IC 16-42-25

Chapter 25. Drugs: Biosimilar Biological Products

IC 16-42-25-1

"Biological product"

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.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-2

"Biosimilar"

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.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-3

"Interchangeable"

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.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-4

Substitution; conditions

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.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-5

Records of dispensing biologic product; time frame; exception

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.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-6

Record retention; pharmacy; prescribing practitioner

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.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-7

Link to current list of interchangeable biological products; rules

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.

As added by P.L.96-2014, SEC.6.

IC 16-42-25-8

Compliance with prescription requirements

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

As added by P.L.96-2014, SEC.6.