



March 30, 1999

**ENGROSSED
SENATE BILL No. 10**

DIGEST OF SB 10 (Updated March 24, 1999 8:10 pm - DI 77)

Citations Affected: IC 12-15; IC 16-18; IC 16-42.

Synopsis: Generic drug substitutions. Requires the Medicaid program to cover certain legend drugs that are recommended by the drug utilization review board. Except as provided by other laws, requires a legend drug be dispensed with the drug product specified on the prescription or drug order or by authorization of the practitioner.
(Continued next page)

Effective: Upon passage; July 1, 1999.

Simpson, Miller, Lawson C
(HOUSE SPONSORS — WELCH, BECKER, BROWN C)

January 6, 1999, read first time and referred to Committee on Health and Provider Services.
February 25, 1999, amended, reported favorably — Do Pass.
March 1, 1999, read second time, ordered engrossed.
March 2, 1999, engrossed.
March 3, 1999, read third time, passed. Yeas 49, nays 0. Rule 33(c) technical correction adopted.
March 4, 1999, engrossed.

HOUSE ACTION

March 8, 1999, read first time and referred to Committee on Public Health.
March 29, 1999, amended, reported — Do Pass.

C
O
P
Y

ES 10—LS 6094/DI 97+



Digest Continued

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

C
o
p
y



March 30, 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.

ENGROSSED 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 12-15-5-4 IS ADDED TO THE INDIANA CODE
2 AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE
3 UPON PASSAGE]: **Sec. 4. (a) The Medicaid program and the**
4 **program's agents, contractors, and vendors shall provide coverage**
5 **and reimbursement for outpatient single source legend drugs:**

6 (1) **in compliance with federal law under 42 U.S.C. 1396 et**
7 **seq. and IC 12-15-35; and**

8 (2) **based on the recommendations of the drug utilization**
9 **review board established under IC 12-15-35.**

10 (b) **The drug utilization review board shall adopt rules under**
11 **IC 4-22-2 to implement this section not later than December 31,**
12 **1999.**

13 SECTION 2. IC 16-42-19-2 IS AMENDED TO READ AS
14 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 2. As used in this
15 chapter, "drug" means the following:

ES 10—LS 6094/DI 97+



C
O
P
Y

- 1 (1) Articles or substances recognized in United States
 2 Pharmacopeial Convention, Inc.; The United States
 3 Pharmacopeia, Twenty-Second Edition (1990) or United States
 4 Pharmacopeial Convention, Inc.; The National Formulary,
 5 Seventeenth Edition (1990) as revised by United States
 6 Pharmacopeial Convention, Inc.; Supplement 1 to The United
 7 States Pharmacopeia, Twenty-Second Edition and The National
 8 Formulary, Seventeenth Edition (1990); **and any supplements**
 9 **printed after 1990.**
- 10 (2) Articles or substances intended for use in the diagnosis, cure,
 11 mitigation, treatment, or prevention of disease in human beings or
 12 other animals.
- 13 (3) Articles other than food intended to affect the structure or any
 14 function of the body of human beings or other animals.
- 15 (4) Articles intended for use as a component of any article
 16 specified in subdivision (1), (2), or (3).
- 17 (5) Devices.
- 18 SECTION 3. IC 16-42-19-11 IS AMENDED TO READ AS
 19 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 11. (a) Except as
 20 provided in section 21 of this chapter, a person may not sell a legend
 21 drug unless either of the following conditions exist:
- 22 (1) **Except as provided in subsection (b),** the legend drug is
 23 dispensed by a pharmacist upon an original prescription or drug
 24 order **with the drug product specified on the prescription or**
 25 **drug order or by the authorization of the practitioner** and
 26 there is affixed to the immediate container in which the drug is
 27 delivered a label bearing the following:
- 28 (A) The name, address, and phone number of the
 29 establishment from which the drug was dispensed.
- 30 (B) The date on which the prescription for the drug was filled.
- 31 (C) The number of the prescription as filed in the prescription
 32 files of the pharmacist who filled the prescription.
- 33 (D) The name of the practitioner who prescribed the drug.
- 34 (E) The name of the patient, or if the drug was prescribed for
 35 an animal, a statement of the species of the animal.
- 36 (F) The directions for the use of the drug as contained in the
 37 prescription.
- 38 (2) The legend drug is delivered by the practitioner in good faith
 39 in the course of practice and the immediate container in which the
 40 drug is delivered bears a label on which appears the following:
- 41 (A) The directions for use of the drug.
- 42 (B) The name and address of the practitioner.



C
O
P
Y

1 (C) The name of the patient.

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

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

8 **(b) Notwithstanding subsection (a)(1), the following apply:**

9 **(1) A pharmacist at a hospital licensed under IC 16-21 may fill**
10 **a drug order for a legend drug with a drug product allowed**
11 **under the hospital's policies and procedures for the use,**
12 **selection, and procurement of drugs.**

13 **(2) A pharmacist who fills a prescription for a legend drug**
14 **must comply with IC 16-42-22 and IC 25-26-16.**

15 SECTION 4. IC 16-42-19-16 IS AMENDED TO READ AS
16 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 16. A person may not
17 do any of the following:

18 (1) Obtain or attempt to obtain a legend drug or procure or
19 attempt to procure the administration of a legend drug by any of
20 the following:

21 (A) Fraud, deceit, misrepresentation, or subterfuge.

22 (B) The forgery or alteration of a prescription, drug order, or
23 written order.

24 (C) The concealment of a material fact.

25 (D) The use of a false name or the giving of a false address.

26 (2) Communicate information to a physician in an effort
27 unlawfully to procure a legend drug or unlawfully to procure the
28 administration of a legend drug. Such a communication is not
29 considered a privileged communication.

30 (3) Intentionally make a false statement in a prescription, drug
31 order, order, report, or record required by this chapter.

32 (4) For the purpose of obtaining a legend drug, falsely assume the
33 title of or represent oneself to be a manufacturer, wholesaler,
34 pharmacist, physician, dentist, veterinarian, or other person.

35 (5) Make or utter a false or forged prescription or false drug order
36 or forged written order.

37 (6) Affix a false or forged label to a package or receptacle
38 containing legend drugs. This subdivision does not apply to law
39 enforcement agencies or their representatives while engaged in
40 enforcing this chapter.

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

42 SECTION 5. IC 16-42-22-4 IS AMENDED TO READ AS



C
O
P
Y

1 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 4. (a) As used in this
 2 chapter, "generically equivalent drug product" means a **multiple**
 3 **source** drug product:

4 (1) that contains an identical quantity of **identical** active
 5 ingredients in the identical dosage forms (but not necessarily
 6 containing the same inactive ingredients) that meet the identical
 7 physical and chemical standards in The United States
 8 Pharmacopeia (USP) ~~on July 1, 1987~~, **described in**
 9 **IC 16-42-19-2, or its supplements**, as the prescribed brand name
 10 drug; and

11 (2) if applicable, for which the manufacturer or distributor holds
 12 either an approved new drug application or an approved
 13 abbreviated new drug application unless other approval by law or
 14 of the federal Food and Drug Administration is required.

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

18 SECTION 6. IC 16-42-22-4.5 IS AMENDED TO READ AS
 19 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 4.5. As used in this
 20 chapter, "practitioner" means any of the following:

- 21 (1) A licensed physician.
 22 (2) A dentist licensed to practice dentistry in Indiana.
 23 (3) A podiatrist licensed to practice podiatric medicine in Indiana.
 24 (4) An optometrist who is:
 25 (A) licensed to practice optometry in Indiana; and
 26 (B) certified under IC 25-26-15.

27 **(5) An advanced practice nurse licensed and granted the**
 28 **authority to prescribe legend drugs under IC 25-23.**

29 SECTION 7. IC 16-42-22-5.5 IS ADDED TO THE INDIANA
 30 CODE AS A NEW SECTION TO READ AS FOLLOWS
 31 [EFFECTIVE JULY 1, 1999]: **Sec. 5.5. Nothing in this chapter**
 32 **authorizes any substitution other than substitution of a generically**
 33 **equivalent drug product.**

34 SECTION 8. IC 16-42-22-8 IS AMENDED TO READ AS
 35 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 8. **(a)** For substitution
 36 to occur for a prescription other than a prescription filled under the
 37 Medicaid program (42 U.S.C. 1396 et seq.) or the Medicare program
 38 (42 U.S.C. 1395 et seq.):

- 39 **(1)** the practitioner must sign on the line under which the words
 40 "May substitute" appear; **and**
 41 **(2) the pharmacist must inform the customer of the**
 42 **substitution.**



C
O
P
Y

1 **(b) This section does not authorize any substitution other than**
2 **substitution of a generically equivalent drug product.**
3 SECTION 9. IC 16-42-22-10 IS AMENDED TO READ AS
4 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 10. (a) If a prescription
5 is filled under the Medicaid program (42 U.S.C. 1396 et seq.) or the
6 Medicare program (42 U.S.C. 1395 et seq.), the pharmacist shall
7 substitute a generically equivalent drug product **and inform the**
8 **customer of the substitution** if the substitution would result in a lower
9 price unless:
10 (1) the words "Brand Medically Necessary" are written in the
11 practitioner's own writing on the form; or
12 (2) the practitioner has indicated that the pharmacist may not
13 substitute a generically equivalent drug product by orally stating
14 that a substitution is not permitted.
15 (b) If a practitioner orally states that a generically equivalent drug
16 product may not be substituted, the practitioner must subsequently
17 forward to the pharmacist a written prescription with the "Brand
18 Medically Necessary" instruction appropriately indicated in the
19 physician's own handwriting.
20 **(c) This section does not authorize any substitution other than**
21 **substitution of a generically equivalent drug product.**
22 SECTION 10. THE FOLLOWING ARE REPEALED [EFFECTIVE
23 JULY 1, 1999]: IC 16-18-2-54; IC 16-42-22-2; IC 16-42-22-7.
24 SECTION 11. **An emergency is declared for this act.**

C
O
P
Y



SENATE MOTION

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

SIMPSON

C
o
p
y



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.

C
o
p
y



COMMITTEE REPORT

Mr. President: The Senate Committee on Rules and Legislative Procedure reports that, pursuant to Senate Rule 33(c), the following technical corrections are to be made to Senate Bill 10.

Page 2, line 11, delete "roduct" and insert "**product**".

(Reference is to SB 10 as printed February 26, 1999.)

GARTON

C
o
p
y



SENATE MOTION

Mr. President: I move that Senator Lawson C be added as coauthor of Senate Bill 10.

SIMPSON

C
o
p
y



COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 109, 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:

Delete the amendment made pursuant to Senate Rule 33(c) on motion of Senator Garton adopted March 3, 1999.

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 12-15-5-4 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 4. (a) The Medicaid program and the program's agents, contractors, and vendors shall provide coverage and reimbursement for outpatient single source legend drugs:**

(1) in compliance with federal law under 42 U.S.C. 1396 et seq. and IC 12-15-35; and

(2) based on the recommendations of the drug utilization review board established under IC 12-15-35.

(b) The drug utilization review board shall adopt rules under IC 4-22-2 to implement this section not later than December 31, 1999."

Page 2, line 7, after "11." insert "(a)".

Page 2, line 10, after "(1)" insert "**Except as provided in subsection (b),**".

Page 2, line 10, delete "The" and insert "the".

Page 2, line 11, delete "roduct" and insert "**product**".

Page 2, between lines 36 and 37, begin a new paragraph and insert:

"(b) Notwithstanding subsection (a)(1), the following apply:

(1) A pharmacist at a hospital licensed under IC 16-21 may fill a drug order for a legend drug with a drug product allowed under the hospital's policies and procedures for the use, selection, and procurement of drugs.

(2) A pharmacist who fills a prescription for a legend drug must comply with IC 16-42-22 and IC 25-26-16."

Page 5, after line 3, begin a new paragraph and insert:

"SECTION 11. An emergency is declared for this act."

Renumber all SECTIONS consecutively.

C
O
P
Y



and when so amended that said bill do pass.

(Reference is to SB 10 as printed February 26, 1999, and as amended pursuant to Senate Rule 33(c) on motion of Senator Garton adopted March 3, 1999.)

BROWN C, Chair

Committee Vote: yeas 12, nays 0.

C
o
p
y

