



February 26, 1999

SENATE BILL No. 10

DIGEST OF SB 10 (Updated February 24, 1999 11:49 am - DI 97)

Citations Affected: IC 16-18; IC 16-42.

Synopsis: Generic drug substitutions. Specifies that a legend drug must be dispensed with the drug product specified on the prescription or drug order or by authorization of the practitioner. Specifies that a "generically equivalent drug product" means a multiple source drug product containing identical active ingredients. Prohibits dispensing a legend drug except as provided in the legend drug act. Requires that only generically equivalent drug products may be substituted under the generic drugs law. Adds advanced practice nurses to the definition of "practitioner" in the generic drugs law. Requires the pharmacist to inform the customer when a generic substitution is made. Repeals the definition of "chemically equivalent drug products". (The introduced
(Continued next page)

Effective: July 1, 1999.

Simpson, Miller

January 6, 1999, read first time and referred to Committee on Health and Provider Services.
February 25, 1999, amended, reported favorably — Do Pass.

SB 10—LS 6094/DI 97+



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version of this bill was drafted by the Interim Study Committee on Health Issues.)

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SB 10—LS 6094/DI 97+



February 26, 1999

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.

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SENATE BILL No. 10

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 16-42-19-2 IS AMENDED TO READ AS
2 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 2. As used in this
3 chapter, "drug" means the following:
4 (1) Articles or substances recognized in United States
5 Pharmacopeial Convention, Inc.; The United States
6 Pharmacopeia, Twenty-Second Edition (1990) or United States
7 Pharmacopeial Convention, Inc.; The National Formulary,
8 Seventeenth Edition (1990) as revised by United States
9 Pharmacopeial Convention, Inc.; Supplement 1 to The United
10 States Pharmacopeia, Twenty-Second Edition and The National
11 Formulary, Seventeenth Edition (1990); **and any supplements**
12 **printed after 1990.**
13 (2) Articles or substances intended for use in the diagnosis, cure,
14 mitigation, treatment, or prevention of disease in human beings or
15 other animals.

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1 (3) Articles other than food intended to affect the structure or any
2 function of the body of human beings or other animals.

3 (4) Articles intended for use as a component of any article
4 specified in subdivision (1), (2), or (3).

5 (5) Devices.

6 SECTION 2. IC 16-42-19-11 IS AMENDED TO READ AS
7 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 11. Except as provided
8 in section 21 of this chapter, a person may not sell a legend drug unless
9 either of the following conditions exist:

10 (1) The legend drug is dispensed by a pharmacist upon an original
11 prescription or drug order **with the drug roduct specified on the**
12 **prescription or drug order or by the authorization of the**
13 **practitioner** and there is affixed to the immediate container in
14 which the drug is delivered a label bearing the following:

15 (A) The name, address, and phone number of the
16 establishment from which the drug was dispensed.

17 (B) The date on which the prescription for the drug was filled.

18 (C) The number of the prescription as filed in the prescription
19 files of the pharmacist who filled the prescription.

20 (D) The name of the practitioner who prescribed the drug.

21 (E) The name of the patient, or if the drug was prescribed for
22 an animal, a statement of the species of the animal.

23 (F) The directions for the use of the drug as contained in the
24 prescription.

25 (2) The legend drug is delivered by the practitioner in good faith
26 in the course of practice and the immediate container in which the
27 drug is delivered bears a label on which appears the following:

28 (A) The directions for use of the drug.

29 (B) The name and address of the practitioner.

30 (C) The name of the patient.

31 (D) If the drug is prescribed for an animal, a statement of the
32 species of the animal.

33 This section does not prohibit a practitioner from delivering
34 professional samples of legend drugs in their original containers in the
35 course of the practitioner's practice when oral directions for use are
36 given at the time of delivery.

37 SECTION 3. IC 16-42-19-16 IS AMENDED TO READ AS
38 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 16. A person may not
39 do any of the following:

40 (1) Obtain or attempt to obtain a legend drug or procure or
41 attempt to procure the administration of a legend drug by any of
42 the following:

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- 1 (A) Fraud, deceit, misrepresentation, or subterfuge.
- 2 (B) The forgery or alteration of a prescription, drug order, or
- 3 written order.
- 4 (C) The concealment of a material fact.
- 5 (D) The use of a false name or the giving of a false address.
- 6 (2) Communicate information to a physician in an effort
- 7 unlawfully to procure a legend drug or unlawfully to procure the
- 8 administration of a legend drug. Such a communication is not
- 9 considered a privileged communication.
- 10 (3) Intentionally make a false statement in a prescription, drug
- 11 order, order, report, or record required by this chapter.
- 12 (4) For the purpose of obtaining a legend drug, falsely assume the
- 13 title of or represent oneself to be a manufacturer, wholesaler,
- 14 pharmacist, physician, dentist, veterinarian, or other person.
- 15 (5) Make or utter a false or forged prescription or false drug order
- 16 or forged written order.
- 17 (6) Affix a false or forged label to a package or receptacle
- 18 containing legend drugs. This subdivision does not apply to law
- 19 enforcement agencies or their representatives while engaged in
- 20 enforcing this chapter.

(7) Dispense a legend drug except as provided in this chapter.

SECTION 4. IC 16-42-22-4 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 4. (a) As used in this chapter, "generically equivalent drug product" means a **multiple source** drug product:

- 26 (1) that contains an identical quantity of **identical** active
- 27 ingredients in the identical dosage forms (but not necessarily
- 28 containing the same inactive ingredients) that meet the identical
- 29 physical and chemical standards in The United States
- 30 Pharmacopeia (USP) ~~on July 1, 1987~~; **described in**
- 31 **IC 16-42-19-2, or its supplements**, as the prescribed brand name
- 32 drug; and
- 33 (2) if applicable, for which the manufacturer or distributor holds
- 34 either an approved new drug application or an approved
- 35 abbreviated new drug application unless other approval by law or
- 36 of the federal Food and Drug Administration is required.

(b) A drug does not constitute a generically equivalent drug product if it is listed by the federal Food and Drug Administration on **or after** July 1, 1987, as having actual or potential bioequivalence problems.

SECTION 5. IC 16-42-22-4.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 4.5. As used in this chapter, "practitioner" means any of the following:



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- 1 (1) A licensed physician.
 2 (2) A dentist licensed to practice dentistry in Indiana.
 3 (3) A podiatrist licensed to practice podiatric medicine in Indiana.
 4 (4) An optometrist who is:
 5 (A) licensed to practice optometry in Indiana; and
 6 (B) certified under IC 25-26-15.
 7 **(5) An advanced practice nurse licensed and granted the**
 8 **authority to prescribe legend drugs under IC 25-23.**
 9 SECTION 6. IC 16-42-22-5.5 IS ADDED TO THE INDIANA
 10 CODE AS A NEW SECTION TO READ AS FOLLOWS
 11 [EFFECTIVE JULY 1, 1999]: **Sec. 5.5. Nothing in this chapter**
 12 **authorizes any substitution other than substitution of a generically**
 13 **equivalent drug product.**
 14 SECTION 7. IC 16-42-22-8 IS AMENDED TO READ AS
 15 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 8. (a) For substitution
 16 to occur for a prescription other than a prescription filled under the
 17 Medicaid program (42 U.S.C. 1396 et seq.) or the Medicare program
 18 (42 U.S.C. 1395 et seq.):
 19 (1) the practitioner must sign on the line under which the words
 20 "May substitute" appear; **and**
 21 (2) **the pharmacist must inform the customer of the**
 22 **substitution.**
 23 **(b) This section does not authorize any substitution other than**
 24 **substitution of a generically equivalent drug product.**
 25 SECTION 8. IC 16-42-22-10 IS AMENDED TO READ AS
 26 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 10. (a) If a prescription
 27 is filled under the Medicaid program (42 U.S.C. 1396 et seq.) or the
 28 Medicare program (42 U.S.C. 1395 et seq.), the pharmacist shall
 29 substitute a generically equivalent drug product **and inform the**
 30 **customer of the substitution** if the substitution would result in a lower
 31 price unless:
 32 (1) the words "Brand Medically Necessary" are written in the
 33 practitioner's own writing on the form; or
 34 (2) the practitioner has indicated that the pharmacist may not
 35 substitute a generically equivalent drug product by orally stating
 36 that a substitution is not permitted.
 37 (b) If a practitioner orally states that a generically equivalent drug
 38 product may not be substituted, the practitioner must subsequently
 39 forward to the pharmacist a written prescription with the "Brand
 40 Medically Necessary" instruction appropriately indicated in the
 41 physician's own handwriting.
 42 (c) **This section does not authorize any substitution other than**

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1 **substitution of a generically equivalent drug product.**
2 SECTION 9. THE FOLLOWING ARE REPEALED [EFFECTIVE
3 JULY 1, 1999]: IC 16-18-2-54; IC 16-42-22-2; IC 16-42-22-7.

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SENATE MOTION

Mr. President: I move that Senator Miller be added as second author of Senate Bill 10.

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COMMITTEE REPORT

Mr. President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 10, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 2, line 11, delete "in the manner designated" and insert "**with the drug product specified**".

and when so amended that said bill do pass.

(Reference is to SB 10 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 9, Nays 0.

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