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HOUSE REPUBLICAN STAFF ANALYSIS

Bill:	HF 305	House Committee:	**PASSED** 2/2/17 **(19-0)**
Committee:	Human Resources	House Floor:	**PASSED** 2/22/17 **(99-0)**
Floor Manager:	Rep. Best	Senate Floor:	**PASSED** 3/1/17 **(50-0)**
Date:	Final	Governor:	**Signed on March 13, 2017**
Staff:	Carrie Malone (5-2063)		

Pharmacist Substitution of Interchangeable Biologic Products

- This bill was brought by the Iowa Biotech Association. The bill allows Iowa pharmacists the ability to dispense safe and potentially less expensive biologic medications to patients by substituting an FDA approved interchangeable biologic for a prescribed biologic product. A biological product is a medical product, often made from a variety of natural sources, used for a broad range of diseases or conditions.

- Physicians will retain the authority to request that no product selection be made. This is identical to the authority they currently have to prevent generic substitution.

- The bill will allow pharmacists to substitute an FDA approved interchangeable biologic without first seeking approval. However, since biologic products differ from generics in complexity and are not identical chemical products, the bill ensures there will be transparent communication between pharmacists and prescribers to ensure medical records reflect which specific product has been dispensed to the patient. This information would be relayed after the prescription is dispensed to alleviate the need for waiting for pre-approval, as current law requires.

- The bill adds definitions that are currently absent from Iowa statute and administrative code. It also assures only FDA approved "interchangeable" biologic products may be substituted without prior prescriber consent and ensures patients will be informed of the substitution.

- The bill ensures the pharmacist will inform the prescriber of the substitution within 5 business days, including the name and manufacturer of the interchangeable biosimilar dispensed to the patient to ensure medical records reflect which specific product has been dispensed.

Section by Section Analysis

Section 1
This section adds definitions that are currently absent from Iowa law and administrative code. Those definitions are "biological product" and "interchangeable biological product."

Section 2 - Label of Prescription Drugs - Interchangeable Biological Product List

This section requires the Board of Pharmacy to maintain a link on its website to the current list of all biological products that the FDA has determined are interchangeable.

Section 3 - Drug Product Selection - Restrictions

This section relates to drug product selection. This section allows pharmacists to use their professional judgment to distribute an interchangeable biological product when a doctor prescribes a biological product. The pharmacist can't dispense an interchangeable biologic if the doctor indicates that they need to dispense as written. If the pharmacist does prescribe an interchangeable, within five days they have to make an entry into the patient's electronic health record and the doctor must be notified.
