containing more than nine grams of ephedrine, pseudoephedrine, or phenylpropanolamine.

(2) An individual may not purchase in any single day a nonprescription product or a combination of nonprescription products containing more than 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine; and an individual may not purchase in a thirty‑day period a nonprescription product or a combination of nonprescription products containing more than nine grams of ephedrine, pseudoephedrine, or phenylpropanolamine.

(C) It is unlawful for a retailer to purchase any product containing ephedrine ~~or~~, pseudoephedrine, or phenylpropanolamine from any person or entity other than a manufacturer or a wholesale distributor registered by the United States Drug Enforcement Administration.

(D)(1) A retailer selling nonprescription products containing ephedrine ~~or~~ , pseudoephedrine, or phenylpropanolamine ~~pursuant to subsection (A)~~ shall require the purchaser to produce a government issued photo identification showing the date of birth of the person and require the purchaser to sign ~~a written or~~ an electronic log showing the date and time of the transaction, the person’s name and address, the type, issuing governmental entity, identification number, and the amount of the compound, mixture, or preparation. The retailer shall determine that the name entered in the log corresponds to the name on the identification and that the date and time entered are correct and shall enter in the log the name of the product and the quantity sold. The retailer shall ensure that the product is delivered directly into the custody of that purchaser. The log must include a notice to purchasers that entering false statements or misrepresentations in the ~~logbook~~ log may subject the purchaser to criminal penalties. ~~The retailer shall retain this log for two years after which the log may be destroyed. The log must be made available for inspection within twenty‑four hours of a request made by a local, state, or federal law enforcement officer.~~

(2) Before completing a sale of a product regulated by this section, the retailer electronically shall transmit the information entered in the log to a data collection system provided by the National Association of Drug Diversion Investigators, or a successor or similar entity. The system must collect this data in real time and generate a stop sale alert if the sale would result in a violation of subsection (B) or a federal quantity restriction, which must be assessed on the basis of sales or purchases made in any state to the extent that information is available in the data collection system. If the retailer receives a stop sale alert, the retailer must not complete the sale unless the retailer, upon notifying the purchaser the sale cannot be completed, reasonably fears bodily harm if he denies the sale due to the stop sale alert. A product regulated by this section may not be sold without being reported to the data collection system unless the system is experiencing temporary technical difficulties that prevent a retailer from reporting the information to the system, and in that case, the retailer shall enter the necessary information in a written log, which must subsequently be entered into the electronic log within three business days of each business day that the electronic log was not operational. A retailer using a written log under these circumstances is immune from liability during the time the system is temporarily disabled.

(3) ~~A log~~ Any information entered in the electronic log that is retained by a retailer, or information maintained by a retailer pursuant to subsection (J)(2), is confidential and not a public record as defined in Section 30‑4‑20(C) of the Freedom of Information Act. A retailer or an employee or agent of a retailer who in good faith releases information in a log to federal, state, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or wilful misrepresentation.

(E) Except as authorized by this section, it is unlawful for any person to possess, have under his or her control, manufacture, deliver, distribute, dispense, administer, purchase, sell, or possess with intent to distribute, any substance containing any amount of ephedrine, pseudoephedrine, or phenylpropanolamine or any of ~~its~~ their salts, optical isomers, or salts of optical isomers which have been altered from their original condition so as to be powdered, liquefied, dissolved, solvated, or crushed. This subsection does not apply to any of the substances identified within this subsection which are possessed or altered for a legitimate medical purpose as directed by a person licensed under Title 40 and authorized to prescribe legend drugs.

(F) It is unlawful for a person to enter false statements or misrepresentations on the log required pursuant to subsection (D)(1).

(G) This section preempts all local ordinances or regulations governing the retail sale or purchase of ~~over the counter~~ nonprescription products containing ephedrine ~~or~~, pseudoephedrine, or phenylpropanolamine ~~by a retailer~~ except such local ordinances or regulations that existed on or before December 31, 2004.

(H)(1) Except as otherwise provided in this section, it is unlawful for a retailer knowingly to violate subsection (A), (B)(1), (C), ~~or~~ (D)(1), or (D)(2), and it is unlawful for a person knowingly to violate subsection (B)(2), (E), or (F).

(2) A retailer convicted of a violation of subsection (A) or (B)(1) is guilty of a misdemeanor and, upon conviction for a first offense, must be fined not more than five thousand dollars and, upon conviction for a second or subsequent offense, must be fined not more than ten thousand dollars.

(3) A retailer convicted of a violation of subsection (C) is guilty of a misdemeanor and, upon conviction for a first offense, ~~is guilty of a misdemeanor and~~ must be imprisoned not more than one year or fined not more than one thousand dollars, or both~~;~~ and , upon conviction for a second or subsequent offense, ~~is guilty of a misdemeanor and~~ must be imprisoned not more than three years or fined not more than five thousand dollars, or both.

(4) A retailer convicted of a violation of subsection (D)(1), (D)(2), or (J) (2) is guilty of a misdemeanor and, upon conviction for a first offense, must be fined not more than one thousand dollars and not less than five hundred dollars. Upon conviction for a second offense, a retailer must be fined not more than five thousand dollars and not less than one thousand dollars. Upon conviction for a third or subsequent offense, a person must be fined not more than ten thousand dollars and not less than five thousand dollars.

(5) A person convicted of a violation of subsection (B)(2) or (E) is guilty of a felony and, upon conviction for a first offense, must be imprisoned not more than five years and fined not more than five thousand dollars. The court, upon approval from the solicitor, may request as part of the sentence, that the offender enter and successfully complete a drug treatment program. For a second or subsequent offense, the offender is guilty of a felony and, upon conviction, must be imprisoned not more than ten years or fined not less than ten thousand dollars.

(6) A person convicted of a violation of subsection (F), upon conviction for a first offense, is guilty of a misdemeanor and must be fined not more than one thousand dollars and, upon conviction for a second or subsequent offense, is guilty of a felony and must be fined not more than five thousand dollars.

(7) It is an affirmative defense to a violation of subsection (A), (C), or (D)(1) if a retailer provided the training, maintained records, and obtained employee and agent statements of agreement required by subsection (I) for all employees and agents at the retail location where the violation occurred and at the time the violation occurred.

(8) It is an affirmative defense to completing a sale following receipt of a stop sale alert received pursuant to subsection (D)(2) if the retailer, upon notifying the purchaser the sale cannot be completed, reasonably fears bodily harm if he denies the sale due to the stop sale alert.

(I) A retailer shall provide training on the requirements of this section to all agents and employees who are responsible for delivering the products regulated by this section into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products. A retailer shall obtain a signed, written agreement from each employee or agent that the employee or agent agrees to comply with the requirements of this section. The retailer shall maintain records demonstrating that these employees and agents have been provided this training and the documents executed by the retailer’s employees and agents agreeing to comply with this section.

(J)(1) The following are exempt from the electronic log requirements of this section but shall maintain a written log containing the information required to be entered in the electronic log, as provided for in subsection (D)(1):

(a) a retailer that only sells single dose packages of nonprescription ephedrine, pseudoephedrine, or phenylpropanolamine;

(b) a pharmacy that does not have a compatible point of sale system.

(2) A retailer who maintains a written log pursuant to this subsection shall retain the written log for two years after which the log may be destroyed. The log must be made available for inspection within twenty‑four hours of a request made by a local, state, or federal law enforcement officer.

(3) A retailer who violates the requirements of maintaining a written log as provided for in subsection (J)(2) is subject to the penalties provided for in subsection (H)(4).

(K) The sheriff or chief of police shall monitor and determine if retailers, other than licensed pharmacies, are in compliance with the provisions of this section by ensuring that a retailer:

(1) is entering all sales of a product regulated by this section in an electronic log as required by this section;

(2) if not maintaining an electronic log, is exempt as provided for in subsection (J)(1), and is continuing to maintain the written log as provided for in subsection (J);

(3) is not selling products regulated by this section.

(L) This section does not apply to:

(1) pediatric products labeled pursuant to federal regulation as primarily intended for administration to children under twelve years of age according to label instructions; and

(2) products that the Board of Pharmacy, upon application of a manufacturer, exempts because the product is formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine or its salts or precursors;

(3) a purchase of a single sales package containing not more than sixty milligrams of pseudoephedrine.

~~(K)~~(M) For purposes of this section ‘retailer’ means a retail distributor, including a pharmacy, where ephedrine, pseudoephedrine, or phenylpropanolamine products are available for sale and does not include an employee or agent of a retailer.”

SECTION 2. Chapter 3, Title 23 of the 1976 Code is amended by adding:

“CHAPTER 14

Electronic Monitoring System

Section 23‑3‑1200. (A) The State Law Enforcement Division (SLED) shall serve as the statewide, central repository for log information submitted electronically in real time to the data collection system pursuant to Section 44‑53‑398(D)(2) and transferred to SLED in order to monitor the sales and purchases of nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine. SLED shall maintain the information received from the data collection system in SLED’s electronic monitoring system and must not be charged any vendor or other fees associated with the requirements of this chapter.

(B) The data collection system upon which SLED’s electronic monitoring system is based must have the capability to:

(1) calculate state and federal sales and purchase limitations for ephedrine, pseudoephedrine, and phenylpropanolamine;

(2) match similar purchaser identification information;

(3) alert retailers of potential illegal sales and purchases;

(4) allow a retailer to override an alert of a potential illegal sale or purchase;

(5) receive ephedrine, pseudoephedrine, and phenylpropanolamine sales data from retailers in the format in which the date was submitted so that retailers are not required to use any one particular vendor’s product to comply with the requirements of this section and Section 44‑53‑398(D)(2);

(6) interface with existing and future operational systems used by pharmacies at no cost to these pharmacies.

(C) The data transmitted to the data collection system must be recorded in real time and the storage of this data must be housed by an information technology company operating under strict security standards that only may be accessed by local, state, or federal law enforcement authorized by SLED.

(D)(1) No fee may be charged to retailers for access to the data collection system to which information is required to be transmitted pursuant to Section 44‑53‑398(D)(2), and no other fee or assessment may be imposed on retailers to fund program operations.

(2) No fee may be charged to local, state, or federal law enforcement officers or entities for access to or retention, analysis, or use of information in the system concerning sales and purchases of nonprescription ephedrine, pseudoephedrine, and phenylpropanolamine that violate or potentially violate subsection 44‑53‑398(B)(1) or (2).

(E) The information in SLED’s electronic monitoring system is confidential and not a public record as defined in Section 30‑4‑20(C) of the Freedom of Information Act. SLED only shall provide access to information maintained in the monitoring system to:

(1) a local, state, or federal law enforcement official, a state attorney, or a United States attorney;

(2) a local, state, or federal official who requests access to the monitoring system for the purpose of facilitating a product recall necessary for the protection of the public health and safety; and

(3) the Board of Pharmacy for the purpose of investigating misconduct or a suspicious transaction committed by a retailer, a pharmacist, or an employee or agent of a pharmacy.

(F) For purposes of this section ‘retailer’ means a retail distributor, including a pharmacy, where ephedrine, pseudoephedrine, or phenylpropanolamine products are available for sale and does not include an employee or agent of a retailer.

(G) The division shall promulgate regulations necessary to carry out its responsibilities under this section.

(H) Nothing in this chapter prohibits SLED or any retailer from participating in other data submission, collection, or monitoring systems that monitor the sales and purchases of nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine.”

SECTION 3. Before January 1, 2011, the State Law Enforcement Division (SLED) shall enter into a memorandum of agreement with the National Association of Drug Diversion Investigators (NADDI), or a successor or other entity, to identify the roles and responsibilities of SLED and NADDI, or a successor or other entity, in carrying out the collection of sales and purchase data of ephedrine, pseudoephedrine, or phenylpropanolamine products and the transference of this information to the State Law Enforcement Division as provided for in this act. The memorandum must provide that the data and information in SLED’s electronic monitoring system is property of the State and that NADDI will provide SLED with that data and information at least four times a year in a format agreed to by SLED and NADDI and that is consistent with the most recent standards adopted by the American Society for Automation in Pharmacy (ASAP), as well as the most recent standards adopted by the National Information Exchange Model (NIEM).

SECTION 4. The electronic logbook, central data collection system, and the State Law Enforcement Division electronic monitoring system required pursuant to Section 44‑53‑398 of the 1976 Code, as amended in Section 1 of this act, and Section 23‑3‑1200, as added by Section 2 of this act, must be implemented before January 1, 2011, and take effect upon this implementation.

SECTION 5. Except as otherwise provided for in this act, this act takes effect July 1, 2010.

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