HB3519

LRB09909712AMC29921b

99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

HB3519

by Rep. David Harris

SYNOPSIS AS INTRODUCED:

225 ILCS 85/19.5 new

Amends the Pharmacy Practice Act. Provides that a pharmacist may substitute a prescription biosimilar product for a prescribed biological product under certain circumstances. Provides that the Board shall adopt rules for compliance with these provisions. Effective immediately.

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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. Biosimilar products.

(a) For the purposes of this Section:

"Biological product", "biosimilar", and "interchangeable" have the same meanings as under Section 351 of the Public Health Service Act (42 U.S.C. 262).

"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 biosimilar product for a prescribed biological product only if:

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

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

(3) the pharmacy informs the patient of the substitution and the patient agrees to accept the biosimilar product;

(4) the cost of the biosimilar product is less than the cost of the biological product or, if the cost of the biosimilar product is more than cost of the biological product, the patient is informed and has agreed to accept the higher cost biosimilar product;

(5) the pharmacist informs the prescriber within 3 business days of the substitution, including the name and manufacturer of the interchangeable biosimilar dispensed; and

(6) the pharmacy retains a written record of the interchangeable biosimilar substitution for a period of no less than 5 years.

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

Section 99. Effective date. This Act takes effect upon becoming law.