



Reprinted
March 19, 2013

ENGROSSED HOUSE BILL No. 1315

DIGEST OF HB 1315 (Updated March 18, 2013 3:00 pm - DI 77)

Citations Affected: Noncode.

Synopsis: Biosimilar biological products. Requires the health finance commission to study, during the 2013 legislative interim, how Indiana law should address the prescribing and substituting of biosimilar biological products.

Effective: July 1, 2013.

**Clere, Davisson, Shackelford,
Candelaria Reardon**

(SENATE SPONSORS — MILLER PATRICIA, GROOMS, BREAUX)

January 17, 2013, read first time and referred to Committee on Public Health.
January 29, 2013, amended, reported — Do Pass.
January 31, 2013, read second time, amended, ordered engrossed.
February 1, 2013, engrossed.
February 4, 2013, read third time, passed. Yeas 77, nays 18.

SENATE ACTION

February 25, 2013, read first time and referred to Committee on Health and Provider Services.
March 12, 2013, amended, reported favorably — Do Pass.
March 18, 2013, read second time, amended, ordered engrossed.

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EH 1315—LS 7359/DI 77+



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First Regular Session 118th General Assembly (2013)

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 2012 Regular Session of the General Assembly.

ENGROSSED HOUSE BILL No. 1315

A BILL FOR AN ACT concerning health.

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

- 1 SECTION 1. [EFFECTIVE JULY 1, 2013] (a) As used in this
2 SECTION, "commission" refers to the health finance commission
3 established by IC 2-5-23-3.
4 (b) During the 2013 legislative interim, the commission shall
5 study how Indiana law should address the prescribing and
6 substituting of biosimilar biological products for other drugs.
7 (c) This SECTION expires December 31, 2013.

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COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1315, 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:

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

"SECTION 1. IC 16-18-2-288 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 288. (a) "Practitioner", for purposes of IC 16-42-19, has the meaning set forth in IC 16-42-19-5.

(b) "Practitioner", for purposes of IC 16-41-14, has the meaning set forth in IC 16-41-14-4.

(c) "Practitioner", for purposes of IC 16-42-21, has the meaning set forth in IC 16-42-21-3.

(d) "Practitioner", for purposes of IC 16-42-22 **and IC 16-42-25**, has the meaning set forth in IC 16-42-22-4.5."

Page 2, line 11, delete "product for the specified indicated use." and insert "**product**".

Page 2, delete lines 12 through 13, begin a new line block indented and insert:

"(2) The prescribing practitioner has:

(A) for a written prescription, signed on the line under which the words "May substitute" appear; or

(B) for an electronically transmitted prescription, electronically transmitted the instruction "May substitute"."

Page 2, line 14, delete "patient or the patient's authorized representative" and insert "**pharmacist has informed the customer of the substitution**".

Page 2, delete line 15.

Page 2, line 16, delete "physician" and insert "**prescribing practitioner**".

Page 2, line 19, delete "physician" and insert "**practitioner**".

Page 2, line 20, before "biosimilar" insert "**interchangeable**".

Page 2, line 23, after "public" insert "**Internet**".

Page 2, delete lines 28 through 29, begin a new paragraph and insert:

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"Sec. 5. A written or electronic prescription for a biological product must comply with the requirements under IC 16-42-22-6."

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1315 as introduced.)

CLERE, Chair

Committee Vote: yeas 10, nays 2.

HOUSE MOTION

Mr. Speaker: I move that House Bill 1315 be amended to read as follows:

Page 2, line 31, delete "twenty-four (24)" and insert **"seventy-two (72)"**.

(Reference is to HB 1315 as printed January 29, 2013.)

CLERE

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1315, 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 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 16-18-2-35.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 35.8. "Biological product", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-1.

SECTION 2. IC 16-18-2-36.2 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 36.2. "Biosimilar", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-2.

SECTION 3. IC 16-18-2-191.2 IS ADDED TO THE INDIANA

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CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2013]: **Sec. 191.2. "Interchangeable", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-3."**

Page 2, line 13, delete "This chapter applies to a prescription for a biological" and insert "As used in this chapter, "biological product" means:

- (1) a virus;
 - (2) a therapeutic serum;
 - (3) a toxin;
 - (4) an antitoxin;
 - (5) a vaccine;
 - (6) blood;
 - (7) a blood component;
 - (8) a blood derivative;
 - (9) an allergenic product;
 - (10) a protein (except any chemically synthesized polypeptide);
 - (11) a product analogous to a product described in subdivisions (1) through (10);
 - (12) arsphenamine;
 - (13) an arsphenamine derivative; or
 - (14) any other trivalent organic arsenic compound;
- applicable to the prevention, treatment, or cure of a disease or condition for human beings.

Sec. 2. As used in this chapter, "biosimilar" means a biological product that:

- (1) has been licensed as a biosimilar product under 41 U.S.C. 262(k); and
- (2) is highly similar to the reference product, with:
 - (A) no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product; and
 - (B) only minor differences in clinically inactive components.

Sec. 3. As used in this chapter, "interchangeable" means a determination by the Federal Food and Drug Administration that a biosimilar product may be substituted for a reference biological product without the intervention of the health care provider that prescribed the biological product."

Page 2, delete lines 14 through 16.

Page 2, line 17, delete "3." and insert "4."



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Page 2, line 24, delete "substitute"" and insert "**substitute.**".

Page 2, line 27, delete "substitute." and insert "**substitute.**".

Page 2, line 30, after "practitioner," insert "**orally,**".

Page 2, line 31, after "writing" insert ",".

Page 2, line 31, delete "seventy-two (72) hours" and insert "**five (5) calendar days**".

Page 2, line 36, delete "4." and insert "**5.**".

Page 2, line 42, delete "5." and insert "**6.**".

Page 3, after line 1, begin a new paragraph and insert:

"SECTION 5. [EFFECTIVE JULY 1, 2013] **(a) As used in this SECTION, "commission" refers to the health finance commission established by IC 2-5-23-3.**

(b) During the 2013 legislative interim, the commission shall study how Indiana law should address the prescribing and substituting of biosimilar biological products for other drugs.

(c) This SECTION expires December 31, 2013."

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1315 as reprinted February 1, 2013.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 8, Nays 4.

SENATE MOTION

Madam President: I move that Engrossed House Bill 1315 be amended to read as follows:

Delete the title and insert the following:

A BILL FOR AN ACT concerning health.

Page 1, delete lines 1 through 17.

Delete pages 2 through 3.

Page 4, delete lines 1 through 3.

Page 4, line 4, delete "7." and insert "1."

(Reference is to EHB 1315 as printed March 13, 2013.)

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