

SENATE BILL No. 211

DIGEST OF INTRODUCED BILL

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

Synopsis: Generic drug bidding program. Requires the drug utilization review board (board) to establish a competitive bidding program for generically equivalent drug product manufacturers (manufacturer) of drugs in therapeutic drug classifications with at least three manufactured generically equivalent drug products. Requires a manufacturer that participates in Medicaid or the children's health insurance program (CHIP) to participate in the competitive bidding program. Requires the board to establish a Medicaid preferred generic drug list (list) based on the successful bids and requires prior authorization on the Medicaid program and CHIP for a generically equivalent drug product that is not included on the list. Requires a manufacturer of a generically equivalent drug product that is included on the list to offer state supplement rebates. Requires the office of Medicaid policy and planning to request bids under the competitive bidding program at least one time every five years.

Effective: July 1, 2012.

Gard

January 4, 2012, read first time and referred to Committee on Health and Provider Services.

C
O
P
Y



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 2011 Regular Session of the General Assembly.

C
o
p
y

SENATE BILL No. 211



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, 2012]: **Sec. 91.7. (a) "Generically equivalent drug product", for**
 4 **purposes of IC 12-15-35, means a multiple source drug product:**
 5 **(1) that contains an identical quantity of identical active**
 6 **ingredients in the identical dosage forms (but not necessarily**
 7 **containing the same inactive ingredients) that meet the**
 8 **identical physical and chemical standards in The United**
 9 **States Pharmacopeia (USP) described in IC 16-42-19-2, or its**
 10 **supplements, as the prescribed brand name drug; and**
 11 **(2) if applicable, for which the manufacturer or distributor**
 12 **holds either an approved new drug application or an**
 13 **approved abbreviated new drug application unless other**
 14 **approval by law or of the federal Food and Drug**
 15 **Administration is required.**
 16 **(b) The term does not include a drug product if the drug**
 17 **product is listed by the federal Food and Drug Administration on**



1 **or after July 1, 1987, as having actual or potential bioequivalence**
 2 **problems.**

3 SECTION 2. IC 12-15-35-28, AS AMENDED BY P.L.101-2005,
 4 SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 5 JULY 1, 2012]: Sec. 28. (a) The board has the following duties:

6 (1) The adoption of rules to carry out this chapter, in accordance
 7 with the provisions of IC 4-22-2 and subject to any office
 8 approval that is required by the federal Omnibus Budget
 9 Reconciliation Act of 1990 under Public Law 101-508 and its
 10 implementing regulations.

11 (2) The implementation of a Medicaid retrospective and
 12 prospective DUR program as outlined in this chapter, including
 13 the approval of software programs to be used by the pharmacist
 14 for prospective DUR and recommendations concerning the
 15 provisions of the contractual agreement between the state and any
 16 other entity that will be processing and reviewing Medicaid drug
 17 claims and profiles for the DUR program under this chapter.

18 (3) The development and application of the predetermined criteria
 19 and standards for appropriate prescribing to be used in
 20 retrospective and prospective DUR to ensure that such criteria
 21 and standards for appropriate prescribing are based on the
 22 compendia and developed with professional input with provisions
 23 for timely revisions and assessments as necessary.

24 (4) The development, selection, application, and assessment of
 25 interventions for physicians, pharmacists, and patients that are
 26 educational and not punitive in nature.

27 (5) The publication of an annual report that must be subject to
 28 public comment before issuance to the federal Department of
 29 Health and Human Services and to the Indiana legislative council
 30 by December 1 of each year. The report issued to the legislative
 31 council must be in an electronic format under IC 5-14-6.

32 (6) The development of a working agreement for the board to
 33 clarify the areas of responsibility with related boards or agencies,
 34 including the following:

35 (A) The Indiana board of pharmacy.

36 (B) The medical licensing board of Indiana.

37 (C) The SURS staff.

38 (7) The establishment of a grievance and appeals process for
 39 physicians or pharmacists under this chapter.

40 (8) The publication and dissemination of educational information
 41 to physicians and pharmacists regarding the board and the DUR
 42 program, including information on the following:

C
o
p
y



- 1 (A) Identifying and reducing the frequency of patterns of
 2 fraud, abuse, gross overuse, or inappropriate or medically
 3 unnecessary care among physicians, pharmacists, and
 4 recipients.
 5 (B) Potential or actual severe or adverse reactions to drugs.
 6 (C) Therapeutic appropriateness.
 7 (D) Overutilization or underutilization.
 8 (E) Appropriate use of generic drugs.
 9 (F) Therapeutic duplication.
 10 (G) Drug-disease contraindications.
 11 (H) Drug-drug interactions.
 12 (I) Incorrect drug dosage and duration of drug treatment.
 13 (J) Drug allergy interactions.
 14 (K) Clinical abuse and misuse.
- 15 (9) The adoption and implementation of procedures designed to
 16 ensure the confidentiality of any information collected, stored,
 17 retrieved, assessed, or analyzed by the board, staff to the board, or
 18 contractors to the DUR program that identifies individual
 19 physicians, pharmacists, or recipients.
- 20 (10) The implementation of additional drug utilization review
 21 with respect to drugs dispensed to residents of nursing facilities
 22 shall not be required if the nursing facility is in compliance with
 23 the drug regimen procedures under 410 IAC 16.2-3.1 and 42 CFR
 24 483.60.
- 25 (11) The research, development, and approval of a preferred drug
 26 list for:
- 27 (A) Medicaid's fee for service program;
 28 (B) Medicaid's primary care case management program;
 29 (C) Medicaid's risk based managed care program, if the office
 30 provides a prescription drug benefit and subject to IC 12-15-5;
 31 and
 32 (D) the children's health insurance program under IC 12-17.6;
 33 in consultation with the therapeutics committee.
- 34 (12) The approval of the review and maintenance of the preferred
 35 drug list at least two (2) times per year.
- 36 (13) The preparation and submission of a report concerning the
 37 preferred drug list at least two (2) times per year to the select joint
 38 commission on Medicaid oversight established by IC 2-5-26-3.
- 39 (14) The collection of data reflecting prescribing patterns related
 40 to treatment of children diagnosed with attention deficit disorder
 41 or attention deficit hyperactivity disorder.
- 42 (15) Advising the Indiana comprehensive health insurance

C
O
P
Y

1 association established by IC 27-8-10-2.1 concerning
 2 implementation of chronic disease management and
 3 pharmaceutical management programs under IC 27-8-10-3.5.

4 **(16) The establishment, in consultation with the office of the**
 5 **secretary and the therapeutics committee, of a competitive**
 6 **bidding program:**

7 **(A) in which manufacturers of generically equivalent drug**
 8 **products participate; and**

9 **(B) for therapeutic drug classifications with at least three**

10 **(3) manufactured generically equivalent drug products;**

11 **as set forth in section 50.5 of this chapter.**

12 (b) The board shall use the clinical expertise of the therapeutics
 13 committee in developing a preferred drug list. The board shall also
 14 consider expert testimony in the development of a preferred drug list.

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

17 (1) Use literature abstracting technology.

18 (2) Use commonly accepted guidance principles of disease
 19 management.

20 (3) Develop therapeutic classifications for the preferred drug list.

21 (4) Give primary consideration to the clinical efficacy or
 22 appropriateness of a particular drug in treating a specific medical
 23 condition.

24 (5) Include in any cost effectiveness considerations the cost
 25 implications of other components of the state's Medicaid program
 26 and other state funded programs.

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

30 (e) The board shall determine whether to include a single source
 31 covered outpatient drug that is newly approved by the federal Food and
 32 Drug Administration on the preferred drug list not later than sixty (60)
 33 days after the date on which the manufacturer notifies the board in
 34 writing of the drug's approval. However, if the board determines that
 35 there is inadequate information about the drug available to the board
 36 to make a determination, the board may have an additional sixty (60)
 37 days to make a determination from the date that the board receives
 38 adequate information to perform the board's review. Prior authorization
 39 may not be automatically required for a single source drug that is newly
 40 approved by the federal Food and Drug Administration, and that is:

41 (1) in a therapeutic classification:

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

C
o
p
y



- 1 (B) for which prior authorization is not required; or
 2 (2) the sole drug in a new therapeutic classification that has not
 3 been reviewed by the board.
 4 (f) The board may not exclude a drug from the preferred drug list
 5 based solely on price.
 6 (g) The following requirements apply to a preferred drug list
 7 developed under subsection (a)(11):
 8 (1) Except as provided by IC 12-15-35.5-3(b) and
 9 IC 12-15-35.5-3(c), the office or the board may require prior
 10 authorization for a drug that is included on the preferred drug list
 11 under the following circumstances:
 12 (A) To override a prospective drug utilization review alert.
 13 (B) To permit reimbursement for a medically necessary brand
 14 name drug that is subject to generic substitution under
 15 IC 16-42-22-10.
 16 (C) To prevent fraud, abuse, waste, overutilization, or
 17 inappropriate utilization.
 18 (D) To permit implementation of a disease management
 19 program.
 20 (E) To implement other initiatives permitted by state or federal
 21 law.
 22 (2) All drugs described in IC 12-15-35.5-3(b) must be included on
 23 the preferred drug list.
 24 (3) The office may add a drug that has been approved by the
 25 federal Food and Drug Administration to the preferred drug list
 26 without prior approval from the board.
 27 (4) The board may add a drug that has been approved by the
 28 federal Food and Drug Administration to the preferred drug list.
 29 (h) At least two (2) times each year, the board shall provide a report
 30 to the select joint commission on Medicaid oversight established by
 31 IC 2-5-26-3. The report must contain the following information:
 32 (1) The cost of administering the preferred drug list.
 33 (2) Any increase in Medicaid physician, laboratory, or hospital
 34 costs or in other state funded programs as a result of the preferred
 35 drug list.
 36 (3) The impact of the preferred drug list on the ability of a
 37 Medicaid recipient to obtain prescription drugs.
 38 (4) The number of times prior authorization was requested, and
 39 the number of times prior authorization was:
 40 (A) approved; and
 41 (B) disapproved.
 42 (i) The board shall provide the first report required under subsection

C
O
P
Y



1 (h) not later than six (6) months after the board submits an initial
2 preferred drug list to the office.

3 SECTION 3. IC 12-15-35-28.5 IS AMENDED TO READ AS
4 FOLLOWS [EFFECTIVE JULY 1, 2012]: Sec. 28.5. The therapeutics
5 committee established under section 20.5 of this chapter shall do the
6 following:

7 (1) Advise and make recommendations to the board in the board's
8 development and maintenance of a preferred drug list under
9 section 28 of this chapter.

10 (2) Submit to the board a proposed preferred drug list that has
11 been approved by a majority of a quorum of the therapeutics
12 committee.

13 (3) Advise and make recommendations to the board in the board's
14 review and maintenance of a preferred drug list.

15 **(4) Advise and make recommendations to the board in the
16 board's development, establishment, and maintenance of the
17 generically equivalent drug product competitive bidding
18 program described in sections 28(a)(16) and 50.5 of this
19 chapter.**

20 SECTION 4. 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, 2012]: **Sec. 50.5. (a) In order to participate
23 in the Medicaid program or the children's health insurance
24 program under IC 12-17.6, a generically equivalent drug
25 manufacturer doing business in Indiana shall participate in a
26 competitive bidding program administered by the office that is
27 consistent with the rules under IC 5-22-7 to ensure that Medicaid
28 recipients are provided high quality generically equivalent drug
29 products at a competitively bid low cost.**

30 **(b) The board, in consultation with the therapeutics committee,
31 shall review all bids submitted by generically equivalent drug
32 product manufacturers, and based on the bids, recommend to the
33 office two (2) manufacturers for each therapeutic drug
34 classification that has at least three (3) manufactured generically
35 equivalent drug products to provide generically equivalent drug
36 products for Medicaid recipients and recipients under IC 12-17.6.
37 The board shall maintain a Medicaid preferred generic drug list
38 that includes the successful bids.**

39 **(c) The board shall use the following criteria in evaluating bids
40 by a generically equivalent drug product manufacturer under this
41 section:**

42 **(1) The manufacturer's ability to manage expenses of the**

C
o
p
y



- 1 generically equivalent drug product.
- 2 **(2) The manufacturer's proven ability to work with health**
- 3 **insurance programs.**
- 4 **(3) The manufacturer's efficiency of claim payment**
- 5 **procedures.**
- 6 **(4) The manufacturer's provider contracting, discounts, and**
- 7 **adequacy of network.**
- 8 **(5) Other criteria established by the office.**
- 9 **(d) The office shall enter into arrangements to require**
- 10 **generically equivalent drug product manufacturers on the**
- 11 **Medicaid preferred generic drug list to provide supplemental state**
- 12 **rebates based on the competitive bidding process of the generically**
- 13 **equivalent drug product.**
- 14 **(e) The office or a contractor of the office shall require prior**
- 15 **authorization under the Medicaid program and the children's**
- 16 **health insurance program for a generically equivalent drug**
- 17 **product that is not included on the Medicaid preferred generic**
- 18 **drug list.**
- 19 **(f) The office shall request bids for the Medicaid preferred**
- 20 **generic drug list at least one (1) time every five (5) years.**
- 21 **(g) The office may adopt rules under IC 4-22-2 necessary to**
- 22 **implement this section.**

C
O
P
Y

