

98TH GENERAL ASSEMBLY State of Illinois 2013 and 2014 SB1934

Introduced 2/15/2013, by Sen. Antonio Muñoz - Iris Y. Martinez - Pamela J. Althoff - Melinda Bush

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.

LRB098 10574 MGM 40827 b

FISCAL NOTE ACT MAY APPLY

1	AN	ACT	concerning	regu.	lation.
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2	Ве	it	enacted	by	the	People	of	the	State	of	Illinois,
3	represe	nte	d in the (Gene	eral A	ssembly	':				

- Section 5. The Pharmacy Practice Act is amended by adding Section 19.5 as follows:
- 6 (225 ILCS 85/19.5 new)
- 7 <u>Sec. 19.5. Biosimilars products.</u>
- 8 (a) For the purposes of this Section:
- 9 "Biological product", "biosimilar", and "interchangeable"
- 10 <u>have the same meanings as under Section 351 of the Public</u>
- 11 Health Service Act (42 U.S.C. 262).
- 12 "Prescription", with respect to a biological product,
- means a product that is subject to Section 503 (b) of the
- 14 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:
- 17 (1) the biosimilar product has been determined by the
- 18 <u>United States Food and Drug Administration to be</u>
- interchangeable with the prescribed biological product;
- 20 (2) the prescribing physician does not designate
- orally, in writing, or electronically that substitution is
- 22 prohibited in a manner inconsistent with Section 25 of this
- 23 <u>Act;</u>

1	(3) the pharmacy informs the patient of the					
2	substitution;					
3	(4) the pharmacist informs the prescriber within 5					
4	business days of the substitution, including the name and					
5	manufacturer of the interchangeable biosimilar dispensed;					
6	(5) the pharmacy retains a written record of the					
7	interchangeable biosimilar substitution for a period of no					
8	<u>less than 5 years.</u>					
9	(c) The Board shall adopt rules for compliance with this					
10	Section.					
11						
12	Section 99. Effective date. This Act takes effect upon					
13	becoming law.					