

# HOUSE BILL No. 1068

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## DIGEST OF INTRODUCED BILL

**Citations Affected:** IC 16-42-25; IC 25-26-13-29.

**Synopsis:** Regulation of ephedrine products. 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.

**Effective:** July 1, 1999.

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January 6, 1999, read first time and referred to Committee on Public Health.

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First Regular Session 111th General Assembly (1999)

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 1998 General Assembly.

## HOUSE BILL No. 1068

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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  
2 AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE  
3 JULY 1, 1999]:

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**  
16 **consistent with the pertinent Over the Counter (OTC)**  
17 **Tentative Final or Final Monograph.**



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- 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**  
 5           **caplet, 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**  
 12           **five 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**  
 23                   **provided in applicable regulations adopted by the United**  
 24                   **States Food and Drug Administration.**  
 25               **(B) More than twenty (20) milligrams of hydrochloride or**  
 26               **sulfate salts of ephedrine alkaloids that have been added to**  
 27               **the product.**  
 28           **(2) The product is packaged with a prominent label securely**  
 29           **affixed to each package that states the following:**  
 30               **(A) The amount in milligrams of ephedrine or its salts in a**  
 31               **dose or serving.**  
 32               **(B) The amount of the food product or dietary supplement**  
 33               **that constitutes a dose or serving.**  
 34               **(C) That the maximum recommended dose of ephedrine or**  
 35               **its salts for a healthy adult human is the lesser of:**  
 36                   **(i) one hundred (100) milligrams in a twenty-four (24)**  
 37                   **hour period; or**  
 38                   **(ii) the maximum recommended dose or period of use**  
 39                   **provided in applicable regulations adopted by the United**  
 40                   **States Food and Drug Administration.**  
 41               **(D) That improper use of the product may be hazardous to**  
 42               **a person's health.**



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

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

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

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

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

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

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

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

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

37           **SECTION 2. IC 25-26-13-29 IS AMENDED TO READ AS**  
 38 **FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 29. (a) It is unlawful:**

- 39           **(1) For any person to display or permit to be displayed a**  
 40 **pharmacy permit in any facility or place of business other than**  
 41 **that for which it was issued.**  
 42           **(2) For any person to accept a prescription for filling or**

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- 1           compounding at any place or facility for which there is not a valid  
2           pharmacy permit.
- 3           (3) For any person to operate a pharmacy or to take, assume,  
4           exhibit, display, or advertise by any medium the title "drugs",  
5           "prescriptions", "medicine", "drug store", "pharmacy", or  
6           "apothecary shop", or any combination of such titles or any other  
7           title, symbol, term, or description of like import intended to cause  
8           the public to believe that it is a pharmacy unless he holds a valid  
9           pharmacy permit.
- 10          (4) For any person to engage or offer to engage in the practice of  
11          pharmacy or to hold himself out as a pharmacist without a valid  
12          pharmacist's license that is classified as active by the board.
- 13          (b) A person who violates a provision of subsection (a) of this  
14          section commits a Class D felony.
- 15          (c) **Except as provided in IC 16-42-25-4**, nothing in this chapter  
16          shall apply to, nor in any manner interfere with, the business of a  
17          general merchant in selling and distributing nonnarcotic,  
18          nonprescription medicines or drugs which are prepackaged, fully  
19          prepared by the manufacturer for use by the consumer, and labeled in  
20          accordance with the requirements of the state and federal food and drug  
21          acts.

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