SENATE ENROLLED ACT No. 262

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.

President of the Senate

President Pro Tempore

Speaker of the House of Representatives

Governor of the State of Indiana

Date: _____ Time: _____