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" has the meaning given to that term in 42 U.S.C. 262.

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

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

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

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

(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 5 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of 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 that can be electronically accessed by the prescriber through:

(1) an interoperable electronic medical records system;

(2) an electronic prescribing technology;

(3) a pharmacy benefit management system; or

(4) a pharmacy record.

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

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

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

(B) 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 Department shall maintain a link on its 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 Department may adopt rules for compliance with this Section.