Rep. David Harris

Filed: 3/13/2015

AMENDMENT TO HOUSE BILL 3519

AMENDMENT NO. _____. Amend House Bill 3519 by replacing everything after the enacting clause with the following:

"Section 5. The Pharmacy Practice Act is amended by adding Section 19.5 as follows:

(225 ILCS 85/19.5 new)

Sec. 19.5. Biological products.

(a) For the purposes of this Section:

"Biological product" means a biological product as defined in subsection (i) of Section 351 of the federal Public Health Service Act (42 U.S.C. 262(i)).

"Interchangeable" means a biological product that is licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(4) or is deemed therapeutically equivalent to another biological product by the United States Food and Drug Administration and appears in the latest edition

or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

"Prescription", with respect to a biological product, means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(b) A pharmacist may substitute a prescription biological product for a prescribed biological product only if:

(1) the substituted product has been determined by the United States Food and Drug Administration to be interchangeable, as defined in subsection (a) of this Section, with the prescribed biological product;

(2) the prescribing physician does not designate orally, in writing, or electronically that substitution is prohibited in a manner consistent with Section 25 of this Act;

(3) the pharmacy informs the patient of the substitution; and

(4) the selected drug product that will be used as the substitution has a unit price less than the drug product specified in the prescription or, if the unit price of the selected drug is higher than the unit price of the prescribed biological product, the patient is informed and has agreed to accept the selected drug.

(c) Within a reasonable time following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the

specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biologic product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

(1) there is no FDA-approved interchangeable biological product for the product prescribed; or

(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(d) The pharmacy shall retain a record of the biological product dispensed for a period of 5 years.

(e) The Board shall maintain a link on the Department's Internet website to the current list of all biological products determined by the United States Food and Drug Administration to be interchangeable with a specific biological product.

(f) The Board shall adopt rules for compliance with this Section.

Section 99. Effective date. This Act takes effect July 1, 2016.".