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# SENATE BILL No. 394

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## DIGEST OF INTRODUCED BILL

**Citations Affected:** IC 4-6-2-12; IC 25-26-13-4; IC 35-48-4.

**Synopsis:** Sale and tracking of ephedrine and pseudoephedrine. Requires the attorney general to enter into a memorandum of understanding with an entity to provide a pseudoephedrine (PSE) tracking system that meets certain standards. Requires a retailer to electronically transmit certain information concerning the sale of ephedrine and PSE to a statewide PSE tracking system. Requires the board of pharmacy to adopt certain rules concerning a pharmacy that does not comply with PSE tracking requirements. Provides that a retailer must begin entering data into the PSE tracking system not later than 180 days after the attorney general enters into the memorandum of understanding. Provides that an exemption to the tracking requirement for persons who do not sell exclusively to walk in customers applies only to persons who do not sell to any walk in customers. Requires the state police to report to the legislative council concerning the effectiveness of PSE tracking in reducing the illicit production of methamphetamine.

**Effective:** January 1, 2012.

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January 11, 2011, read first time and referred to Committee on Health and Provider Services.

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First Regular Session 117th General Assembly (2011)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2010 Regular Session of the General Assembly.

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## SENATE BILL No. 394



A BILL FOR AN ACT to amend the Indiana Code concerning criminal law and procedure.

*Be it enacted by the General Assembly of the State of Indiana:*

1 SECTION 1. IC 4-6-2-12 IS ADDED TO THE INDIANA CODE  
2 AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE  
3 JANUARY 1, 2012]: **Sec. 12. The attorney general shall enter into  
4 a memorandum of understanding with an entity to implement an  
5 electronic system to track the sale of ephedrine and  
6 pseudoephedrine as required by IC 35-48-4-14.9.**

7 SECTION 2. IC 25-26-13-4, AS AMENDED BY P.L.182-2009(ss),  
8 SECTION 371, IS AMENDED TO READ AS FOLLOWS  
9 [EFFECTIVE JANUARY 1, 2012]: Sec. 4. (a) The board may:

- 10 (1) promulgate rules and regulations under IC 4-22-2 for  
11 implementing and enforcing this chapter;
- 12 (2) establish requirements and tests to determine the moral,  
13 physical, intellectual, educational, scientific, technical, and  
14 professional qualifications for applicants for pharmacists'  
15 licenses;
- 16 (3) refuse to issue, deny, suspend, or revoke a license or permit or  
17 place on probation or fine any licensee or permittee under this



1 chapter;  
 2 (4) regulate the sale of drugs and devices in the state of Indiana;  
 3 (5) impound, embargo, confiscate, or otherwise prevent from  
 4 disposition any drugs, medicines, chemicals, poisons, or devices  
 5 which by inspection are deemed unfit for use or would be  
 6 dangerous to the health and welfare of the citizens of the state of  
 7 Indiana; the board shall follow those embargo procedures found  
 8 in IC 16-42-1-18 through IC 16-42-1-31, and persons may not  
 9 refuse to permit or otherwise prevent members of the board or  
 10 their representatives from entering such places and making such  
 11 inspections;  
 12 (6) prescribe minimum standards with respect to physical  
 13 characteristics of pharmacies, as may be necessary to the  
 14 maintenance of professional surroundings and to the protection of  
 15 the safety and welfare of the public;  
 16 (7) subject to IC 25-1-7, investigate complaints, subpoena  
 17 witnesses, schedule and conduct hearings on behalf of the public  
 18 interest on any matter under the jurisdiction of the board;  
 19 (8) prescribe the time, place, method, manner, scope, and subjects  
 20 of licensing examinations, which shall be given at least twice  
 21 annually; and  
 22 (9) perform such other duties and functions and exercise such  
 23 other powers as may be necessary to implement and enforce this  
 24 chapter.  
 25 (b) The board shall adopt rules under IC 4-22-2 for the following:  
 26 (1) Establishing standards for the competent practice of  
 27 pharmacy.  
 28 (2) Establishing the standards for a pharmacist to counsel  
 29 individuals regarding the proper use of drugs.  
 30 (3) Establishing standards and procedures before January 1, 2006,  
 31 to ensure that a pharmacist:  
 32 (A) has entered into a contract that accepts the return of  
 33 expired drugs with; or  
 34 (B) is subject to a policy that accepts the return of expired  
 35 drugs of;  
 36 a wholesaler, manufacturer, or agent of a wholesaler or  
 37 manufacturer concerning the return by the pharmacist to the  
 38 wholesaler, the manufacturer, or the agent of expired legend drugs  
 39 or controlled drugs. In determining the standards and procedures,  
 40 the board may not interfere with negotiated terms related to cost,  
 41 expenses, or reimbursement charges contained in contracts  
 42 between parties, but may consider what is a reasonable quantity

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1 of a drug to be purchased by a pharmacy. The standards and  
2 procedures do not apply to vaccines that prevent influenza,  
3 medicine used for the treatment of malignant hyperthermia, and  
4 other drugs determined by the board to not be subject to a return  
5 policy. An agent of a wholesaler or manufacturer must be  
6 appointed in writing and have policies, personnel, and facilities  
7 to handle properly returns of expired legend drugs and controlled  
8 substances.

9 (c) The board may grant or deny a temporary variance to a rule it  
10 has adopted if:

- 11 (1) the board has adopted rules which set forth the procedures and
- 12 standards governing the grant or denial of a temporary variance;
- 13 and
- 14 (2) the board sets forth in writing the reasons for a grant or denial
- 15 of a temporary variance.

16 (d) The board shall adopt rules and procedures, in consultation with  
17 the medical licensing board, concerning the electronic transmission of  
18 prescriptions. The rules adopted under this subsection must address the  
19 following:

- 20 (1) Privacy protection for the practitioner and the practitioner's
- 21 patient.
- 22 (2) Security of the electronic transmission.
- 23 (3) A process for approving electronic data intermediaries for the
- 24 electronic transmission of prescriptions.
- 25 (4) Use of a practitioner's United States Drug Enforcement
- 26 Agency registration number.
- 27 (5) Protection of the practitioner from identity theft or fraudulent
- 28 use of the practitioner's prescribing authority.

29 (e) The governor may direct the board to develop:

- 30 (1) a prescription drug program that includes the establishment of
- 31 criteria to eliminate or significantly reduce prescription fraud; and
- 32 (2) a standard format for an official tamper resistant prescription
- 33 drug form for prescriptions (as defined in IC 16-42-19-7(1)).

34 The board may adopt rules under IC 4-22-2 necessary to implement  
35 this subsection.

36 (f) The standard format for a prescription drug form described in  
37 subsection (e)(2) must include the following:

- 38 (1) A counterfeit protection bar code with human readable
- 39 representation of the data in the bar code.
- 40 (2) A thermochromic mark on the front and the back of the
- 41 prescription that:

42 (A) is at least one-fourth (1/4) of one (1) inch in height and

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1 width; and  
 2 (B) changes from blue to clear when exposed to heat.  
 3 (g) The board may contract with a supplier to implement and  
 4 manage the prescription drug program described in subsection (e). The  
 5 supplier must:  
 6 (1) have been audited by a third party auditor using the SAS 70  
 7 audit or an equivalent audit for at least the three (3) previous  
 8 years; and  
 9 (2) be audited by a third party auditor using the SAS 70 audit or  
 10 an equivalent audit throughout the duration of the contract;  
 11 in order to be considered to implement and manage the program.  
 12 **(h) The board shall adopt rules and procedures regarding a**  
 13 **pharmacist or pharmacy that violates IC 35-48-4-14.8.**  
 14 SECTION 3. IC 35-48-4-14.7, AS AMENDED BY P.L.97-2010,  
 15 SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
 16 JANUARY 1, 2012]: Sec. 14.7. (a) This section does not apply to the  
 17 following:  
 18 (1) Ephedrine or pseudoephedrine dispensed pursuant to a  
 19 prescription.  
 20 (2) The sale of a drug containing ephedrine or pseudoephedrine  
 21 to a licensed health care provider, pharmacist, retail distributor,  
 22 wholesaler, manufacturer, or an agent of any of these persons if  
 23 the sale occurs in the regular course of lawful business activities.  
 24 However, a retail distributor, wholesaler, or manufacturer is  
 25 required to report a suspicious order to the state police department  
 26 in accordance with subsection (f).  
 27 (3) The sale of a drug containing ephedrine or pseudoephedrine  
 28 by a person who does not sell ~~exclusively~~ to walk-in customers.  
 29 ~~for the personal use of the walk-in customers.~~ However, if the  
 30 person described in this subdivision is a retail distributor,  
 31 wholesaler, or manufacturer, the person is required to report a  
 32 suspicious order to the state police department in accordance with  
 33 subsection (f).  
 34 (b) The following definitions apply throughout this section:  
 35 (1) "Constant video monitoring" means the surveillance by an  
 36 automated camera that:  
 37 (A) records at least one (1) photograph or digital image every  
 38 ten (10) seconds;  
 39 (B) retains a photograph or digital image for at least  
 40 seventy-two (72) hours;  
 41 (C) has sufficient resolution and magnification to permit the  
 42 identification of a person in the area under surveillance; and

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1 (D) stores a recorded photograph or digital image at a location  
 2 that is immediately accessible to a law enforcement officer.  
 3 (2) "Convenience package" means a package that contains a drug  
 4 having as an active ingredient not more than one hundred twenty  
 5 (120) milligrams of ephedrine or pseudoephedrine, or both.  
 6 (3) "Ephedrine" means pure or adulterated ephedrine.  
 7 (4) "Pseudoephedrine" means pure or adulterated  
 8 pseudoephedrine.  
 9 (5) "Suspicious order" means a sale or transfer of a drug  
 10 containing ephedrine or pseudoephedrine if the sale or transfer:  
 11 (A) is a sale or transfer that the retail distributor, wholesaler,  
 12 or manufacturer is required to report to the United States Drug  
 13 Enforcement Administration;  
 14 (B) appears suspicious to the retail distributor, wholesaler, or  
 15 manufacturer in light of the recommendations contained in  
 16 Appendix A of the report to the United States attorney general  
 17 by the suspicious orders task force under the federal  
 18 Comprehensive Methamphetamine Control Act of 1996; or  
 19 (C) is for cash or a money order in a total amount of at least  
 20 two hundred dollars (\$200).  
 21 (6) "Unusual theft" means the theft or unexplained disappearance  
 22 from a particular retail store of drugs containing ten (10) grams or  
 23 more of ephedrine, pseudoephedrine, or both in a twenty-four (24)  
 24 hour period.  
 25 (c) This subsection does not apply to a convenience package. A  
 26 person may sell a drug that contains the active ingredient of ephedrine,  
 27 pseudoephedrine, or both only if the person complies with the  
 28 following conditions:  
 29 (1) The person does not sell the drug to a person less than  
 30 eighteen (18) years of age.  
 31 (2) The person does not sell drugs containing more than three and  
 32 six-tenths (3.6) grams of ephedrine or pseudoephedrine, or both,  
 33 to one (1) individual on one (1) day, or nine (9) grams of  
 34 ephedrine or pseudoephedrine, or both, to one (1) individual in a  
 35 thirty (30) day period.  
 36 (3) The person requires:  
 37 (A) the purchaser to produce a state or federal identification  
 38 card;  
 39 (B) the purchaser to complete a paper or an electronic log in  
 40 a format approved by the state police department with the  
 41 purchaser's name, address, and driver's license or other  
 42 identification number; ~~and~~

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(C) the clerk who is conducting the transaction to initial or electronically record the clerk's identification on the log; **and (D) the clerk who is conducting the transaction to electronically transmit information relating to the sale of ephedrine or pseudoephedrine to the PSE tracking system in accordance with section 14.8 of this chapter.**

Records from the completion of a log must be retained for at least two (2) years. A law enforcement officer has the right to inspect and copy a log or the records from the completion of a log in accordance with state and federal law. A person may not sell or release a log or the records from the completion of a log for a commercial purpose. The Indiana criminal justice institute may obtain information concerning a log or the records from the completion of a log from a law enforcement officer if the information may not be used to identify a specific individual and is used only for statistical purposes. A retailer who in good faith releases information maintained under this subsection is immune from civil liability unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

- (4) The person stores the drug:
  - (A) behind a counter in an area inaccessible to a customer or in a locked display case that makes the drug unavailable to a customer without the assistance of an employee; or
  - (B) directly in front of the pharmacy counter in the direct line of sight of an employee at the pharmacy counter, in an area under constant video monitoring, if the drug is sold in a retail establishment that:
    - (i) is a pharmacy; or
    - (ii) contains a pharmacy that is open for business.
- (5) The person posts a sign warning that:
  - (A) it is a criminal offense for a person to purchase drugs containing more than nine (9) grams of ephedrine or pseudoephedrine, or both, in a thirty (30) day period;
  - (B) it is a criminal offense for a person to purchase drugs containing more than three and six-tenths (3.6) grams of ephedrine or pseudoephedrine, or both, on one (1) day; and
  - (C) depending on the amount of ephedrine or pseudoephedrine contained in the drug, purchasing more than one (1) package of drugs containing ephedrine or pseudoephedrine on one (1) day may be a crime.

The warning sign must list maximum amounts of ephedrine or pseudoephedrine that may be purchased in both grams and

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milligrams.

(d) A person may not purchase drugs containing more than three and six-tenths (3.6) grams of ephedrine or pseudoephedrine, or both, on one (1) day, or more than nine (9) grams of ephedrine or pseudoephedrine, or both, in a thirty (30) day period.

(e) This subsection only applies to convenience packages. A person may not sell drugs containing more than one hundred twenty (120) milligrams of ephedrine or pseudoephedrine, or both in any one (1) transaction if the drugs are sold in convenience packages. A person who sells convenience packages must secure the convenience packages in at least one (1) of the following ways:

- (1) The convenience package must be stored not more than thirty (30) feet away from a checkout station or counter and must be in the direct line of sight of an employee at the checkout station or counter.
- (2) The convenience package must be protected by a reliable anti-theft device that uses package tags and detection alarms designed to prevent theft.
- (3) The convenience package must be stored in restricted access shelving that permits a purchaser to remove not more than one (1) package every fifteen (15) seconds.
- (4) The convenience package must be stored in an area that is under constant video monitoring, and a sign placed near the convenience package must warn that the area is under constant video monitoring.

(f) A retail distributor, wholesaler, or manufacturer shall report a suspicious order to the state police department in writing.

(g) Not later than three (3) days after the discovery of an unusual theft at a particular retail store, the retailer shall report the unusual theft to the state police department in writing. If three (3) unusual thefts occur in a thirty (30) day period at a particular retail store, the retailer shall, for at least one hundred eighty (180) days after the date of the last unusual theft, locate all drugs containing ephedrine or pseudoephedrine at that particular retail store behind a counter in an area inaccessible to a customer or in a locked display case that makes the drug unavailable to customers without the assistance of an employee.

(h) A unit (as defined in IC 36-1-2-23) may not adopt an ordinance after February 1, 2005, that is more stringent than this section.

(i) A person who knowingly or intentionally violates this section commits a Class C misdemeanor. However, the offense is a Class A misdemeanor if the person has a prior unrelated conviction under this section.

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1 (j) Before June 30, ~~2007~~, **2014**, the state police department shall  
2 submit a report to the legislative council detailing the effectiveness of  
3 this section in reducing the illicit production of methamphetamine. The  
4 report must describe the number of arrests or convictions that are  
5 attributable to the identification and logging requirements contained in  
6 this section, and must include recommendations for future action. The  
7 report must be in an electronic format under IC 5-14-6.

8 SECTION 4. IC 35-48-4-14.8 IS ADDED TO THE INDIANA  
9 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
10 [EFFECTIVE JANUARY 1, 2012]: **Sec. 14.8. (a) This section does**  
11 **not apply to the following:**

12 (1) **Ephedrine or pseudoephedrine dispensed under a**  
13 **prescription.**

14 (2) **The sale of a drug containing ephedrine or**  
15 **pseudoephedrine to a licensed health care provider,**  
16 **pharmacist, retail distributor, wholesaler, or manufacturer,**  
17 **or an agent of any of these persons if the sale occurs in the**  
18 **regular course of lawful business activities. However, a retail**  
19 **distributor, wholesaler, or manufacturer shall report a**  
20 **suspicious order to the state police department under section**  
21 **14.7(f) of this chapter.**

22 (3) **The sale of a drug containing ephedrine or**  
23 **pseudoephedrine by a person who does not sell to walk-in**  
24 **customers.**

25 (b) **As used in this section, "PSE tracking system" means a**  
26 **statewide electronic system to track the sale of ephedrine and**  
27 **pseudoephedrine.**

28 (c) **As used in this section, "stop sale alert" means a notification**  
29 **from the PSE tracking system that the completion of a sale would**  
30 **result in the purchaser violating state or federal quantity limits**  
31 **relating to the sale or purchase of ephedrine or pseudoephedrine.**

32 (d) **A person who sells ephedrine or pseudoephedrine shall enter**  
33 **the following information into the PSE tracking system before**  
34 **completing the sale:**

35 (1) **The name of the purchaser.**

36 (2) **The address of the purchaser.**

37 (3) **The name of the product containing ephedrine or**  
38 **pseudoephedrine that is being purchased.**

39 (4) **The amount of the product containing ephedrine or**  
40 **pseudoephedrine that is being purchased.**

41 (e) **The PSE tracking system must issue a stop sale alert if the**  
42 **completion of a sale would result in the purchaser violating state**

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or federal quantity limits relating to the sale or purchase of ephedrine or pseudoephedrine. A person may not complete a transaction if the PSE tracking system issues a stop sale alert for the transaction.

(f) A person shall begin entering data into the PSE tracking system not later than one hundred eighty (180) days after the attorney general enters into a memorandum of understanding described in section 14.9 of this chapter.

SECTION 5. IC 35-48-4-14.9 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2012]: **Sec. 14.9. (a) As used in this section, "PSE tracking system" has the meaning set forth in section 14.8 of this chapter.**

(b) As used in this section, "stop sale alert" has the meaning set forth in section 14.8 of this chapter.

(c) The attorney general shall enter into a memorandum of understanding with an entity to implement the PSE tracking system. The memorandum of understanding must establish the roles and responsibilities of the attorney general and the entity.

(d) The memorandum of understanding must provide:

(1) that:

(A) retailers; and

(B) law enforcement agencies;

may not be required to pay a fee for access to the system;

(2) that for investigative purposes, a law enforcement officer is entitled to access to all information on the PSE tracking system;

(3) that sales transaction data will be housed by an information technology company operating under strict security standards;

(4) that information on the PSE tracking system will be accessible only to authorized law enforcement officers;

(5) that the entity will forward the data, including data concerning a transaction that could not be completed due to the issuance of a stop sale alert, to the state police department weekly;

(6) that the entity may not modify sales transaction data that is provided to law enforcement; and

(7) that the entity will ensure that the PSE tracking system will have stop sale capability throughout Indiana as set forth in section 14.8 of this chapter.

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