



Reprinted  
April 8, 1999

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## ENGROSSED SENATE BILL No. 10

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DIGEST OF SB 10 (Updated April 7, 1999 4:25 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 single source legend drugs that are recommended by the drug utilization review board. Modifies the conditions for the drug utilization board to place a single source drug on prior approval, restrict the drug's use, or establish a drug monitoring program. 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. Specifies that a "generically equivalent drug product" means a multiple source drug product containing identical active ingredients. Prohibits dispensing a legend  
(Continued next page)

**Effective:** Upon passage; July 1, 1999.

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### Simpson, Miller, Lawson C

(HOUSE SPONSORS — WELCH, BECKER, BROWN C, CROSBY)

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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.  
April 7, 1999, read second time, amended, ordered engrossed.

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ES 10—LS 6094/DI 97+



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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.)

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ES 10—LS 6094/DI 97+



Reprinted  
April 8, 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

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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 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. The Medicaid program and the**  
4 **program's agents, contractors, and vendors shall provide coverage**  
5 **and reimbursement for outpatient single source legend drugs in**  
6 **compliance with federal law under 42 U.S.C. 1396 et seq. and**  
7 **IC 12-15-35.**

8 SECTION 2. IC 12-15-35-35 IS AMENDED TO READ AS  
9 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 35. (a) As used in this  
10 section, "single source drug" means a covered outpatient drug that is  
11 produced or distributed under an original new drug application  
12 approved by the federal Food and Drug Administration, including a  
13 drug product marketed by any cross-licensed producers or distributors  
14 operating under the new drug application.

15 (b) Before the ~~approval or implementation~~ of a board places a

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1 **single source drug on prior approval, program for outpatient single**  
 2 **source drugs, restricts the drug in its use, or establishes a drug**  
 3 **monitoring process or program to measure or restrict utilization of**  
 4 **single source drugs other than in the SURS program, the program**  
 5 **board must meet the following conditions:**

6 (1) **An outpatient single source drug may not be placed on prior**  
 7 **approval or restricted in its use for other than medical reasons.**  
 8 **Make a determination after considering evidence and**  
 9 **information provided to the board by the office and the public**  
 10 **that placing a single source drug on prior approval or**  
 11 **restricting the drug's use will not impede the quality of**  
 12 **patient care.**

13 (2) **Before a single source drug is placed on prior approval or**  
 14 **restricted in its use, the board must Hold a public hearing under**  
 15 **IC 4-22 at least ninety (90) days before taking the action.**

16 (3) **The board must Provide evidence that placing a single source**  
 17 **drug on prior approval or restricting its use will not: impede the**  
 18 **quality of patient care and that the single source drug is subject to**  
 19 **clinical abuse or misuse before the board recommends that the**  
 20 **drug be placed on prior approval or restricted in its use.**

21 (A) **increase costs in other parts of the Medicaid program,**  
 22 **including hospital costs and physician costs; and**

23 (B) **result in less than optimal therapeutic outcomes.**

24 (4) **Any single source drug placed on prior approval or restricted**  
 25 **in its use will be reconsidered for Reconsider the removal from**  
 26 **its restricted status by the board from prior approval not later than**  
 27 **six (6) months after the single source drug is placed on prior**  
 28 **approval or restricted in its use.**

29 (5) **Any prior approval program Must provide ensure that the**  
 30 **program provides either telephone or FAX approval or denial**  
 31 **Monday through Friday, twenty-four (24) hours a day. The office**  
 32 **must provide the approval or denial within twenty-four (24) hours**  
 33 **after receipt of a prior approval request. The program must**  
 34 **provide for the dispensing of at least a seventy-two (72) -hour**  
 35 **supply of the drug in an emergency situation or on weekends.**

36 (6) **Ensure that any prior approval program or restriction on the**  
 37 **use of a single source drug may is not be applied to prevent**  
 38 **acceptable medical use for appropriate off-label indications.**

39 (c) **The DUR board shall advise the office on the implementation of**  
 40 **any program to restrict the use of brand name multisource drugs.**

41 (d) **This section does not prohibit the board from considering**  
 42 **health, economic, or cost data.**



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1 SECTION 3. 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.

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

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

20 (5) Devices.

21 SECTION 4. IC 16-42-19-11 IS AMENDED TO READ AS  
 22 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 11. (a) Except as  
 23 provided in section 21 of this chapter, a person may not sell a legend  
 24 drug unless either of the following conditions exist:

25 (1) **Except as provided in subsection (b),** the legend drug is  
 26 dispensed by a pharmacist upon an original prescription or drug  
 27 order **with the drug product specified on the prescription or**  
 28 **drug order or by the authorization of the practitioner** and  
 29 there is affixed to the immediate container in which the drug is  
 30 delivered a label bearing the following:

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

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

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

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

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

39 (F) The directions for the use of the drug as contained in the  
 40 prescription.

41 (2) The legend drug is delivered by the practitioner in good faith  
 42 in the course of practice and the immediate container in which the

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1 drug is delivered bears a label on which appears the following:

- 2 (A) The directions for use of the drug.  
 3 (B) The name and address of the practitioner.  
 4 (C) The name of the patient.  
 5 (D) If the drug is prescribed for an animal, a statement of the  
 6 species of the animal.

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

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

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

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

18 SECTION 5. IC 16-42-19-16 IS AMENDED TO READ AS  
 19 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 16. A person may not  
 20 do any of the following:

21 (1) Obtain or attempt to obtain a legend drug or procure or  
 22 attempt to procure the administration of a legend drug by any of  
 23 the following:

- 24 (A) Fraud, deceit, misrepresentation, or subterfuge.  
 25 (B) The forgery or alteration of a prescription, drug order, or  
 26 written order.  
 27 (C) The concealment of a material fact.  
 28 (D) The use of a false name or the giving of a false address.

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

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

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

38 (5) Make or utter a false or forged prescription or false drug order  
 39 or forged written order.

40 (6) Affix a false or forged label to a package or receptacle  
 41 containing legend drugs. This subdivision does not apply to law  
 42 enforcement agencies or their representatives while engaged in

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1 enforcing this chapter.

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

3 SECTION 6. IC 16-42-22-4 IS AMENDED TO READ AS  
4 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 4. (a) As used in this  
5 chapter, "generically equivalent drug product" means a **multiple**  
6 **source** drug product:

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

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

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

21 SECTION 7. IC 16-42-22-4.5 IS AMENDED TO READ AS  
22 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 4.5. As used in this  
23 chapter, "practitioner" means any of the following:

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

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

32 SECTION 8. IC 16-42-22-5.5 IS ADDED TO THE INDIANA  
33 CODE AS A **NEW SECTION** TO READ AS FOLLOWS  
34 [EFFECTIVE JULY 1, 1999]: **Sec. 5.5. Nothing in this chapter**  
35 **authorizes any substitution other than substitution of a generically**  
36 **equivalent drug product.**

37 SECTION 9. IC 16-42-22-8 IS AMENDED TO READ AS  
38 FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 8. (a) For substitution  
39 to occur for a prescription other than a prescription filled under the  
40 Medicaid program (42 U.S.C. 1396 et seq.) or the Medicare program  
41 (42 U.S.C. 1395 et seq.):

42 (1) the practitioner must sign on the line under which the words

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

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SENATE MOTION

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

SIMPSON

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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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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

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SENATE MOTION

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

SIMPSON

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## COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 10, 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 GARTON

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.

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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

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## HOUSE MOTION

Mr. Speaker: I move that Engrossed Senate Bill 10 be amended to read as follows:

Page 1, line 3, delete "(a)".

Page 1, line 5, delete ":".

Page 1, line 6, delete "(1)".

Page 1, line 7, delete "; and" and insert "."

Page 1, run in lines 5 through 7

Page 1, delete lines 8 through 12.

Page 1, between lines 12 and 13, begin a new paragraph and insert:  
 "SECTION 2. IC 12-15-35-35 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 35. (a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(b) Before the ~~approval or implementation of a board places a single source drug on~~ prior approval, ~~program for outpatient single source drugs, restricts the drug in its use,~~ or ~~establishes~~ a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the ~~program board~~ must meet the following conditions:

(1) ~~An outpatient single source drug may not be placed on prior approval or restricted in its use for other than medical reasons. Make a determination after considering evidence and information provided to the board by the office and the public that placing a single source drug on prior approval or restricting the drug's use will not impede the quality of patient care.~~

(2) ~~Before a single source drug is placed on prior approval or restricted in its use, the board must~~ Hold a public hearing under IC 4-22 at least ninety (90) days before taking the action.

(3) ~~The board must~~ Provide evidence that placing a single source drug on prior approval or restricting its use will not: ~~impede the quality of patient care and that the single source drug is subject to clinical abuse or misuse before the board recommends that the drug be placed on prior approval or restricted in its use:~~

(A) ~~increase costs in other parts of the Medicaid program, including hospital costs and physician costs; and~~

(B) ~~result in less than optimal therapeutic outcomes.~~

(4) ~~Any single source drug placed on prior approval or restricted~~



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~~in its use will be reconsidered for~~ **Reconsider the** removal from its restricted status by the board from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) ~~Any prior approval program~~ Must ~~provide~~ **ensure that the program provides** either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) **Ensure that** any prior approval program or restriction on the use of a single source drug ~~may is not be~~ applied to prevent acceptable medical use for appropriate off-label indications.

(c) The DUR board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(d) **This section does not prohibit the board from considering health, economic, or cost data."**

Renumber all SECTIONS consecutively.

(Reference is to ESB 10 as printed March 30, 1999.)

WELCH

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