

January 29, 1998

HOUSE BILL No. 1100

DIGEST OF HB 1100 (Updated January 27, 1998 9:20 pm - DI 77)

Citations Affected: IC 16-42; IC 25-26; IC 35-48.

Synopsis: Ephedrine regulation. Provides, with certain exceptions, that a product that contains ephedrine may only be dispensed under a physician's or an advanced practice nurse's prescription. Provides that ephedrine products that meet certain requirements may be sold without a prescription. Requires the Indiana board of pharmacy to adopt standards to determine if an over the counter product that contains ephedrine meets marketing and labeling requirements. Makes violation of the ephedrine requirements a Class B misdemeanor. Requires a court to assess a fee for conviction of certain offenses related to controlled substances to cover the costs of an environmental cleanup incurred by a law enforcement agency as a result of the offense. Provides that a person who (1) possesses ephedrine or a related substance with the intent to manufacture or (2) sells, distributes, or otherwise supplies ephedrine or a related substance to an individual with knowledge that
(Continued next page)

Effective: July 1, 1998.

Mahern, Kruse

January 6, 1998, read first time and referred to Committee on Public Health.
January 28, 1998, amended, reported — Do Pass.

HB 1100—LS 6294/DI 93



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the individual intends to manufacture certain controlled substances
commits a Class C felony.

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HB 1100—LS 6294/DI 93



January 29, 1998

Second Regular Session 110th General Assembly (1998)

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 1997 General Assembly.

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HOUSE BILL No. 1100

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 16-42-25 IS ADDED TO THE INDIANA CODE
2 AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE
3 JULY 1, 1998]:

4 **Chapter 25. Drugs: Ephedrine Products**
5 **Sec. 1. Except as provided in sections 2 and 3 of this chapter, a**
6 **product that contains ephedrine or its salts may only be dispensed**
7 **with a prescription from a licensed physician or an advanced**
8 **practice nurse authorized to prescribe legend drugs under**
9 **IC 25-23-1-19.5.**

10 **Sec. 2. A product that contains ephedrine or its salts may be sold**
11 **without a prescription if the product meets all of the following**
12 **requirements:**

- 13 (1) The product may be sold over the counter without a
14 prescription under the federal Food, Drug, and Cosmetic Act.
15 (2) The product is labeled and marketed in a manner

HB 1100—LS 6294/DI 93



1 consistent with the pertinent Over the Counter (OTC)
2 Tentative Final or Final Monograph.

3 (3) The product is manufactured and distributed for medical
4 use in a manner that reduces the likelihood of abuse.

5 (4) The product is in one (1) of the following forms:

6 (A) A solid oral dosage form, including a soft gelatin
7 caplet, that:

8 (i) combines, as active ingredients, sixteen (16) parts
9 guaifenesin to one (1) part ephedrine by weight; and

10 (ii) contains not more than twenty-five (25) milligrams of
11 ephedrine;

12 per dose, according to label instructions.

13 (B) An anorectal preparation containing not more than
14 five percent (5%) ephedrine.

15 Sec. 3. (a) A product that contains ephedrine or its salts may be
16 dispensed or sold without a prescription, and marketed, advertised,
17 or labeled for indications of stimulation, mental alertness, weight
18 loss, appetite control, or energy, if the product is a food product or
19 dietary supplement that meets all of the following criteria:

20 (1) The product does not contain, per dose or serving, any of
21 the following:

22 (A) More than the lesser of:

23 (i) twenty-five (25) milligrams of ephedrine alkaloids; or

24 (ii) the maximum amount of ephedrine alkaloids
25 provided in applicable regulations adopted by the United
26 States Food and Drug Administration.

27 (B) More than twenty (20) milligrams of hydrochloride or
28 sulfate salts of ephedrine alkaloids that have been added to
29 the product.

30 (2) The product is packaged with a prominent label securely
31 affixed to each package that states the following:

32 (A) The amount in milligrams of ephedrine or its salts in a
33 dose or serving.

34 (B) The amount of the food product or dietary supplement
35 that constitutes a dose or serving.

36 (C) That the maximum recommended dose of ephedrine or
37 its salts for a healthy adult human is the lesser of:

38 (i) one hundred (100) milligrams in a twenty-four (24)
39 hour period; or

40 (ii) the maximum recommended dose or period of use
41 provided in applicable regulations adopted by the United
42 States Food and Drug Administration.

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1 **(D) That improper use of the product may be hazardous to**
 2 **a person's health.**

3 **(b) A person may not dispense, sell, or otherwise give a food**
 4 **product or dietary supplement containing ephedrine or its salts to**
 5 **an individual who is less than eighteen (18) years of age. However,**
 6 **this subsection does not apply to:**

- 7 **(1) a physician or pharmacist;**
 8 **(2) a parent or guardian of the individual; or**
 9 **(3) a person authorized by the parent or guardian of the**
 10 **individual;**

11 **who dispenses, sells, or otherwise gives a product described in**
 12 **subsection (a) to an individual who is less than eighteen (18) years**
 13 **of age.**

14 **(c) A person in the course of selling, offering for sale, or**
 15 **otherwise distributing a product that contains ephedrine or its salts**
 16 **may not advertise or represent in any manner that the product:**

- 17 **(1) causes euphoria, ecstasy, a "buzz" or "high", or an altered**
 18 **mental state;**
 19 **(2) heightens sexual performance; or**
 20 **(3) increases muscle mass because the product contains**
 21 **ephedrine alkaloids.**

22 **Sec. 4. (a) Except as provided in section 3 of this chapter, a**
 23 **product that contains ephedrine or its salts may not be marketed,**
 24 **advertised, or labeled for indications of stimulation, mental**
 25 **alertness, weight loss, appetite control, or energy.**

26 **(b) The Indiana board of pharmacy shall adopt rules under**
 27 **IC 4-22-2 that include standards to determine compliance with this**
 28 **section. The Indiana board of pharmacy may consider the**
 29 **following factors when adopting rules under this section:**

- 30 **(1) The packaging of the product.**
 31 **(2) The name and labeling of the product.**
 32 **(3) The manner of distribution, advertising, and promotion of**
 33 **the product.**
 34 **(4) Verbal representations made concerning the product.**
 35 **(5) The duration, scope, and significance of abuse or misuse of**
 36 **the particular product.**

37 **Sec. 5. A person who knowingly or intentionally violates this**
 38 **chapter commits a Class B misdemeanor.**

39 **SECTION 2. IC 25-26-13-29 IS AMENDED TO READ AS**
 40 **FOLLOWS [EFFECTIVE JULY 1, 1998]: Sec. 29. (a) It is unlawful:**

- 41 **(1) For any person to display or permit to be displayed, a**
 42 **pharmacy permit in any facility or place of business other than**

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1 that for which it was issued.

2 (2) For any person to accept a prescription for filling or
3 compounding at any place or facility for which there is not a valid
4 pharmacy permit.

5 (3) For any person to operate a pharmacy or to take, assume,
6 exhibit, display, or advertise by any medium, the title "drugs",
7 "prescriptions", "medicine", "drug store", "pharmacy", or
8 "apothecary shop", or any combination of such titles or any other
9 title, symbol, term, or description of like import intended to cause
10 the public to believe that it is a pharmacy unless he holds a valid
11 pharmacy permit.

12 (4) For any person to engage or offer to engage in the practice of
13 pharmacy or to hold himself out as a pharmacist without a valid
14 pharmacist's license that is classified as active by the board.

15 (b) A person who violates a provision of subsection (a) of this
16 section commits a Class D felony.

17 (c) **Except as provided in IC 16-42-25-4**, nothing in this chapter
18 shall apply to, nor in any manner interfere with the business of a
19 general merchant in selling and distributing nonnarcotic,
20 nonprescription medicines or drugs which are prepackaged, fully
21 prepared by the manufacturer for use by the consumer, and labeled in
22 accordance with the requirements of the state and federal food and drug
23 acts.

24 SECTION 3. IC 35-48-4-4.6 IS AMENDED TO READ AS
25 FOLLOWS [EFFECTIVE JULY 1, 1998]: Sec. 4.6. (a) A person who
26 knowingly or intentionally:

- 27 (1) manufactures;
- 28 (2) finances the manufacture of;
- 29 (3) advertises;
- 30 (4) distributes; or
- 31 (5) possesses with intent to manufacture, finance the manufacture
32 of, advertise, or distribute;

33 a substance described in section 4.5 of this chapter commits a Class C
34 felony.

35 (b) A person who knowingly or intentionally possesses a substance
36 described in section 4.5 of this chapter commits a Class C
37 misdemeanor. However, the offense is a Class A misdemeanor if the
38 person has a previous conviction under this section.

39 (c) In any prosecution brought under this section it is not a defense
40 that the person believed the substance actually was a controlled
41 substance.

42 (d) This section does not apply to the following:



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1 (1) The manufacture, financing the manufacture of, processing,
 2 packaging, distribution, or sale of noncontrolled substances to
 3 licensed medical practitioners for use as placebos in professional
 4 practice or research.

5 (2) Persons acting in the course and legitimate scope of their
 6 employment as law enforcement officers.

7 (3) The retention of production samples of noncontrolled
 8 substances produced before September 1, 1986, where such
 9 samples are required by federal law.

10 **(e) In addition to any other fee imposed for conviction of an**
 11 **offense under this section, a court shall assess a fee against the**
 12 **defendant to cover the costs of an environmental cleanup incurred**
 13 **by a law enforcement agency as a result of the offense.**

14 **(f) The fee collected under subsection (e) must be used to**
 15 **reimburse the law enforcement agency that assumed the costs**
 16 **associated with an environmental cleanup described in subsection**
 17 **(e).**

18 SECTION 4. IC 35-48-4-16 IS ADDED TO THE INDIANA CODE
 19 AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
 20 1, 1998]: **Sec. 16. A person who knowingly or intentionally:**

21 **(1) possesses ephedrine or pseudoephedrine or their salts or**
 22 **isomers with intent to manufacture; or**

23 **(2) sells, distributes, or otherwise supplies ephedrine or**
 24 **pseudoephedrine or their salts or isomers with knowledge that**
 25 **the recipient intends to use the substance to manufacture;**
 26 **methcathinone, a schedule I controlled substance under**
 27 **IC 35-48-2-4, methamphetamine, a schedule II controlled**
 28 **substance under IC 35-48-2-6, amphetamine, a schedule II**
 29 **controlled substance under IC 35-48-2-6, or phentermine, a**
 30 **schedule IV controlled substance under IC 35-48-2-10, commits a**
 31 **Class C felony.**

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1100, 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 2, line 25, delete "Hydrochloride" and insert "**More than twenty (20) milligrams of hydrochloride**".

Page 3, line 23, delete "To" and insert "**The Indiana board of pharmacy shall adopt rules under IC 4-22-2 that include standards to**".

Page 3, line 23, delete ", the" and insert ". **The**".

Page 3, line 24, after "factors" insert "**when adopting rules under this section**".

Page 3, between lines 33 and 34, begin a new paragraph and insert: "SECTION 2. IC 25-26-13-29 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1998]: Sec. 29. (a) It is unlawful:

(1) For any person to display or permit to be displayed, a pharmacy permit in any facility or place of business other than that for which it was issued.

(2) For any person to accept a prescription for filling or compounding at any place or facility for which there is not a valid pharmacy permit.

(3) For any person to operate a pharmacy or to take, assume, exhibit, display, or advertise by any medium, the title "drugs", "prescriptions", "medicine", "drug store", "pharmacy", or "apothecary shop", or any combination of such titles or any other title, symbol, term, or description of like import intended to cause the public to believe that it is a pharmacy unless he holds a valid pharmacy permit.

(4) For any person to engage or offer to engage in the practice of pharmacy or to hold himself out as a pharmacist without a valid pharmacist's license that is classified as active by the board.

(b) A person who violates a provision of subsection (a) of this section commits a Class D felony.

(c) **Except as provided in IC 16-42-25-4**, nothing in this chapter shall apply to, nor in any manner interfere with the business of a general merchant in selling and distributing nonnarcotic, nonprescription medicines or drugs which are prepackaged, fully prepared by the manufacturer for use by the consumer, and labeled in accordance with the requirements of the state and federal food and drug acts."

Page 4, line 39, delete "Class D felony" and insert "**Class C felony**".

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Renumber all SECTIONS consecutively.
and when so amended that said bill do pass.
(Reference is to House Bill 1100 as introduced.)

C. BROWN, Chair

Committee Vote: yeas 8, nays 5.

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