SB1611

LRB09909151AMC29348b

99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

SB1611

Introduced 2/20/2015, by Sen. Antonio Muñoz

SYNOPSIS AS INTRODUCED:

225 ILCS 85/19.5 new

Amends the Pharmacy Practice Act. Provides that a pharmacist may substitute a prescription biological product for a prescribed biological product only if specified criteria are met. Requires that, 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. Requires the pharmacy to retain a record of the biological product dispensed for a period of 5 years. Requires the State Board of Pharmacy to maintain a link on the Department'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 biological product. Effective immediately.

LRB099 09151 AMC 29348 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

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; and

(3) the pharmacy informs the patient of the substitution.

(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 upon becoming law.