A-Engrossed
Senate Bill 460

Ordered by the Senate April 22
Including Senate Amendments dated April 22

Sponsored by Senators MONNES ANDERSON, WINTERS, Representatives KOTEK, THOMPSON; Senators KNOPP, STARR

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

Restricts substitution of biosimilar product for prescribed biological product.
Becomes operative on January 1, 2014.
Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to biological products; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Section 2 of this 2013 Act is added to and made a part of ORS chapter 689.

SECTION 2. (1) As used in this section:

(a) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(b) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).

(c) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4).

(d) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

(2) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

(d) The pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product; and

(e) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

(3) The State Board of Pharmacy shall post and regularly update on a website maintained by the board a list of biosimilar products determined by the United States Food and Drug Administration to be interchangeable.

SECTION 3. (1) Section 2 of this 2013 Act becomes operative on January 1, 2014.

(2) The State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all the duties, functions and powers conferred on the board by section 2 of this 2013 Act.

SECTION 4. Section 2 of this 2013 Act is amended to read:

Sec. 2. (1) As used in this section:

(a) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(b) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).

(c) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4).

(d) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

(2) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product; **and**

[*(d) The pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product; and*]

[*(e)*] **(d)** The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

(3) The State Board of Pharmacy shall post and regularly update on a website maintained by the board a list of biosimilar products determined by the United States Food and Drug Administration to be interchangeable.

SECTION 5. The amendments to section 2 of this 2013 Act by section 4 of this 2013 Act

become operative on January 1, 2016.

SECTION 6. This 2013 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2013 Act takes effect on its passage.