



Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 334

129th General Assembly
(As Reported by H. Health & Aging)

Reps. Johnson and Bubb, Amstutz, Barnes, Buchy, Butler, Fende, Goodwin, Gonzales, Kozlowski, O'Brien, Peterson, Rosenberger, Stebelton, Uecker, Wachtmann, Yuko, Antonio, Duffey, Garland, Hackett

BILL SUMMARY

- Beginning January 1, 2013, generally requires that retailers and terminal distributors of dangerous drugs participate in electronically tracking over-the-counter pseudoephedrine and ephedrine product sales through the National Precursor Log Exchange.
- Exempts a retailer or terminal distributor from required participation in the Exchange if there is any charge for using the Exchange, there is any fee from the Exchange related to funding its operation or maintenance, or the equipment or software needed to use the Exchange is not technologically capable of interfacing with operational systems used by the retailer or terminal distributor.
- Authorizes the Attorney General to enter into a contract or memorandum of understanding governing access to the Exchange with the National Association of Drug Diversion Investigators and any individual administering the Exchange.
- Regulates over-the-counter sales of ephedrine in the same manner that over-the-counter sales of pseudoephedrine products are currently regulated.
- Imposes daily limits on the amount of pseudoephedrine products and ephedrine products that an individual may purchase or receive without a prescription.
- Grants qualified immunity from civil liability to retailers and terminal distributors regarding over-the-counter pseudoephedrine product and ephedrine product sales.
- Makes all products containing pseudoephedrine that are purchased or obtained without a prescription subject to the restrictions that apply under existing law.

CONTENT AND OPERATION

Electronic tracking of pseudoephedrine and ephedrine product sales

The bill generally requires over-the-counter pseudoephedrine product and ephedrine product sales to be electronically tracked through a national exchange known as the National Precursor Log Exchange.¹ According to the Exchange's web site, the Exchange is "a unique public/private partnership offering a real-time electronic methamphetamine precursor tracking service, free of charge, to law enforcement and state governments." The Exchange is provided by the National Association of Drug Diversion Investigators, but is sponsored and paid for entirely by the over-the-counter medicine manufacturers who are members of the Consumer Healthcare Products Association.²

Beginning January 1, 2013, the bill requires retailers and terminal distributors of dangerous drugs to submit the following information to the Exchange regarding each sale of pseudoephedrine product and ephedrine product that is not made pursuant to a valid prescription:

- (1) The purchaser's name and address;
- (2) The name and quantity of the product purchased;
- (3) The date and time of the purchase;
- (4) The government-issued identification card used when making the purchase, the identification number (if any) on the identification, and the agency that issued the identification.³

Exemption from required participation in Exchange

The bill exempts a retailer or terminal distributor from required participation in the Exchange if one or more of the following apply:

- (1) There is any charge for using the Exchange, including a charge for obtaining access to, submitting information to, or receiving a stop-sale alert from the Exchange.

¹ R.C. 3715.052.

² National Precursor Log Exchange, *Frequently Asked Questions* (last visited April 17, 2012), available at <<http://www.nplexservice.com/FAQ.html>>.

³ R.C. 3715.052(A)(1).

(2) There is any fee from the Exchange related to funding its operation or maintenance.

(3) The equipment or software needed to use the Exchange is not technologically capable of interfacing with existing and future operational systems used by the retailer or terminal distributor.⁴

Stop-sale alerts and equipment malfunction

Beginning January 1, 2013, a retailer or terminal distributor is not to complete a pseudoephedrine or ephedrine product sale if the Exchange generates a stop-sale alert. However, a retailer or terminal distributor is permitted to complete the sale even though the Exchange has generated a stop-sale alert if the retailer or terminal distributor has a reasonable fear of imminent bodily harm should the sale not be completed. To accommodate such circumstances, the retailer or terminal distributor must ensure that the override function of the Exchange has been enabled.⁵

A retailer or terminal distributor that is unable to submit information to the Exchange as required by the bill due to experiencing mechanical or electronic failure of the equipment used to submit the information or due to the temporary inability of the retailer or terminal distributor to obtain Internet service must maintain a written or electronic record of the information and complete the information submission as soon as practicable after the mechanical or electronic failure has been rectified or Internet service has been restored.⁶ Under these circumstances, if a stop-sale alert is generated after the information submission is completed, the bill specifies that the daily or monthly limits on the amount of over-the-counter pseudoephedrine and ephedrine products that may be purchased or provided to an individual after the mechanical or electronic failure has been rectified or Internet service has been restored if a stop-sale alert is generated after completing the information submission have not been violated (see "**Purchase limits on pseudoephedrine and ephedrine products**," below).⁷

Criminal prohibitions

The bill prohibits a retailer or terminal distributor from failing to comply with the information submission requirements regarding the Exchange that are described above. A violation of this prohibition is the offense of "failing to submit information to

⁴ R.C. 3715.053.

⁵ R.C. 3715.05(B).

⁶ R.C. 3715.052(A)(2).

⁷ R.C. 2925.56(A).

the National Precursor Log Exchange," a misdemeanor for which the offender is to be fined not more than \$1,000 per violation.⁸

A retailer or terminal distributor is also prohibited from failing to comply with the bill's stop-sale provisions. A violation of this prohibition is the offense of "improper sale of a pseudoephedrine product or ephedrine product," a second degree misdemeanor.⁹

Definitions

The bill defines the "National Precursor Log Exchange" as the electronic system for tracking sales of pseudoephedrine products and ephedrine products on a national basis that is administered by the National Association of Drug Diversion Investigators or a successor organization. A "stop-sale alert" is defined as a notification sent from the Exchange to a retailer or terminal distributor of dangerous drugs indicating that the completion of a sale of a pseudoephedrine product or ephedrine product would result in violating the daily or monthly limits on pseudoephedrine or ephedrine products that may be sold to an individual under Ohio or federal law.¹⁰

Law enforcement access to Exchange

The bill authorizes the Attorney General to enter into a contract or memorandum of understanding with the National Association of Drug Diversion Investigators or its successor organization and, if the Attorney General determines it to be appropriate, a person to whom the authority to administer the National Precursor Log Exchange has been delegated. If the Attorney General enters into such a contract or memorandum, it is to govern the Attorney General's access to and use of information from the Exchange and the responsibilities of each party to the contract or memorandum relative to such access and use.¹¹

In furtherance of the purpose of the contract or memorandum of understanding, the bill requires the contract or memorandum to include terms that do all of the following:

(1) Authorize the Attorney General to obtain real-time access to information from the Exchange;

⁸ R.C. 2925.56(D) and (H).

⁹ R.C. 2925.56(C) and (G).

¹⁰ R.C. 3715.05(A)(6) and (13).

¹¹ R.C. 109.88(B).

(2) Authorize the Attorney General to receive a weekly report regarding pseudoephedrine product and ephedrine product sales transactions made in Ohio as monitored by the Exchange, the specific content of which is to be identified in the contract or memorandum;

(3) Authorize the Attorney General to disseminate any information listed above to other state and local law enforcement officers as the Attorney General determines appropriate;

(4) Specify that neither the Attorney General nor any local or state law enforcement officer is to be charged a fee for access to or use of the Exchange or information from the Exchange authorized by the bill or the contract or memorandum;

(5) Require all parties to the contract or memorandum to comply with federal and state laws governing the confidentiality of patient-specific information;

(6) Specify how the contract or memorandum may be amended or revoked.¹²

Qualified immunity from civil liability

The bill provides that a retailer or terminal distributor of dangerous drugs is not liable in damages in a civil action for injury, death, or loss to person or property resulting from any act or omission in carrying out the retailer's or terminal distributor's duties regarding over-the-counter pseudoephedrine product and ephedrine product sales, unless the act or omission is negligent or reckless or constitutes willful or wanton misconduct.¹³

Restrictions on over-the-counter sales of ephedrine products

Consistent with federal law, the bill regulates over-the-counter sales of ephedrine products in the same manner that over-the-counter sales of pseudoephedrine products are regulated under current Ohio law.¹⁴ The federal Combat Methamphetamine Epidemic Act of 2005 (P.L. 109-177) was enacted to reduce the illicit production of methamphetamine by requiring that retail sales of pseudoephedrine products and ephedrine products be regulated. Current Ohio law restricts over-the-counter sales only with respect to pseudoephedrine products.

¹² R.C. 109.88(C).

¹³ R.C. 3715.054.

¹⁴ R.C. 2925.55 and 2925.56.

Specifically, the bill does all of the following with respect to over-the-counter sales of ephedrine products:

- Imposes daily and monthly limits on the amount of over-the-counter ephedrine products that may be purchased or received by an individual (see "**Purchase limits on pseudoephedrine and ephedrine products,**" below).
- Generally prohibits a retailer or terminal distributor of dangerous drugs from knowingly selling or otherwise providing to an individual an amount of ephedrine product that exceeds the daily or monthly limits.
- Requires retailers and terminal distributors to segregate ephedrine products from other merchandise so that no member of the public may purchase or procure ephedrine products without the direct assistance of a pharmacist or other authorized employee of the retailer or terminal distributor.
- Requires retailers and terminal distributors to maintain a log book of all over-the-counter ephedrine product purchases made.
- Requires each individual who purchases or receives an over-the-counter ephedrine product to sign and print their name in the log book and to present a government-issued identification card to the retailer or terminal distributor.
- Generally prohibits an individual under age 18 from knowingly purchasing or receiving an ephedrine product unless dispensed by a pharmacist pursuant to a valid prescription.
- Generally prohibits a retailer or terminal distributor from selling or otherwise providing an ephedrine product to an individual under age 18 unless dispensed by a pharmacist pursuant to a valid prescription.¹⁵

Definitions

The bill defines "ephedrine" as any material, compound, mixture, or preparation that contains any quantity of ephedrine, any of its salts, optical isomers, or salts of

¹⁵ R.C. 2925.55, 2925.56, 3715.05, and 3715.051.

optical isomers. "Ephedrine product" is defined as any consumer product that contains ephedrine.¹⁶

Purchase limits on pseudoephedrine and ephedrine products

Consistent with federal law, the bill imposes daily limits on the amount of pseudoephedrine products and ephedrine products that an individual may purchase or receive without a prescription. Currently, Ohio law limits to nine grams the amount of pseudoephedrine product that may be purchased or received without a prescription in a period of 30 consecutive days.¹⁷

The federal Combat Methamphetamine Epidemic Act of 2005 limits the amount of pseudoephedrine products or ephedrine products an individual may purchase in a single transaction to not more than 3.6 grams per day. The bill applies the same daily limit to state law.

The bill specifies that the daily and monthly limits on the purchase or receipt of over-the-counter pseudoephedrine products or ephedrine products apply to the total amount of base pseudoephedrine or base ephedrine in the product, and not the product's overall weight.¹⁸

Restrictions on retailers and terminal distributors

The bill imposes additional requirements on retailers and terminal distributors of dangerous drugs regarding the sale or provision of over-the-counter pseudoephedrine products and ephedrine products. Currently, a retailer or terminal distributor is required to do all of the following: (1) segregate pseudoephedrine products from other merchandise, (2) determine that an individual seeking to purchase or receive a pseudoephedrine product is at least age 18, (3) make a reasonable attempt to ensure that the individual does not purchase or receive more than the monthly limit, and (4) maintain a log book of all over-the-counter pseudoephedrine product purchases.¹⁹

The bill adds that retailers and terminal distributors must do the following: (1) make a reasonable attempt to ensure that an individual does not purchase or receive more than the daily and monthly product limits *by using any information available, including information from the National Precursor Log Exchange if the information is*

¹⁶ R.C. 2925.55(A)(7) and (8).

¹⁷ R.C. 2925.55(B).

¹⁸ R.C. 2925.55(B).

¹⁹ R.C. 3715.05(B).

accessible, and (2) if required to participate in the Exchange, submit information from the log book to the Exchange.²⁰

Regulation of pseudoephedrine product sales

The bill makes all products containing pseudoephedrine that are purchased or obtained without a prescription subject to the restrictions that apply under existing law. Under current law, both of the following are excluded from the definition of "pseudoephedrine product": (1) a consumer product containing pseudoephedrine that is in a liquid, liquid capsule, or gel capsule form and (2) a consumer product primarily intended for administration to children under age 12, in solid dosage form, including chewable tablets, when individual dosage units do not exceed 15 milligrams of pseudoephedrine.²¹ This means that these products are not subject to current law's restrictions governing over-the-counter pseudoephedrine sales. The bill removes the exclusions and applies the restrictions to all over-the counter sales of products containing pseudoephedrine.

Transaction scans

Current law authorizes a seller or agent to perform a transaction scan by using a transaction scan device to check the validity of an individual's driver's license or government-issued identification card as a condition of selling, giving away, or distributing a pseudoephedrine product. A seller or agent is generally prohibited from electronically or mechanically recording or maintaining any information derived from a transaction scan. The prohibition does not currently apply to the individual's name and date of birth listed on the driver's license or identification card and to the expiration date and identification number of the license or card.

The bill adds all of the following to the items excluded from the prohibition against recording information derived from a transaction scan performed in relation to over-the-counter pseudoephedrine sales and, under the bill, ephedrine product sales: (1) the information required by the bill to be submitted to the National Precursor Log Exchange for each over-the-counter sale of a pseudoephedrine or ephedrine product, (2) an individual's address, and (3) the issuing agency of the individual's driver's license or identification card.²²

²⁰ R.C. 3715.05(B)(2) and (4).

²¹ R.C. 2925.55(A)(4).

²² R.C. 2925.57(D).

Sales permitted by prescription

Under the bill, the restrictions that apply to over-the-counter sales of pseudoephedrine products and ephedrine products generally do not apply if the product is dispensed by a pharmacist pursuant to a valid prescription issued by the following licensed health professionals authorized to prescribe drugs: (1) physicians, (2) dentists, (3) advanced practice nurses holding certificates to prescribe, (4) physician assistants holding certificates to prescribe, and (5) veterinarians.²³

Current law authorizing pseudoephedrine sales pursuant to prescriptions does not include references to the prescriptive authority of physician assistants, which was implemented after the pseudoephedrine law was enacted.²⁴

HISTORY

ACTION	DATE
Introduced	09-27-11
Reported, H. Health & Aging	03-28-12

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²³ R.C. 2925.55 and 2925.56.

²⁴ Am. Sub. S.B. 53 and Sub. S.B. 154 of the 126th General Assembly, both effective May 17, 2006.

