



Reprinted  
February 25, 2010

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**ENGROSSED**  
**HOUSE BILL No. 1320**

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DIGEST OF HB 1320 (Updated February 24, 2010 4:50 pm - DI 77)

**Citations Affected:** IC 4-6; IC 25-26; IC 35-48; noncode.

**Synopsis:** Ephedrine and medication substitution. Allows the state police department to enter into a contract with a vendor before July 1, 2010 to provide a pseudoephedrine (PSE) tracking system that meets certain standards. Prohibits a retailer from selling, and a purchaser from purchasing, more than 3.6 grams of ephedrine or pseudoephedrine on one day, or nine grams of ephedrine or pseudoephedrine in a 30 day period. Requires a retailer to electronically transmit certain information concerning the sale of ephedrine and PSE to a statewide PSE tracking system. Specifies that the board of pharmacy (board) shall adopt certain rules concerning a pharmacy that does not comply with PSE tracking requirements. Provides that, effective January 1, 2011, a retailer must begin entering data into the PSE tracking system not later than 180 days after the state police department enters into a contract. Requires  
(Continued next page)

**Effective:** Upon passage; July 1, 2010; January 1, 2011.

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**Harris, Brown C, Brown T**

(SENATE SPONSORS — MILLER, RANDOLPH, BREAUX, SKINNER)

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January 13, 2010, read first time and referred to Committee on Public Health.  
January 26, 2010, amended, reported — Do Pass.  
February 1, 2010, read second time, ordered engrossed.  
February 2, 2010, engrossed. Read third time, passed. Yeas 97, nays 0.

SENATE ACTION

February 8, 2010, read first time and referred to Committee on Health and Provider Services.  
February 18, 2010, amended, reported favorably — Do Pass.  
February 24, 2010, read second time, amended, ordered engrossed.

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a retailer that sells drugs containing ephedrine or pseudoephedrine to: (1) post a sign warning that it is a criminal offense for a person to purchase drugs containing more than certain quantities of ephedrine or pseudoephedrine; and (2) require the clerk who is conducting the transaction to personally advise a purchaser that it is a criminal offense for a person to purchase drugs containing more than certain quantities of ephedrine or pseudoephedrine. Provides that, upon request, the clerk who conducts the transaction shall advise the purchaser how many grams of ephedrine or pseudoephedrine are contained in the drugs being purchased. Provides that an exemption to the tracking requirement for persons who do not sell exclusively to walk-in customers will apply 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. Requires the board to report concerning drug substitution and the implementation of the PSE tracking system to the health finance commission. Requires the health finance commission to study the implementation and effectiveness of the PSE tracking system during the 2012 interim.

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Second Regular Session 116th General Assembly (2010)

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 2009 Regular and Special Sessions of the General Assembly.

## ENGROSSED HOUSE BILL No. 1320

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A BILL FOR AN ACT to amend the Indiana Code concerning health.

*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 JULY  
3 1, 2010]: **Sec. 12. The attorney general shall enter into a**  
4 **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 JULY 1, 2010]: 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

EH 1320—LS 7080/DI 77+



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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.186-2007,  
 15 SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
 16 JANUARY 1, 2011]: 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 ~~(3)~~  
32 **and six-tenths (3.6)** grams of ephedrine or pseudoephedrine, or  
33 both, ~~in one (1) transaction; to one (1) individual on one (1) day,~~  
34 **or nine (9) grams of ephedrine or pseudoephedrine, or both,**  
35 **to one (1) individual in a 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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1 (C) the clerk who is conducting the transaction to ~~initial or~~  
 2 electronically record the clerk's identification on the log; and  
 3 **(D) the clerk who is conducting the transaction to**  
 4 **electronically transmit information relating to the sale of**  
 5 **ephedrine or pseudoephedrine to the PSE tracking system**  
 6 **in accordance with section 14.8 of this chapter.**

7 Records from the completion of a log must be retained for at least  
 8 two (2) years. A law enforcement officer has the right to inspect  
 9 and copy a log or the records from the completion of a log in  
 10 accordance with state and federal law. A person may not sell or  
 11 release a log or the records from the completion of a log for a  
 12 commercial purpose. The Indiana criminal justice institute may  
 13 obtain information concerning a log or the records from the  
 14 completion of a log from a law enforcement officer if the  
 15 information may not be used to identify a specific individual and  
 16 is used only for statistical purposes. A retailer who in good faith  
 17 releases information maintained under this subsection is immune  
 18 from civil liability unless the release constitutes gross negligence  
 19 or intentional, wanton, or willful misconduct. ~~This subdivision~~  
 20 ~~expires June 30, 2012.~~

21 (4) The person stores the drug:

22 (A) behind a counter in an area inaccessible to a customer or  
 23 in a locked display case that makes the drug unavailable to a  
 24 customer without the assistance of an employee; or

25 (B) directly in front of the pharmacy counter in the direct line  
 26 of sight of an employee at the pharmacy counter, in an area  
 27 under constant video monitoring, if the drug is sold in a retail  
 28 establishment that:

29 (i) is a pharmacy; or

30 (ii) contains a pharmacy that is open for business.

31 **(5) The person posts a sign warning that:**

32 **(A) it is a criminal offense for a person to purchase drugs**  
 33 **containing more than nine (9) grams of ephedrine or**  
 34 **pseudoephedrine, or both, in a thirty (30) day period;**

35 **(B) it is a criminal offense for a person to purchase drugs**  
 36 **containing more than three and six-tenths (3.6) grams of**  
 37 **ephedrine or pseudoephedrine, or both, on one (1) day;**  
 38 **and**

39 **(C) depending on the amount of ephedrine or**  
 40 **pseudoephedrine contained in the drug, purchasing more**  
 41 **than one (1) package of drugs containing ephedrine or**  
 42 **pseudoephedrine on one (1) day may be a crime.**

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1 (d) A person may not purchase drugs containing more than three ~~(3)~~  
 2 **and six-tenths (3.6)** grams of ephedrine or pseudoephedrine, or both,  
 3 ~~in on one (1) week day, or more than nine (9) grams of ephedrine~~  
 4 **or pseudoephedrine, or both, in a thirty (30) day period.**

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

11 (1) The convenience package must be stored not more than thirty  
 12 (30) feet away from a checkout station or counter and must be in  
 13 the direct line of sight of an employee at the checkout station or  
 14 counter.

15 (2) The convenience package must be protected by a reliable  
 16 anti-theft device that uses package tags and detection alarms  
 17 designed to prevent theft.

18 (3) The convenience package must be stored in restricted access  
 19 shelving that permits a purchaser to remove not more than one (1)  
 20 package every fifteen (15) seconds.

21 (4) The convenience package must be stored in an area that is  
 22 under constant video monitoring, and a sign placed near the  
 23 convenience package must warn that the area is under constant  
 24 video monitoring.

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

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

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

38 (i) A person who knowingly or intentionally violates this section  
 39 commits a Class C misdemeanor. However, the offense is a Class A  
 40 misdemeanor if the person has a prior unrelated conviction under this  
 41 section **or has violated section 14.8 of this chapter.**

42 (j) Before June 30, ~~2007~~, **2013**, the state police department shall

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1 submit a report to the legislative council detailing the effectiveness of  
2 this section in reducing the illicit production of methamphetamine. The  
3 report must describe the number of arrests or convictions that are  
4 attributable to the identification and logging requirements contained in  
5 this section, and must include recommendations for future action. The  
6 report must be in an electronic format under IC 5-14-6.

7 SECTION 4. IC 35-48-4-14.8 IS ADDED TO THE INDIANA  
8 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
9 [EFFECTIVE JANUARY 1, 2011]: **Sec. 14.8. (a) This section does**  
10 **not apply to the following:**

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

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

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

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

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

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

34 (1) The name of the purchaser.

35 (2) The address of the purchaser.

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

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

40 (e) The PSE tracking system must issue a stop sale alert if the  
41 completion of a sale would result in the purchaser violating state  
42 or federal quantity limits relating to the sale or purchase of

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1 ephedrine or pseudoephedrine. A person may not complete a  
2 transaction if the PSE tracking system issues a stop sale alert.

3 (f) A person shall begin entering data into the PSE tracking  
4 system not later than one hundred eighty (180) days after the state  
5 police department enters into a contract described in section 14.9  
6 of this chapter.

7 SECTION 5. IC 35-48-4-14.9 IS ADDED TO THE INDIANA  
8 CODE AS A NEW SECTION TO READ AS FOLLOWS  
9 [EFFECTIVE UPON PASSAGE]: **Sec. 14.9. (a) Before July 1, 2010,**  
10 **the state police department may enter into a contract with a**  
11 **vendor to implement a real time PSE tracking system (as defined**  
12 **by section 14.8(b) of this chapter) that includes the following**  
13 **capabilities:**

- 14 (1) Monitor the sale of nonprescriptive products that contain
- 15 ephedrine or pseudoephedrine.
- 16 (2) Track sales, inquiries to purchase, and denials to purchase
- 17 ephedrine or pseudoephedrine.
- 18 (3) Contain a real time stop sale function:
  - 19 (A) that accesses sales records of all state retail locations
  - 20 and retail locations in states bordering Indiana that use
  - 21 similar tracking systems; and
  - 22 (B) enforces state and federal quantity limits.

23 (b) The state police department may enter into a contract with  
24 a vendor that provides a similar PSE tracking system in a state  
25 bordering Indiana. The contract must establish the roles and  
26 responsibilities of the state police department and the vendor. shall  
27 enter into a memorandum of understanding with an entity to  
28 implement the PSE tracking system. The memorandum of  
29 understanding must establish the roles and responsibilities of the  
30 attorney general and the entity.

31 (c) The contract must provide:

- 32 (1) that:
  - 33 (A) retailers; and
  - 34 (B) law enforcement agencies;
 may not be required to pay a fee for access to or  
 35 implementation or maintenance of the system;
- 36 (2) that for investigative purposes, a law enforcement officer
- 37 shall have access to all information on the PSE tracking
- 38 system as authorized by the state police department;
- 39 (3) that sales transaction data will be housed by an
- 40 information technology company operating under strict
- 41 security standards;
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- 1 (4) that the data will be accessible only to authorized law
- 2 enforcement officers;
- 3 (5) that the vendor will forward the data to the state police
- 4 department weekly;
- 5 (6) that the vendor may not modify, sell, use, or compromise
- 6 the sales transaction data that is provided to law enforcement,
- 7 except that the vendor may analyze sales data to access and
- 8 improve efficiency of the system; and
- 9 (7) that the vendor will ensure that the PSE tracking system
- 10 will have stop sale capability throughout the state and with
- 11 Indiana's bordering states that use a similar system as set
- 12 forth in section 14.8 of this chapter.

13 SECTION 6. [EFFECTIVE JULY 1, 2010] (a) As used in this  
 14 SECTION, "board" refers to the Indiana board of pharmacy.

15 (b) The board shall, during the 2010 legislative interim, report  
 16 to the health finance commission established by IC 2-5-23-3  
 17 concerning the following:

- 18 (1) Drug substitutions by pharmacists, including the
- 19 procedures followed by a pharmacist in the substitution of a
- 20 drug.
- 21 (2) The implementation of the statewide electronic system to
- 22 track the sale of ephedrine and pseudoephedrine, as required
- 23 by this act.

24 The attorney general shall assist the board in preparing the report  
 25 required under subdivision (2).

26 (c) This SECTION expires December 31, 2010.

27 SECTION 7. [EFFECTIVE JULY 1, 2010] (a) During the 2011  
 28 legislative interim the health finance commission shall study the  
 29 implementation and effectiveness of the PSE tracking system (as  
 30 defined by IC 35-48-4-14.8(b), as added by this act).

31 (b) This SECTION expires January 1, 2012.

32 SECTION 8. An emergency is declared for this act.

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1320, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, line 15, before "manufacturer" insert "**brand name**".

Page 1, line 17, before "manufacturer" insert "**brand name**".

Page 2, line 2, before "manufacturer" insert "**brand name**".

and when so amended that said bill do pass.

(Reference is to HB 1320 as introduced.)

BROWN C, Chair

Committee Vote: yeas 9, nays 0.

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COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1320, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Page 1, delete lines 1 through 17, begin a new paragraph and insert:

"SECTION 1. IC 4-6-2-12 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2010]: **Sec. 12. The attorney general shall enter into a memorandum of understanding with an entity to implement an electronic system to track the sale of ephedrine and pseudoephedrine as required by IC 35-48-4-14.9.**

SECTION 2. IC 25-26-13-4, AS AMENDED BY P.L.182-2009(ss), SECTION 371, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2010]: Sec. 4. (a) The board may:

- (1) promulgate rules and regulations under IC 4-22-2 for implementing and enforcing this chapter;
- (2) establish requirements and tests to determine the moral, physical, intellectual, educational, scientific, technical, and professional qualifications for applicants for pharmacists'



licenses;

(3) refuse to issue, deny, suspend, or revoke a license or permit or place on probation or fine any licensee or permittee under this chapter;

(4) regulate the sale of drugs and devices in the state of Indiana;

(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or their representatives from entering such places and making such inspections;

(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;

(7) subject to IC 25-1-7, investigate complaints, subpoena witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;

(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; and

(9) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter.

(b) The board shall adopt rules under IC 4-22-2 for the following:

(1) Establishing standards for the competent practice of pharmacy.

(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.

(3) Establishing standards and procedures before January 1, 2006, to ensure that a pharmacist:

(A) has entered into a contract that accepts the return of expired drugs with; or

(B) is subject to a policy that accepts the return of expired drugs of;

a wholesaler, manufacturer, or agent of a wholesaler or manufacturer concerning the return by the pharmacist to the wholesaler, the manufacturer, or the agent of expired legend drugs or controlled drugs. In determining the standards and procedures,

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the board may not interfere with negotiated terms related to cost, expenses, or reimbursement charges contained in contracts between parties, but may consider what is a reasonable quantity of a drug to be purchased by a pharmacy. The standards and procedures do not apply to vaccines that prevent influenza, medicine used for the treatment of malignant hyperthermia, and other drugs determined by the board to not be subject to a return policy. An agent of a wholesaler or manufacturer must be appointed in writing and have policies, personnel, and facilities to handle properly returns of expired legend drugs and controlled substances.

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

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

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

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

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

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

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

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

- (1) A counterfeit protection bar code with human readable representation of the data in the bar code.

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(2) A thermochromic mark on the front and the back of the prescription that:

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

(B) changes from blue to clear when exposed to heat.

(g) The board may contract with a supplier to implement and manage the prescription drug program described in subsection (e). The supplier must:

(1) have been audited by a third party auditor using the SAS 70 audit or an equivalent audit for at least the three (3) previous years; and

(2) be audited by a third party auditor using the SAS 70 audit or an equivalent audit throughout the duration of the contract;

in order to be considered to implement and manage the program.

**(h) The board shall adopt rules and procedures regarding a pharmacist or pharmacy that violates IC 35-48-4-14.8.**

SECTION 3. IC 35-48-4-14.7, AS AMENDED BY P.L.186-2007, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2011]: Sec. 14.7. (a) This section does not apply to the following:

(1) Ephedrine or pseudoephedrine dispensed pursuant to a prescription.

(2) The sale of a drug containing ephedrine or pseudoephedrine to a licensed health care provider, pharmacist, retail distributor, wholesaler, manufacturer, or an agent of any of these persons if the sale occurs in the regular course of lawful business activities. However, a retail distributor, wholesaler, or manufacturer is required to report a suspicious order to the state police department in accordance with subsection (f).

(3) The sale of a drug containing ephedrine or pseudoephedrine by a person who does not sell ~~exclusively~~ to walk-in customers. ~~for the personal use of the walk-in customers.~~ However, if the person described in this subdivision is a retail distributor, wholesaler, or manufacturer, the person is required to report a suspicious order to the state police department in accordance with subsection (f).

(b) The following definitions apply throughout this section:

(1) "Constant video monitoring" means the surveillance by an automated camera that:

(A) records at least one (1) photograph or digital image every ten (10) seconds;

(B) retains a photograph or digital image for at least

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seventy-two (72) hours;

(C) has sufficient resolution and magnification to permit the identification of a person in the area under surveillance; and

(D) stores a recorded photograph or digital image at a location that is immediately accessible to a law enforcement officer.

(2) "Convenience package" means a package that contains a drug having as an active ingredient not more than one hundred twenty (120) milligrams of ephedrine or pseudoephedrine, or both.

(3) "Ephedrine" means pure or adulterated ephedrine.

(4) "Pseudoephedrine" means pure or adulterated pseudoephedrine.

(5) "Suspicious order" means a sale or transfer of a drug containing ephedrine or pseudoephedrine if the sale or transfer:

(A) is a sale or transfer that the retail distributor, wholesaler, or manufacturer is required to report to the United States Drug Enforcement Administration;

(B) appears suspicious to the retail distributor, wholesaler, or manufacturer in light of the recommendations contained in Appendix A of the report to the United States attorney general by the suspicious orders task force under the federal Comprehensive Methamphetamine Control Act of 1996; or

(C) is for cash or a money order in a total amount of at least two hundred dollars (\$200).

(6) "Unusual theft" means the theft or unexplained disappearance from a particular retail store of drugs containing ten (10) grams or more of ephedrine, pseudoephedrine, or both in a twenty-four (24) hour period.

(c) This subsection does not apply to a convenience package. A person may sell a drug that contains the active ingredient of ephedrine, pseudoephedrine, or both only if the person complies with the following conditions:

(1) The person does not sell the drug to a person less than eighteen (18) years of age.

(2) The person does not sell drugs containing more than three ~~(3)~~ **and six-tenths (3.6)** grams of ephedrine or pseudoephedrine, or both, ~~in one (1) transaction:~~ **to one (1) individual on one (1) day, or nine (9) grams of ephedrine or pseudoephedrine, or both, to one (1) individual in a thirty (30) day period.**

(3) The person requires:

(A) the purchaser to produce a state or federal identification card;

(B) the purchaser to complete ~~a paper~~ **or** an electronic log in

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a format approved by the state police department with the purchaser's name, address, and driver's license or other identification number; ~~and~~

(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. ~~This subdivision expires June 30, 2012.~~

(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**

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**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.**

(d) A person may not purchase drugs containing more than three ~~(3)~~ **and six-tenths (3.6)** grams of ephedrine or pseudoephedrine, or both, ~~in on one (1) week 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

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misdemeanor if the person has a prior unrelated conviction under this section **or has violated section 14.8 of this chapter.**

(j) Before June 30, ~~2007~~, **2013**, the state police department shall submit a report to the legislative council detailing the effectiveness of this section in reducing the illicit production of methamphetamine. The report must describe the number of arrests or convictions that are attributable to the identification and logging requirements contained in this section, and must include recommendations for future action. The report must be in an electronic format under IC 5-14-6.

SECTION 4. IC 35-48-4-14.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2011]: **Sec. 14.8. (a) This section does not apply to the following:**

(1) Ephedrine or pseudoephedrine dispensed under a prescription.

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

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

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

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

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

(1) The name of the purchaser.

(2) The address of the purchaser.

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

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

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

(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 JULY 1, 2011]: Sec. 14.9. (a) 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.

(b) 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 or implementation or maintenance of the system;

(2) that for investigative purposes, a law enforcement officer shall have 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 the data will be accessible only to authorized law enforcement officers;

(5) that the entity will forward the data to the state police department weekly;

(6) that the entity may not modify, sell, use, or compromise the 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 the state as set forth in section 14.8 of this chapter.

SECTION 6. [EFFECTIVE JULY 1, 2010] (a) As used in this SECTION, "board" refers to the Indiana board of pharmacy.

(b) The board shall, during the 2010 legislative interim, report to the health finance commission established by IC 2-5-23-3

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concerning the following:

(1) Drug substitutions by pharmacists, including the procedures followed by a pharmacist in the substitution of a drug.

(2) The implementation of the statewide electronic system to track the sale of ephedrine and pseudoephedrine, as required by this act.

The attorney general shall assist the board in preparing the report required under subdivision (2).

(c) This SECTION expires December 31, 2010."

Delete page 2.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1320 as printed January 26, 2010.)

MILLER, Chairperson

Committee Vote: Yeas 7, Nays 0.

SENATE MOTION

Madam President: I move that Engrossed House Bill 1320 be amended to read as follows:

Page 9, delete line 5 and insert "state police department enters into a contract".

Page 9, line 9, delete "JULY 1, 2011]" and insert "UPON PASSAGE]".

Page 9, line 9, delete "The attorney general" and insert "Before July 1, 2010, the state police department may enter into a contract with a vendor to implement a real time PSE tracking system (as defined by section 14.8(b) of this chapter) that includes the following capabilities:

(1) Monitor the sale of nonprescriptive products that contain ephedrine or pseudoephedrine.

(2) Track sales, inquiries to purchase, and denials to purchase ephedrine or pseudoephedrine.

(3) Contain a real time stop sale function:

(A) that accesses sales records of all state retail locations and retail locations in states bordering Indiana that use similar tracking systems; and

(B) enforces state and federal quantity limits.



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**(b) The state police department may enter into a contract with a vendor that provides a similar PSE tracking system in a state bordering Indiana. The contract must establish the roles and responsibilities of the state police department and the vendor."**

Page 9, line 14, delete "(b) The memorandum of understanding" and insert "**(c) The contract**".

Page 9, line 22, after "system" insert "**as authorized by the state police department**".

Page 9, line 28, delete "entity" and insert "**vendor**".

Page 9, line 30, delete "entity" and insert "**vendor**".

Page 9, line 31, after "enforcement" insert", **except that the vendor may analyze sales data to access and improve efficiency of the system**".

Page 9, line 33, delete "entity" and insert "**vendor**".

Page 9, line 34, after "state" insert "**and with Indiana's bordering states that use a similar system**".

Page 10, after line 7, begin a new paragraph and insert:

**"SECTION 7. [EFFECTIVE JULY 1, 2010] (a) During the 2011 legislative interim the health finance commission shall study the implementation and effectiveness of the PSE tracking system (as defined by IC 35-48-4-14.8(b), as added by this act).**

**(b) This SECTION expires January 1, 2012.**

**SECTION 8. An emergency is declared for this act."**

Re-number all SECTIONS consecutively.

(Reference is to EHB 1230 as printed February 19, 2010.)

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