House Study Bill 38 - Introduced

HOUSE FILE _____
BY (PROPOSED COMMITTEE ON HUMAN RESOURCES BILL BY CHAIRPERSON FRY)

A BILL FOR

An Act relating to the prescribing of biological products and making penalties applicable.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 155A.3, Code 2017, is amended by adding the following new subsections:

NEW SUBSECTION. 2A. *"Biological product"* means the same as defined in 42 U.S.C. §262.

NEW SUBSECTION. 19A. *"Interchangeable biological product"* means either of the following:

a. A biological product that the United States food and drug administration has licensed and has determined meets the standards for interchangeability pursuant to 42 U.S.C. §262(k)(4).

b. A biological product that the United States food and drug administration has determined to be therapeutically equivalent to another biological product as set forth in the latest edition or supplement of the United States food and drug administration approved drug products with therapeutic equivalence evaluations publication.

Sec. 2. Section 155A.28, Code 2017, is amended to read as follows:

155A.28 Label of prescription drugs —— interchangeable biological product list.

1. The label of any drug, biological product, or device sold and dispensed on the prescription of a practitioner shall be in compliance with rules adopted by the board.

2. The board shall maintain a link on its internet site to the current list of all biological products that the United States food and drug administration has determined to be interchangeable biological products.

Sec. 3. Section 155A.32, Code 2017, is amended to read as follows:

155A.32 Drug product selection —— restrictions.

1. *a.* If an authorized prescriber prescribes, in writing, electronically, by facsimile, or orally, a drug by its brand or trade name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name

and demonstrated bioavailability as the ~~one~~ drug product prescribed for dispensing and sale to the patient. If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a drug product with the same generic name and demonstrated bioavailability as the ~~one~~ drug product prescribed for dispensing and sale. If the pharmacist exercises drug product selection, the pharmacist shall inform the patient of the savings which the patient will obtain as a result of the drug product selection and pass on to the patient no less than fifty percent of the difference in actual acquisition costs between the drug prescribed and the drug substituted.

b. If an authorized prescriber prescribes a biological product, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a biological product that is an interchangeable biological product for the biological product prescribed for dispensing and sale to the patient. If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a biological product that is an interchangeable biological product for the biological product prescribed for dispensing and sale. If the pharmacist exercises biological product selection, the pharmacist shall inform the patient of the savings which the patient will obtain as a result of the biological product selection and pass on to the patient no less than fifty percent of the difference in actual acquisition costs between the biological product prescribed and the interchangeable biological product substituted.

2. The pharmacist shall not exercise the drug or biological product selection described in this section if ~~either~~ any of the following is true:

a. The prescriber specifically indicates that no drug or biological product selection shall be made.

b. The person presenting the prescription indicates that only the specific drug product prescribed should be dispensed. ~~However~~ Except for biological products, this paragraph does not apply if the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A.

3. If selection of a generically equivalent drug product or an interchangeable biological product is made under this section, the pharmacist making the selection shall note that fact and the name of the manufacturer of the selected drug on the prescription presented by the patient or the patient's adult representative or transmitted by the prescriber or the prescriber's authorized agent.

4. *a.* Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The entry shall be electronically accessible to the prescriber through one of the following means:

(1) An interoperable electronic medical records system.

(2) An electronic prescribing technology.

(3) A pharmacy benefit management system.

(4) A pharmacy record.

b. An entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. If the entry is not made electronically, the pharmacist shall communicate the name and manufacturer of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means.

c. Communication under this subsection shall not be required in either of the following circumstances:

(1) There is no federal food and drug administration-approved interchangeable biological product for the product prescribed.

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill adopts by reference to federal law a definition of "biological product" and defines "interchangeable biological product". As described by the United States food and drug administration, a "biological product" is a medical product, often made from a variety of natural sources, used for a broad range of diseases or conditions, particularly chronic, serious, or life-threatening conditions such as cancer and rheumatoid arthritis.

The bill provides that pharmacists may use professional judgment to distribute an interchangeable biological product when an authorized prescriber prescribes a biological product. The bill requires the board of pharmacy to maintain a link on its internet site to the current list of all biological products that the United States food and drug administration has determined to be interchangeable biological products.

The bill provides that a pharmacist may not dispense an interchangeable biological product if the prescriber specifically indicates that no product selection shall be made or the person presenting the prescription indicates that only the specific biological product prescribed should be dispensed.

The bill requires that within five days of dispensing an interchangeable biological product, a pharmacist must make an entry into one of a specified type of electronic records systems noting the name and manufacturer of the biological product. According to the bill, such an entry is deemed to provide notice to the prescriber if done electronically. If it is not done electronically, the pharmacist must otherwise provide the name and manufacturer of the biological product to the prescriber. Such communication is not required if a refill prescription is not changed from the product dispensed on the

prior filling of the prescription.

A person who violates these provisions with regard to a noncontrolled substance shall be guilty of a serious misdemeanor for a first violation, an aggravated misdemeanor for a second offense or if the person has been convicted with a violation of laws relating to prescription drugs or devices in other jurisdictions, or a class "D" felony for a third offense or a second offense with prior conviction in another jurisdiction. A person who violates these provisions with regard to a controlled substance shall be punished pursuant to Code section 124.401, subsection 1, and other provisions of Code chapter 124, division IV.