

# HOUSE BILL No. 1100

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## DIGEST OF INTRODUCED BILL

**Citations Affected:** IC 16-42-25; IC 35-48-4-4.6; IC 35-48-4-16.

**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. Provides that the Indiana board of pharmacy may 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 the individual intends to manufacture certain controlled substances commits a Class D felony.

**Effective:** July 1, 1998.

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January 6, 1998, read first time and referred to Committee on Public Health.

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Introduced

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.

## HOUSE BILL No. 1100

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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 16-42-25 IS ADDED TO THE INDIANA CODE AS  
2 A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1,  
3 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 consistent**  
16 **with the pertinent Over the Counter (OTC) Tentative Final or**  
17 **Final Monograph.**

1998

IN 1100—LS 6294/DI 93+



- 1           **(3) The product is manufactured and distributed for medical**  
 2           **use in a manner that reduces the likelihood of abuse.**  
 3           **(4) The product is in one (1) of the following forms:**  
 4           **(A) A solid oral dosage form, including a soft gelatin caplet,**  
 5           **that:**  
 6               **(i) combines, as active ingredients, sixteen (16) parts**  
 7               **guaifenesin to one (1) part ephedrine by weight; and**  
 8               **(ii) contains not more than twenty-five (25) milligrams of**  
 9               **ephedrine;**  
 10           **per dose, according to label instructions.**  
 11           **(B) An anorectal preparation containing not more than five**  
 12           **percent (5%) ephedrine.**  
 13           **Sec. 3. (a) A product that contains ephedrine or its salts may be**  
 14           **dispensed or sold without a prescription, and marketed, advertised,**  
 15           **or labeled for indications of stimulation, mental alertness, weight**  
 16           **loss, appetite control, or energy, if the product is a food product or**  
 17           **dietary supplement that meets all of the following criteria:**  
 18           **(1) The product does not contain, per dose or serving, any of**  
 19           **the following:**  
 20               **(A) More than the lesser of:**  
 21                   **(i) twenty-five (25) milligrams of ephedrine alkaloids; or**  
 22                   **(ii) the maximum amount of ephedrine alkaloids provided**  
 23                   **in applicable regulations adopted by the United States**  
 24                   **Food and Drug Administration.**  
 25               **(B) Hydrochloride or sulfate salts of ephedrine alkaloids**  
 26               **that have been added to the product.**  
 27           **(2) The product is packaged with a prominent label securely**  
 28           **affixed to each package that states the following:**  
 29               **(A) The amount in milligrams of ephedrine or its salts in a**  
 30               **dose or serving.**  
 31               **(B) The amount of the food product or dietary supplement**  
 32               **that constitutes a dose or serving.**  
 33               **(C) That the maximum recommended dose of ephedrine or**  
 34               **its salts for a healthy adult human is the lesser of:**  
 35                   **(i) one hundred (100) milligrams in a twenty-four (24)**  
 36                   **hour period; or**  
 37                   **(ii) the maximum recommended dose or period of use**  
 38                   **provided in applicable regulations adopted by the United**  
 39                   **States Food and Drug Administration.**  
 40               **(D) That improper use of the product may be hazardous to**  
 41               **a person's health.**  
 42           **(b) A person may not dispense, sell, or otherwise give a food**



1 product or dietary supplement containing ephedrine or its salts to an  
 2 individual who is less than eighteen (18) years of age. However, this  
 3 subsection does not apply to:

- 4 (1) a physician or pharmacist;
- 5 (2) a parent or guardian of the individual; or
- 6 (3) a person authorized by the parent or guardian of the  
 7 individual;

8 who dispenses, sells, or otherwise gives a product described in  
 9 subsection (a) to an individual who is less than eighteen (18) years of  
 10 age.

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

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

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

23 (b) To determine compliance with this section, the Indiana board  
 24 of pharmacy may consider the following factors:

- 25 (1) The packaging of the product.
- 26 (2) The name and labeling of the product.
- 27 (3) The manner of distribution, advertising, and promotion of  
 28 the product.
- 29 (4) Verbal representations made concerning the product.
- 30 (5) The duration, scope, and significance of abuse or misuse of  
 31 the particular product.

32 Sec. 5. A person who knowingly or intentionally violates this  
 33 chapter commits a Class B misdemeanor.

34 SECTION 2. IC 35-48-4-4.6 IS AMENDED TO READ AS  
 35 FOLLOWS [EFFECTIVE JULY 1, 1998]: Sec. 4.6. (a) A person who  
 36 knowingly or intentionally:

- 37 (1) manufactures;
- 38 (2) finances the manufacture of;
- 39 (3) advertises;
- 40 (4) distributes; or
- 41 (5) possesses with intent to manufacture, finance the manufacture of,  
 42 advertise, or distribute;



1 a substance described in section 4.5 of this chapter commits a Class C  
2 felony.

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

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

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

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

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

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

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

23 (f) **The fee collected under subsection (e) must be used to**  
24 **reimburse the law enforcement agency that assumed the costs**  
25 **associated with an environmental cleanup described in subsection**  
26 **(e).**

27 SECTION 3. IC 35-48-4-16 IS ADDED TO THE INDIANA CODE  
28 AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY  
29 1, 1998]: **Sec. 16. A person who knowingly or intentionally:**

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

32 (2) **sells, distributes, or otherwise supplies ephedrine or**  
33 **pseudoephedrine or their salts or isomers with knowledge that**  
34 **the recipient intends to use the substance to manufacture;**

35 **methcathinone, a schedule I controlled substance under**  
36 **IC 35-48-2-4, methamphetamine, a schedule II controlled substance**  
37 **under IC 35-48-2-6, amphetamine, a schedule II controlled**  
38 **substance under IC 35-48-2-6, or phentermine, a schedule IV**  
39 **controlled substance under IC 35-48-2-10, commits a Class D felony.**

