January 29, 2016

HOUSE BILL No. 1390

DIGEST OF HB 1390 (Updated January 27, 2016 7:47 pm - DI 77)

Citations Affected: IC 25-26; IC 34-30; IC 35-48.

Synopsis: Ephedrine or pseudoephedrine. Requires the Indiana board of pharmacy (board) to adopt emergency rules that are effective July 1, 2016, concerning: (1) professional determinations made; and (2) relationship on record with the pharmacy; concerning the sale of ephedrine or pseudoephedrine. Requires the board to: (1) review professional determinations made; and (2) discipline a pharmacist who violates a rule concerning a professional determination made; concerning the sale of ephedrine or pseudoephedrine. Allows the board, in consultation with the state police, to declare a product to be an extraction resistant or a conversion resistant form of ephedrine or pseudoephedrine. Specifies that a person who is denied the sale of a nonprescription product containing pseudoephedrine or ephedrine is not prohibited from obtaining pseudoephedrine or ephedrine pursuant to a prescription. Allows a pharmacist to deny the sale of ephedrine or pseudoephedrine on the basis of the pharmacist's professional judgment, and provides the pharmacist with civil immunity for making such a denial. Provides that a purchaser has a relationship on record with the pharmacy to purchase pseudoephedrine or ephedrine. Allows the pharmacist to provide certain pseudoephedrine or ephedrine products to a purchaser who does not have a relationship on record with the pharmacy or for whom the pharmacist has made a professional judgment that there is not a medical or pharmaceutical need. Adds ephedrine or pseudoephedrine to the definition of "controlled substance" for purposes of the Indiana scheduled prescription electronic collection and tracking (INSPECT) program. Removes an expired provision. Makes technical changes.

Effective: July 1, 2016.

Smaltz, Bacon, Ober, Brown C

January 13, 2016, read first time and referred to Committee on Public Health.
January 28, 2016, amended, reported — Do Pass.

January 29, 2016

Second Regular Session of the 119th General Assembly (2016)

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 2015 Regular Session of the General Assembly.

HOUSE BILL No. 1390

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:

SECTION 1. IC 25-26-13-4, AS AMENDED BY P.L.182-2009(ss), SECTION 371, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 4. (a) The board may:

(1) ~~promulgate~~ **adopt** 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, 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.

(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 under IC 4-22-2 or emergency rules in the manner provided under IC 4-22-2-37.1, that take effect on January 1, 2017, concerning:

(1) professional determinations made under IC 35-48-4-14.7(d); and

(2) the determination of a relationship on record with the pharmacy under IC 35-48-4-14.7.

(i) The board shall:

(1) review professional determinations made by a pharmacist; and

(2) take appropriate disciplinary action against a pharmacist who violates a rule adopted under subsection (h) concerning a professional determination made;

under IC 35-48-4-14.7 concerning the sale of ephedrine and pseudoephedrine.

SECTION 2. IC 34-30-2-152.3, AS AMENDED BY P.L.193-2013, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 152.3. **(a)** ~~IC 35-48-4-14.7~~ **IC 35-48-4-14.7(d) and IC 35-48-4-14.7(k)** (Concerning a pharmacy or NPLEx retailer who discloses information concerning the sale of a product containing ephedrine or pseudoephedrine).

(b) IC 35-48-4-14.7(d)(3) (Concerning a pharmacist's professional judgment not to sell ephedrine or pseudoephedrine to an individual).

SECTION 3. IC 35-48-4-14.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 14.3. (a) The board may adopt:**

(1) a rule under IC 4-22-2; or

(2) an emergency rule in the manner provided under IC 4-22-2-37.1;

to declare that a product is an extraction resistant or a conversion resistant form of ephedrine or pseudoephedrine.

(b) The board, in consultation with the state police, shall find that a product is an extraction resistant or a conversion resistant form of ephedrine or pseudoephedrine if the board determines that the product does not pose a significant risk of being used in the manufacture of methamphetamine.

SECTION 4. IC 35-48-4-14.7, AS AMENDED BY P.L.193-2013, SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 14.7. (a) This section does not apply to the following:

(1) Ephedrine or pseudoephedrine dispensed pursuant to a prescription. **Nothing in this section prohibits a person who is denied the sale of a nonprescription product containing pseudoephedrine or ephedrine from obtaining pseudoephedrine or ephedrine 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 (g).

(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 (g).

(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 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 sixty (60) milligrams of ephedrine or pseudoephedrine, or both.

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

(4) "Pharmacy or NPLEx retailer" means:

(A) a pharmacy, as defined in IC 25-26-13-2;

(B) a retailer containing a pharmacy, as defined in IC 25-26-13-2; or

(C) a retailer that electronically submits the required

information to the National Precursor Log Exchange (NPLEx) administered by the National Association of Drug Diversion Investigators (NADDI).

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

(6) "Retailer" means a grocery store, general merchandise store, or other similar establishment. The term does not include a pharmacy or NPLEx retailer.

(7) "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).

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

(c) A drug containing ephedrine or pseudoephedrine may be sold only by a pharmacy or NPLEx retailer. ~~Except as provided in subsection (f), a retailer may not sell a drug containing ephedrine or pseudoephedrine.~~

(d) A pharmacy or NPLEx retailer may sell a drug that contains the active ingredient of ephedrine, pseudoephedrine, or both only if the pharmacy or NPLEx retailer complies with the following conditions:

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

(2) The pharmacy or NPLEx retailer does not sell drugs containing more than:

(A) three and six-tenths (3.6) grams of ephedrine or pseudoephedrine, or both, to one (1) individual on one (1) day;

(B) seven and two-tenths (7.2) grams of ephedrine or pseudoephedrine, or both, to one (1) individual in a thirty (30) day period; or

(C) sixty-one and two-tenths (61.2) grams of ephedrine or pseudoephedrine, or both, to one (1) individual in a three

hundred sixty-five (365) day period.

(3) Beginning July 1, 2016, before the sale occurs, the pharmacist shall make a professional determination as to whether there is a legitimate medical or pharmaceutical need for ephedrine or pseudoephedrine before selling ephedrine or pseudoephedrine to an individual. The pharmacist's professional determination must comply with the rules adopted under IC 25-26-13-4 and may include the following:

(A) Prior medication filling history of the individual.

(B) Consulting with the individual.

(C) Other tools that provide professional reassurance to the pharmacist that a legitimate medical or pharmaceutical need for ephedrine or pseudoephedrine exists.

A pharmacist who in good faith does not sell ephedrine or pseudoephedrine to an individual under this subdivision is immune from civil liability unless the refusal to sell constitutes gross negligence or intentional, wanton, or willful misconduct.

~~(3)~~ **(4)** The pharmacy or NPLEx retailer requires:

(A) the purchaser to produce a valid government issued photo identification card showing the date of birth of the person;

(B) the purchaser to sign a written or electronic log attesting to the validity of the information; and

(C) the clerk who is conducting the transaction to initial or electronically record the clerk's identification on the log.

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 pharmacy or NPLEx retailer 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 pharmacy or NPLEx retailer that 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)~~ **(5)** The pharmacy or NPLEx retailer maintains a record of information for each sale of a nonprescription product containing

pseudoephedrine or ephedrine. Required information includes:

(A) the name and address of each purchaser;

(B) the type of identification presented;

(C) the governmental entity that issued the identification;

(D) the identification number; and

(E) the ephedrine or pseudoephedrine product purchased, including the number of grams the product contains and the date and time of the transaction.

~~(5) Beginning January 1, 2012,~~ **(6)** A pharmacy or NPLEx retailer shall, except as provided in subdivision ~~(6),~~ **(7),** before completing a sale of an over-the-counter product containing pseudoephedrine or ephedrine, electronically submit the required information to the National Precursor Log Exchange (NPLEx) administered by the National Association of Drug Diversion Investigators (NADDI), if the NPLEx system is available to pharmacies or NPLEx retailers in the state without a charge for accessing the system. The pharmacy or NPLEx retailer may not complete the sale if the system generates a stop sale alert.

~~(6)~~ **(7)** If a pharmacy or NPLEx retailer selling an over-the-counter product containing ephedrine or pseudoephedrine experiences mechanical or electronic failure of the electronic sales tracking system and is unable to comply with the electronic sales tracking requirement, the pharmacy or NPLEx retailer shall maintain a written log or an alternative electronic recordkeeping mechanism until the pharmacy or NPLEx retailer is able to comply with the electronic sales tracking requirement.

~~(7)~~ **(8)** The pharmacy or NPLEx retailer stores the drug 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.

(9) Beginning July 1, 2016, except as provided in subsection (f), the purchaser has a relationship on record with the pharmacy, as determined by the board under IC 25-26-13-4.

(e) A person may not purchase drugs containing more than:

(1) three and six-tenths (3.6) grams of ephedrine or pseudoephedrine, or both, on one (1) day;

(2) seven and two-tenths (7.2) grams of ephedrine or pseudoephedrine, or both, in a thirty (30) day period; or

(3) sixty-one and two-tenths (61.2) grams of ephedrine or pseudoephedrine, or both, in a three hundred sixty-five (365) day period.

These limits apply to the total amount of base ephedrine and

pseudoephedrine contained in the products and not to the overall weight of the products.

~~(f) This subsection only applies to convenience packages. A retailer may sell convenience packages under this section without complying with the conditions listed in subsection (d):~~

~~(1) after June 30, 2013; and~~

~~(2) before January 1, 2014.~~

~~A retailer may not sell drugs containing more than sixty (60) milligrams of ephedrine or pseudoephedrine, or both in any one (1) transaction. A retailer who sells convenience packages must secure the convenience packages behind the 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. A retailer may not sell a drug containing ephedrine or pseudoephedrine after December 31, 2013.~~

(f) Beginning July 1, 2016, if a purchaser does not have a relationship on record with the pharmacy, as determined by rules adopted by the board under IC 25-26-13-4, or the pharmacist has made a professional determination that there is not a legitimate medical or pharmaceutical need for ephedrine or pseudoephedrine under subsection (d), the purchaser may, at the pharmacist's discretion, purchase only the following:

(1) A product that has been determined under section 14.3 of this chapter to be an extraction resistant or a conversion resistant form of ephedrine or pseudoephedrine.

(2) A product that contains not more than:

(A) a total of seven hundred twenty (720) milligrams of ephedrine or pseudoephedrine per package; and

(B) thirty (30) milligrams of ephedrine or pseudoephedrine per tablet.

The pharmacist may not sell more than one (1) package of ephedrine or pseudoephedrine to a purchaser under this subdivision per day.

However, if the pharmacist believes that the ephedrine or pseudoephedrine purchase will be used to manufacture methamphetamine, the pharmacist may refuse to sell ephedrine or pseudoephedrine to the purchaser.

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

(h) Not later than three (3) days after the discovery of an unusual theft at a particular retail store, the pharmacy or NPLEx 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 pharmacy or NPLEx retailer, the pharmacy or NPLEx 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 pharmacy or NPLEx retailer 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.

(i) 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.

(j) 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.

(k) A pharmacy or NPLEx retailer that uses the electronic sales tracking system in accordance with this section is immune from civil liability for any act or omission committed in carrying out the duties required by this section, unless the act or omission was due to negligence, recklessness, or deliberate or wanton misconduct. A pharmacy or NPLEx retailer is immune from liability to a third party unless the pharmacy or NPLEx retailer has violated a provision of this section and the third party brings an action based on the pharmacy's or NPLEx retailer's violation of this section.

(l) The following requirements apply to the NPLEx:

(1) Information contained in the NPLEx may be shared only with law enforcement officials.

(2) A law enforcement official may access Indiana transaction information maintained in the NPLEx for investigative purposes.

(3) NADDI may not modify sales transaction data that is shared with law enforcement officials.

(4) At least one (1) time per week, NADDI shall forward Indiana data contained in the NPLEx, including data concerning a transaction that could not be completed due to the issuance of a stop sale alert, to the state police department.

SECTION 5. IC 35-48-7-2.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 2.7. As used in this chapter, "controlled substance" has the meaning set forth in IC 35-48-1-9 and includes pure or adulterated ephedrine or pseudoephedrine.**

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1390, 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:

Delete everything after the enacting clause and insert the following:

(SEE TEXT OF BILL)

and when so amended that said bill do pass.

(Reference is to HB 1390 as introduced.)

KIRCHHOFER

Committee Vote: yeas 12, nays 1.