

HOUSE BILL No. 1218

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-42-22-13; IC 25-26-13-4; IC 25-26-13-31.

Synopsis: Drug products list. Requires the consent of a prescribing physician and a patient in order for a pharmacist to interchange a limited class of drugs that may cause a patient to be at risk and that require monitoring for appropriate therapeutic effect. Requires a pharmacist to refill a prescription using the same brand name drug product unless the pharmacist first notifies the prescribing physician and receives written consent from both the prescribing physician and the patient receiving the drug product to dispense another manufacturer's product. Requires the Indiana board of pharmacy to establish and maintain a list containing the brand names of the limited class of drugs that may cause a patient to be at risk and that require
(Continued next page)

Effective: July 1, 1998.

**Klinker, T. Brown, C. Brown,
Becker**

January 8, 1998, read first time and referred to Committee on Public Health.



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Digest Continued

monitoring for appropriate therapeutic effect. Requires the Indiana board of pharmacy to annually distribute a copy of the list to each pharmacy licensed in Indiana. Requires the Indiana board of pharmacy to revise and distribute the list whenever new information on drugs, drug products, and dosage formulations becomes available from the United States Food and Drug Administration or other relevant sources.

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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.

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HOUSE BILL No. 1218



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

Be it enacted by the General Assembly of the State of Indiana:

1 SECTION 1. IC 16-42-22-13 IS ADDED TO THE INDIANA
2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
3 [EFFECTIVE JULY 1, 1998]: **Sec. 13. As required under**
4 **IC 25-26-13-4(b)(3), the Indiana board of pharmacy shall prepare**
5 **and maintain a list of drug products that:**

- 6 (1) **require monitoring to ensure proper therapeutic effect;**
- 7 (2) **contains the brand name of each drug product for which**
- 8 **patient safety is a concern; and**
- 9 (3) **may not be interchanged by a pharmacist without the**
- 10 **consent of the prescribing physician and patient, as provided**
- 11 **under IC 25-26-13-31.**

12 SECTION 2. IC 25-26-13-4, AS AMENDED BY P.L.177-1997,
13 SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
14 JULY 1, 1998]: Sec. 4. (a) The board may:

- 15 (1) promulgate rules and regulations under IC 4-22-2 for



- 1 implementing and enforcing this chapter;
- 2 (2) establish requirements and tests to determine the moral,
- 3 physical, intellectual, educational, scientific, technical, and
- 4 professional qualifications for applicants for pharmacists'
- 5 licenses;
- 6 (3) refuse to issue, deny, suspend, or revoke a license or permit or
- 7 place on probation or fine any licensee or permittee under this
- 8 chapter;
- 9 (4) regulate the sale of drugs and devices in the state of Indiana;
- 10 (5) impound, embargo, confiscate, or otherwise prevent from
- 11 disposition any drugs, medicines, chemicals, poisons, or devices
- 12 which by inspection are deemed unfit for use or would be
- 13 dangerous to the health and welfare of the citizens of the state of
- 14 Indiana; the board shall follow those embargo procedures found
- 15 in IC 16-42-1-18 through IC 16-42-1-31, and persons may not
- 16 refuse to permit or otherwise prevent members of the board or
- 17 their representatives from entering such places and making such
- 18 inspections;
- 19 (6) prescribe minimum standards with respect to physical
- 20 characteristics of pharmacies, as may be necessary to the
- 21 maintenance of professional surroundings and to the protection of
- 22 the safety and welfare of the public;
- 23 (7) subject to IC 25-1-7, investigate complaints, subpoena
- 24 witnesses, schedule and conduct hearings on behalf of the public
- 25 interest on any matter under the jurisdiction of the board;
- 26 (8) prescribe the time, place, method, manner, scope, and subjects
- 27 of licensing examinations which shall be given at least twice
- 28 annually; and
- 29 (9) perform such other duties and functions and exercise such
- 30 other powers as may be necessary to implement and enforce this
- 31 chapter.
- 32 (b) The board shall adopt rules under IC 4-22-2 for the following:
- 33 (1) Establishing standards for the competent practice of
- 34 pharmacy.
- 35 (2) Establishing the standards for a pharmacist to counsel
- 36 individuals regarding the proper use of drugs.
- 37 **(3) Establishing and maintaining a list of drug products that:**
- 38 **(A) require monitoring to ensure proper therapeutic effect**
- 39 **or otherwise meet the description of a drug product under**
- 40 **section 31(b) of this chapter;**
- 41 **(B) contains the brand name of each drug product for**
- 42 **which patient safety is a concern; and**

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1 **(C) may not be interchanged by a pharmacist without the**
 2 **consent of the prescribing physician and the patient.**

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

5 (1) the board has adopted rules which set forth the procedures and
 6 standards governing the grant or denial of a temporary variance;
 7 and

8 (2) the board sets forth in writing the reasons for a grant or denial
 9 of a temporary variance.

10 SECTION 3. IC 25-26-13-31 IS ADDED TO THE INDIANA
 11 CODE AS A NEW SECTION TO READ AS FOLLOWS
 12 [EFFECTIVE JULY 1, 1998]: **Sec. 31. (a) As used in this section,**
 13 **"refilled" includes dispensing a new prescription that is written at**
 14 **the expiration of a prescription that continues a patient's therapy**
 15 **on the same drug.**

16 **(b) A prescription for a drug product with active ingredients or**
 17 **dosage forms with potential bioequivalence problems, drugs**
 18 **characteristically possessing a narrow therapeutic index, or**
 19 **categories of agents for which there is documented evidence of, or**
 20 **a potential for, unequal therapeutic effect or increased patient risk**
 21 **shall be refilled using only the same drug product by the same**
 22 **manufacturer that the pharmacist last dispensed under the**
 23 **prescription, unless:**

24 (1) the physician who prescribed the drug product is notified
 25 by the pharmacist before dispensing another manufacturer's
 26 product; and

27 (2) the:

28 (A) physician who prescribed the drug product; and

29 (B) patient to whom the drug product was dispensed;

30 both provide written consent to the dispensing of another
 31 manufacturer's product.

32 (c) The board shall compile and maintain a list of drugs meeting
 33 the criteria described in subsection (b).

34 (d) The board shall annually distribute a copy of the list
 35 prepared by the board under subsection (c), along with revisions
 36 and additions to the list, to each pharmacy licensed in Indiana. The
 37 board shall also supply a copy of the list to any person, on request,
 38 upon payment of the price established by the board for processing
 39 a copy of the list.

40 (e) The board shall revise and distribute the list prepared by the
 41 board under subsection (c) as often as new information on drugs,
 42 drug products, and dosage formulations becomes available from:



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- 1 **(1) the United States Food and Drug Administration; or**
- 2 **(2) other applicable or relevant sources.**

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