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# SENATE BILL No. 492

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## DIGEST OF INTRODUCED BILL

**Citations Affected:** IC 12-7-2-91.7; 7IC 12-15-35.

**Synopsis:** Medicaid generic drug reimbursement program. Requires the drug utilization review board (board) to develop, implement, and maintain a generically equivalent drug product Medicaid reimbursement program (program). Requires the manufacturer of a generically equivalent drug product to submit the cost that it would offer to a Medicaid provider for its drug in order to participate in the Medicaid program, and specifies that the cost may not exceed the maximum allowable rate determined by the office of Medicaid policy and planning. Requires the board to review the submissions and determine a Medicaid reimbursement rate for the therapeutic drug classification. Requires the office of Medicaid policy and planning to reimburse Medicaid providers at the rate determined by the board for the therapeutic drug classification. Establishes a time line for the implementation of the program for certain therapeutic drug classifications.

**Effective:** July 1, 2011.

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January 13, 2011, read first time and referred to Committee on Health and Provider Services.

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First Regular Session 117th General Assembly (2011)

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 2010 Regular Session of the General Assembly.

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## SENATE BILL No. 492



A BILL FOR AN ACT to amend the Indiana Code concerning Medicaid.

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

1 SECTION 1. IC 12-7-2-91.7 IS ADDED TO THE INDIANA CODE  
2 AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY  
3 1, 2011]: **Sec. 91.7. "Generically equivalent drug product", for**  
4 **purposes of IC 12-15-35 and IC 12-15-35.5, has the meaning set**  
5 **forth in IC 12-15-35-8.5.**

6 SECTION 2. IC 12-15-35-8.5 IS ADDED TO THE INDIANA  
7 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
8 [EFFECTIVE JULY 1, 2011]: **Sec. 8.5. As used in this chapter and**  
9 **IC 12-15-35.5, "generically equivalent drug product" means a**  
10 **multiple source drug product:**

- 11 (1) **that contains an identical quantity of identical active**
- 12 **ingredients in the identical dosage forms (but not necessarily**
- 13 **containing the same inactive ingredients) that meets the**
- 14 **identical physical and chemical standards in The United**
- 15 **States Pharmacopeia (USP) described in IC 16-42-19-2, or its**
- 16 **supplements, as the prescribed brand name drug; and**
- 17 (2) **if applicable, for which the manufacturer or distributor**



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**holds either an approved new drug application or an approved abbreviated new drug application unless other approval by law or of the federal Food and Drug Administration is required.**

**The term does not include a drug product if the drug product is listed by the federal Food and Drug Administration on or after July 1, 1987, as having actual or potential bioequivalence problems.**

SECTION 3. IC 12-15-35-28, AS AMENDED BY P.L.101-2005, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 28. (a) The board has the following duties:

- (1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.
- (2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.
- (3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.
- (4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.
- (5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year. The report issued to the legislative council must be in an electronic format under IC 5-14-6.
- (6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:
  - (A) The Indiana board of pharmacy.
  - (B) The medical licensing board of Indiana.

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- 1 (C) The SURS staff.
- 2 (7) The establishment of a grievance and appeals process for
- 3 **generically equivalent drug product manufacturers,**
- 4 **physicians, or pharmacists under this chapter.**
- 5 (8) The publication and dissemination of educational information
- 6 to physicians and pharmacists regarding the board and the DUR
- 7 program, including information on the following:
- 8 (A) Identifying and reducing the frequency of patterns of
- 9 fraud, abuse, gross overuse, or inappropriate or medically
- 10 unnecessary care among physicians, pharmacists, and
- 11 recipients.
- 12 (B) Potential or actual severe or adverse reactions to drugs.
- 13 (C) Therapeutic appropriateness.
- 14 (D) Overutilization or underutilization.
- 15 (E) Appropriate use of ~~generic drugs~~: **generically equivalent**
- 16 **drug products.**
- 17 (F) Therapeutic duplication.
- 18 (G) Drug-disease contraindications.
- 19 (H) Drug-drug interactions.
- 20 (I) Incorrect drug dosage and duration of drug treatment.
- 21 (J) Drug allergy interactions.
- 22 (K) Clinical abuse and misuse.
- 23 (9) The adoption and implementation of procedures designed to
- 24 ensure the confidentiality of any information collected, stored,
- 25 retrieved, assessed, or analyzed by the board, staff to the board, or
- 26 contractors to the DUR program that identifies individual
- 27 physicians, pharmacists, or recipients.
- 28 (10) The implementation of additional drug utilization review
- 29 with respect to drugs dispensed to residents of nursing facilities
- 30 shall not be required if the nursing facility is in compliance with
- 31 the drug regimen procedures under 410 IAC 16.2-3.1 and 42 CFR
- 32 483.60.
- 33 (11) The research, development, and approval of a preferred drug
- 34 list for:
- 35 (A) Medicaid's fee for service program;
- 36 (B) Medicaid's primary care case management program;
- 37 (C) Medicaid's risk based managed care program, if the office
- 38 provides a prescription drug benefit and subject to IC 12-15-5;
- 39 and
- 40 (D) the children's health insurance program under IC 12-17.6;
- 41 in consultation with the therapeutics committee.
- 42 (12) The approval of the review and maintenance of the preferred

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drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(15) Advising the Indiana comprehensive health insurance association established by IC 27-8-10-2.1 concerning implementation of chronic disease management and pharmaceutical management programs under IC 27-8-10-3.5.

**(16) For therapeutic drug classifications with at least two (2) manufactured generically equivalent drug products, establish a generically equivalent drug product Medicaid reimbursement program, in consultation with the therapeutics committee, that requires a manufacturer of a generically equivalent drug product to submit pricing of the generically equivalent drug product to the board for review in the manner specified in section 50.5 of this chapter in order to participate in the Medicaid program.**

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list **and a generically equivalent drug product Medicaid reimbursement program.** The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

- (1) Use literature abstracting technology.
- (2) Use commonly accepted guidance principles of disease management.
- (3) Develop therapeutic classifications for the preferred drug list.
- (4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.
- (5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that is not included on the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and

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1 Drug Administration on the preferred drug list not later than sixty (60)  
 2 days after the date on which the manufacturer notifies the board in  
 3 writing of the drug's approval. However, if the board determines that  
 4 there is inadequate information about the drug available to the board  
 5 to make a determination, the board may have an additional sixty (60)  
 6 days to make a determination from the date that the board receives  
 7 adequate information to perform the board's review. Prior authorization  
 8 may not be automatically required for a single source drug that is newly  
 9 approved by the federal Food and Drug Administration, and that is:

10 (1) in a therapeutic classification:

11 (A) that has not been reviewed by the board; and

12 (B) for which prior authorization is not required; or

13 (2) the sole drug in a new therapeutic classification that has not  
 14 been reviewed by the board.

15 (f) The board may not exclude a drug from the preferred drug list  
 16 based solely on price.

17 (g) The following requirements apply to a preferred drug list  
 18 developed under subsection (a)(11):

19 (1) Except as provided by IC 12-15-35.5-3(b) and  
 20 IC 12-15-35.5-3(c), the office or the board may require prior  
 21 authorization for a drug that is included on the preferred drug list  
 22 under the following circumstances:

23 (A) To override a prospective drug utilization review alert.

24 (B) To permit reimbursement for a medically necessary brand  
 25 name drug that is subject to generic substitution under  
 26 IC 16-42-22-10.

27 (C) To prevent fraud, abuse, waste, overutilization, or  
 28 inappropriate utilization.

29 (D) To permit implementation of a disease management  
 30 program.

31 (E) To implement other initiatives permitted by state or federal  
 32 law.

33 (2) All drugs described in IC 12-15-35.5-3(b) must be included on  
 34 the preferred drug list.

35 (3) The office may add a drug that has been approved by the  
 36 federal Food and Drug Administration to the preferred drug list  
 37 without prior approval from the board.

38 (4) The board may add a drug that has been approved by the  
 39 federal Food and Drug Administration to the preferred drug list.

40 (h) At least two (2) times each year, the board shall provide a report  
 41 to the select joint commission on Medicaid oversight established by  
 42 IC 2-5-26-3. The report must contain the following information:

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- 1 (1) The cost of administering the preferred drug list.
- 2 (2) Any increase in Medicaid physician, laboratory, or hospital
- 3 costs or in other state funded programs as a result of the preferred
- 4 drug list.
- 5 (3) The impact of the preferred drug list on the ability of a
- 6 Medicaid recipient to obtain prescription drugs.
- 7 (4) The number of times prior authorization was requested, and
- 8 the number of times prior authorization was:
- 9 (A) approved; and
- 10 (B) disapproved.

11 (i) The board shall provide the first report required under subsection  
 12 (h) not later than six (6) months after the board submits an initial  
 13 preferred drug list to the office.

14 **(j) The office shall implement and maintain the generically**  
 15 **equivalent drug Medicaid reimbursement program established by**  
 16 **the board under subsection (a)(16) and as specified in section 50.5**  
 17 **of this chapter.**

18 SECTION 4. IC 12-15-35-28.5 IS AMENDED TO READ AS  
 19 FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 28.5. The therapeutics  
 20 committee established under section 20.5 of this chapter shall do the  
 21 following:

- 22 (1) Advise and make recommendations to the board in the board's
- 23 development and maintenance of a preferred drug list under
- 24 section 28 of this chapter.
- 25 (2) Submit to the board a proposed preferred drug list that has
- 26 been approved by a majority of a quorum of the therapeutics
- 27 committee.
- 28 (3) Advise and make recommendations to the board in the board's
- 29 review and maintenance of a preferred drug list.
- 30 **(4) Advise and make recommendations to the board in the**
- 31 **board's implementation and maintenance of the generically**
- 32 **equivalent drug product Medicaid reimbursement program**
- 33 **described in sections 28(a)(16) and 50.5 of this chapter.**

34 SECTION 5. IC 12-15-35-43.5 IS AMENDED TO READ AS  
 35 FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 43.5. (a) The board, the  
 36 therapeutics committee, or the office may not release proprietary or  
 37 confidential information obtained as part of the development,  
 38 implementation, or maintenance of **the following:**

- 39 (1) A preferred drug list under this chapter.
- 40 **(2) The generically equivalent drug product Medicaid**
- 41 **reimbursement program under this chapter.**
- 42 (b) Information described in subsection (a) is confidential for

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1 purposes of IC 5-14-3-4(a)(1).

2 SECTION 6. IC 12-15-35-50, AS ADDED BY P.L.187-2007,  
3 SECTION 8, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
4 JULY 1, 2011]: Sec. 50. (a) IC 12-15-13-6 does not apply to this  
5 section.

6 (b) The office shall maintain an Internet web site and post on the  
7 web site any changes concerning the office's maximum allowable cost  
8 schedule for drugs.

9 (c) A change in the office's maximum allowable cost schedule for  
10 drugs may not take effect less than thirty (30) days after the change is  
11 posted on the office's Internet web site.

12 (d) The office is not required to mail a notice to providers  
13 concerning a change in the office's maximum allowable cost schedule  
14 for drugs.

15 (e) A pharmacy may determine not to participate in the Medicaid  
16 program because of a change to the office's maximum allowable cost  
17 schedule for drugs **or the reimbursement rate determined under**  
18 **section 50.5 of this chapter** if the pharmacy notifies the office not less  
19 than thirty (30) days after the changes take effect.

20 SECTION 7. IC 12-15-35-50.5 IS ADDED TO THE INDIANA  
21 CODE AS A **NEW** SECTION TO READ AS FOLLOWS  
22 [EFFECTIVE JULY 1, 2011]: **Sec. 50.5 (a) The board shall establish**  
23 **a procedure under the generically equivalent drug product**  
24 **Medicaid reimbursement program for a generically equivalent**  
25 **drug manufacturer to submit to the board the cost the**  
26 **manufacturer would offer the Medicaid program for the**  
27 **generically equivalent drug product of the manufacturer.**

28 (b) **In order to participate in the Medicaid program, a**  
29 **generically equivalent drug manufacturer doing business in**  
30 **Indiana shall submit to the board, in the manner determined by the**  
31 **board, the cost the manufacturer would offer providers of the**  
32 **Medicaid program for the generically equivalent drug product of**  
33 **the manufacturer.**

34 (c) **The cost submitted by the generically equivalent drug**  
35 **product manufacturer under subsection (b) to the office may not**  
36 **be more than the maximum allowable cost for the drug, as**  
37 **determined by the office or a contractor of the office, at the time of**  
38 **the submission.**

39 (d) **The board shall review all the submissions by generically**  
40 **equivalent drug product manufacturers for a therapeutic**  
41 **classification, and based on the submissions, determine the**  
42 **Medicaid reimbursement rate for a generically equivalent drug**

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product for the therapeutic drug classification.

(e) At least annually, and at any other time determined by the board, the office or the board may require a generically equivalent drug product manufacturer to submit the costs of a generically equivalent drug product under subsection (b).

(f) The office shall reimburse a provider under the Medicaid program for a generically equivalent drug product at the rate determined by the drug utilization review board for the therapeutic classification under this section.

(g) In the implementation of the generically equivalent drug product Medicaid reimbursement program, the board shall determine the rates of a therapeutic classification in the following manner:

(1) For the five (5) therapeutic classifications that have:  
(A) at least two (2) manufactured generically equivalent drug products; and

(B) the most expensive generic equivalent drug products; the board shall submit the rate determined by the board under this section to the office not later than January 1, 2012.

(2) For the next five (5) therapeutic classifications that:  
(A) have at least two (2) generically equivalent drug products; and

(B) are prescribed the most frequently in the Medicaid program; the board shall submit the rate determined under this section to the office not later than May 1, 2012.

(3) For the remaining therapeutic classifications that have at least two (2) manufactured generically equivalent drug products, the board shall submit the rate determined under this section to the office not later than September 1, 2012.

(h) The office may adopt rules under IC 4-22-2 necessary to implement this section.

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