SENATE AMENDMENTS TO SENATE BILL 460

By COMMITTEE ON HEALTH CARE AND HUMAN SERVICES

April 22

On page 1 of the printed bill, line 18, after "of" delete the rest of the line and line 19 and insert "a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.".

Delete lines 23 and 24 and insert "ministration to be interchangeable with the prescribed biological product;".

On page 2, delete lines 2 and 3 and insert:

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

In line 6, after "interchangeable" insert a period and delete the rest of the line.

After line 11, insert:

"**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.**".

In line 12, delete "4" and insert "6".