



Reprinted  
February 1, 2013

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## HOUSE BILL No. 1315

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DIGEST OF HB 1315 (Updated January 31, 2013 11:30 am - DI 77)

**Citations Affected:** IC 16-18; IC 16-42.

**Synopsis:** Biosimilar biological products. Provides that a biological product that is substituted under the biosimilar biological products requirements is not subject to the generic drug substitution requirements. Allows a pharmacist to substitute a biosimilar product for a prescribed biological product if certain conditions are met. Requires the board of pharmacy to maintain an Internet web site that lists the biosimilar biological products that are determined to be interchangeable. Allows the board of pharmacy to adopt rules. Provides that a written or electronic prescription for a biological product must comply with the existing prescription form requirements.

**Effective:** July 1, 2013.

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

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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.

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HB 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.

## HOUSE BILL No. 1315

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

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

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

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

11 SECTION 2. IC 16-42-22-8, AS AMENDED BY P.L.204-2005,  
12 SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
13 JULY 1, 2013]: Sec. 8. (a) For substitution to occur for a prescription  
14 other than a prescription filled under the Medicaid program (42 U.S.C.  
15 1396 et seq.), the children's health insurance program established under  
16 IC 12-17.6-2, **the biosimilar biological products requirements under**  
17 **IC 16-42-25**, or the Medicare program (42 U.S.C. 1395 et seq.):

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1 (1) the practitioner must:

2 (A) sign on the line under which the words "May substitute"  
3 appear; or

4 (B) for an electronically transmitted prescription,  
5 electronically transmit the instruction "May substitute."; and

6 (2) the pharmacist must inform the customer of the substitution.

7 (b) This section does not authorize any substitution other than  
8 substitution of a generically equivalent drug product.

9 SECTION 3. IC 16-42-25 IS ADDED TO THE INDIANA CODE  
10 AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE  
11 JULY 1, 2013]:

12 **Chapter 25. Drugs: Biosimilar Biological Products**

13 **Sec. 1. This chapter applies to a prescription for a biological  
14 product that is subject to 21 U.S.C. 353(b).**

15 **Sec. 2. The definitions set forth in 42 U.S.C. 262(i) apply to this  
16 chapter.**

17 **Sec. 3. A pharmacist may substitute a biosimilar product for a  
18 prescribed biological product if the following conditions are met:**

19 (1) The biosimilar product has been determined by the federal  
20 Food and Drug Administration to be interchangeable with the  
21 prescribed biological product.

22 (2) The prescribing practitioner has:

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

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

28 (3) The pharmacist has informed the customer of the  
29 substitution.

30 (4) The pharmacist notifies the prescribing practitioner, in  
31 writing or electronically, within seventy-two (72) hours of the  
32 substitution.

33 (5) The pharmacy and the prescribing practitioner retain a  
34 written or electronic record of the interchangeable biosimilar  
35 substitution for at least five (5) years.

36 **Sec. 4. (a) The Indiana board of pharmacy shall maintain a  
37 public Internet web site that contains a current list of biosimilar  
38 biological products that the federal Food and Drug Administration  
39 has determined to be interchangeable.**

40 **(b) The Indiana board of pharmacy may adopt rules under  
41 IC 4-22-2 necessary to implement this chapter.**

42 **Sec. 5. A written or electronic prescription for a biological**

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1 **product must comply with the requirements under IC 16-42-22-6.**

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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.

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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.)

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