PRELIMINARY DRAFT
No. 3341

PREPARED BY
LEGISLATIVE SERVICES AGENCY
2014 GENERAL ASSEMBLY

DIGEST

Citations Affected: IC 16-18-2; IC 16-42.

Synopsis: Biosimilar products. Allows a pharmacist to substitute an interchangeable 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, 2014.

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); 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.

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

(1) The biosimilar product 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.

(4) The pharmacist notifies the prescribing practitioner, orally, in writing, or electronically, within five (5) calendar days of the substitution.

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

Sec. 5. (a) The Indiana board of pharmacy shall maintain a public Internet web site that contains a current list of biosimilar biological products that the federal Food and Drug Administration has determined to be interchangeable.

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

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