SB 460-6
(LC 986)
4/10/13 (MBM/ps)

PROPOSED AMENDMENTS TO
SENATE BILL 460

On page 2 of the printed bill, after line 11, insert:

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

"(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 biological products as biosimilar products or for determination that biosimilar products are 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 biological product for the use for which the prescribing practitioner prescribed the 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 prescribing practitioner, and the pharmacy or pharmacist, retain 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 with a reference biological product.

"SECTION 5. Section 4 of this 2013 Act becomes operative on January 1, 2016.".

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