February 21, 2014

ENGROSSED
SENATE BILL No. 262

DIGEST OF SB 262 (Updated February 20, 2014 6:39 am - DI 84)

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

Synopsis: Biosimilar drugs. Allows a pharmacist to substitute an interchangeable biosimilar product for a prescribed biological product if certain conditions are met. Requires a pharmacist to record in a certain manner the name and manufacturer of a biologic product that the pharmacist is dispensing not later than ten days after dispensing the biologic product. Requires the board of pharmacy to maintain a link on the board's website to the current list of all biological products that are determined by the United States Food and Drug Administration to be interchangeable with a specific reference biological product. 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. (The introduced version of this bill was prepared by the health finance commission.)

Effective: July 1, 2014.

Hershman, Grooms, Breaux

(HOUSE SPONSORS — CLERE, DAVISSON, CANDELARIA REARDON, SHACKLEFORD)

January 13, 2014, read first time and referred to Committee on Health and Provider Services.
January 23, 2014, amended, reported favorably — Do Pass.
January 27, 2014, read second time, ordered engrossed.
January 28, 2014, engrossed. Read third time, passed. Yeas 38, nays 11.

HOUSE ACTION

February 10, 2014, read first time and referred to Committee on Public Health.
February 20, 2014, reported — Do Pass.

February 21, 2014

Second Regular Session 118th General Assembly (2014)

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 2013 Regular Session and 2013 First Regular Technical Session of the General Assembly.

ENGROSSED
SENATE BILL No. 262

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

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

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, 2014]: **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, 2014]: **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 CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 191.2. "Interchangeable", for purposes of IC 16-42-25, has the meaning set forth in IC 16-42-25-3.**

SECTION 4. IC 16-18-2-288 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: 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.

SECTION 5. IC 16-42-22-8, AS AMENDED BY P.L.204-2005, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 8. (a) For substitution to occur for a prescription other than a prescription filled under the Medicaid program (42 U.S.C. 1396 et seq.), the children's health insurance program established under IC 12-17.6-2, **the biosimilar biological products requirements under IC 16-42-25,** or the Medicare program (42 U.S.C. 1395 et seq.):

(1) the practitioner must:

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

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

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

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

SECTION 6. IC 16-42-25 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]:

Chapter 25. Drugs: Biosimilar Biological Products

Sec. 1. 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" refers to a biological product that:

(1) has been licensed as a biosimilar product under 41 U.S.C. 262(k) or has been approved based on an application filed under 21 U.S.C. 355(b)(2); 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:

(1) 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; or

(2) concerning a biological product filed under 21 U.S.C. 355(b)(2), a product that is designated as therapeutically equivalent by the federal Food and Drug Administration in the Approved Drug Products with Therapeutic Equivalence Evaluations.

Sec. 4. A pharmacist may substitute for a prescribed biological product if the following conditions are met:

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

(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.".

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

Sec. 5. (a) Except as provided in subsection (b), in order to ensure medical records are complete and accurate, a pharmacist shall, not later than ten (10) calendar days after dispensing a

biologic product, record the name and manufacturer of the biologic product dispensed using:

(1) an interoperable electronic health records system shared with the prescribing practitioner, to the extent a system is in place between the pharmacist and the practitioner; or

(2) if an electronic health records system is not in place between the pharmacist and the prescribing practitioner, any prevailing means available to communicate to the prescribing practitioner the name and manufacturer of the biologic product dispensed.

(b) The pharmacist is not required to report to or communicate with the prescribing practitioner under subsection (a)(2) if:

(1) there is no federal Food and Drug Administration approved interchangeable biological product for the prescribed biological product; or

(2) the refill prescription is not changed from the product originally dispensed.

Sec. 6. (a) The pharmacy shall retain a record in accordance with IC 25-26-13-25(a) of the dispensed biological product.

(b) The prescribing practitioner shall retain a record in accordance with IC 16-39-7-1 of the dispensed biological product.

Sec. 7. (a) The Indiana board of pharmacy shall maintain a link on the board's Internet web site to the current list of all biological products determined by the United States Food and Drug Administration to be interchangeable with a specific reference biological product.

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

Sec. 8. A written or electronic prescription for a biological product must comply with the requirements under IC 16-42-22-6.

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 262, 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 3, line 8, delete ";" and insert "**or has been approved based on an application filed under 21 U.S.C. 355(b)(2);**".

Page 3, line 15, delete "means a" and insert "**means:**

(1) 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; or

(2) concerning a biological product filed under 21 U.S.C. 355(b)(2), a product that is designated as therapeutically equivalent by the federal Food and Drug Administration in the Approved Drug Products with Therapeutic Equivalence Evaluations.".

Page 3, delete lines 16 through 19.

Page 3, line 20, delete "a biosimilar product".

Page 3, line 22, delete "biosimilar product" and insert "**substitute**".

Page 3, delete lines 33 through 38.

Page 3, line 39, after "(a)" insert "**Except as provided in subsection (b), in order to ensure medical records are complete and accurate, a pharmacist shall, not later than ten (10) calendar days after dispensing a biologic product, record the name and manufacturer of the biologic product dispensed using:**

(1) an interoperable electronic health records system shared with the prescribing practitioner, to the extent a system is in place between the pharmacist and the practitioner; or

(2) if an electronic health records system is not in place between the pharmacist and the prescribing practitioner, any prevailing means available to communicate to the prescribing practitioner the name and manufacturer of the biologic product dispensed.

(b) The pharmacist is not required to report to or communicate with the prescribing practitioner under subsection (a)(2) if:

(1) there is no federal Food and Drug Administration approved interchangeable biological product for the prescribed biological product; or

(2) the refill prescription is not changed from the product

originally dispensed.

Sec. 6. (a) The pharmacy shall retain a record in accordance with IC 25-26-13-25(a) of the dispensed biological product.

(b) The prescribing practitioner shall retain a record in accordance with IC 16-39-7-1 of the dispensed biological product.

Sec. 7. (a)".

Page 3, line 39, after "maintain a" insert "**link on the board's Internet web site to the current list of all biological products determined by the United States Food and Drug Administration to be interchangeable with a specific reference biological product.**".

Page 3, delete lines 40 through 42.

Page 4, line 3, delete "6." and insert "**8.**".

and when so amended that said bill do pass.

(Reference is to SB 262 as introduced.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 8, Nays 3.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 262, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill do pass.

(Reference is to SB 262 as printed January 24, 2014.)

Committee Vote: Yeas 11, Nays 0

Representative Clere