

1 AN ACT concerning regulation.

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

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

6 (225 ILCS 85/19.5 new)

7 Sec. 19.5. Biological products.

8 (a) For the purposes of this Section:

9 "Biological product" has the meaning given to that term in
10 42 U.S.C. 262.

11 "Interchangeable biological product" means a biological
12 product that the United States Food and Drug Administration:

13 (1) has (A) licensed and (B) determined it to meet the
14 standards for interchangeability pursuant to 42 U.S.C.
15 262(k)(4); or

16 (2) has determined is therapeutically equivalent as
17 set forth in the latest edition of or supplement to the
18 United States Food and Drug Administration's Approved Drug
19 Products with Therapeutic Equivalence Evaluations (Orange
20 Book).

21 (b) A pharmacist may substitute an interchangeable
22 biological product for a prescribed biological product only if
23 all of the following conditions in this subsection (b) are met:

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

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

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

11 (c) Within 5 business days following the dispensing of a
12 biological product, the dispensing pharmacist or the
13 pharmacist's designee shall make an entry of the specific
14 product provided to the patient, including the name of the
15 product and the manufacturer. The communication shall be
16 conveyed by making an entry that can be electronically accessed
17 by the prescriber through:

18 (1) an interoperable electronic medical records
19 system;

20 (2) an electronic prescribing technology;

21 (3) a pharmacy benefit management system; or

22 (4) a pharmacy record.

23 Entry into an electronic records system as described in
24 this subsection (c) is presumed to provide notice in accordance
25 with this subsection (c). Otherwise, the pharmacist shall
26 communicate the biological product dispensed to the prescriber

1 using facsimile, telephone, electronic transmission, or other
2 prevailing means, except that communication shall not be
3 required where:

4 (A) there is no United States Food and Drug
5 Administration-approved interchangeable biological product
6 for the product prescribed; or

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

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

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

15 (f) The Department may adopt rules for compliance with this
16 Section.