# Legislative Analysis

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**INTERCHANGEABLE BIOLOGICAL DRUG PRODUCTS**

**House Bill 4472 as introduced**
**Sponsor: Rep. John Bizon**
**Committee: Health Policy**
**Complete to 10-31-17**

Analysis available at
http://www.legislature.mi.gov

**SUMMARY:**

House Bill 4472 would amend the Public Health Code to allow pharmacists to substitute Food & Drug Association (FDA)-designated interchangeable biological drug products, instead of dispensing higher cost brand-name drugs. The bill would also require that a pharmacist notify a prescriber that he or she has dispensed a biological drug product within five days.

**Substitution**

Currently under the Code, if a pharmacist receives a prescription for a brand name drug product, the pharmacist may dispense a lower cost (but not a higher cost) generically equivalent drug product if the lower cost product is available in the pharmacy. Similarly, if the purchaser requests a lower cost generically equivalent drug product, the pharmacist must dispense it, subject to availability.

The bill would extend that provision to biological drug products and interchangeable biological drug products, so that the pharmacist may dispense the lower cost interchangeable biological drug product at his or her discretion, and must dispense it if requested by the purchaser. However, as now, the purchaser must be notified of the substitution and it must be noted on the prescription label, unless the prescriber has directed that the prescription not be labeled.

**Pass along cost savings**

Just as pharmacists must currently pass along the cost savings associated with substitution of a generically equivalent drug product to the purchaser or third party payment source, the bill would require them to do so when they substitute an interchangeable biological drug product.

**Instances in which substitution is prohibited**

Additionally, under current law, a pharmacist is prohibited from dispensing a generically equivalent drug product if the prescriber writes "dispense as written" or "d.a.w." on the prescription or (in the case of an unwritten prescription) if the prescriber expressly indicates that the prescription is to be dispensed as communicated. The bill would retain these prohibitions, and extend them so they also apply to an interchangeable biological drug product.

**Communication to prescriber of dispensing of biological drug product**

Under the bill, within five days after dispensing a biological drug product, the dispensing pharmacist, a pharmacy technician, or a pharmacist intern must communicate to the prescriber the specific biological drug product dispensed, including the name and manufacturer of the product.

The specific product information must be communicated by making an entry in an interoperable electronic medical records system, through the use of electronic prescribing technology, through the use of a pharmacy benefits management system, or through the use of a pharmacy record, that is electronically accessible by the prescriber. If those methods are unavailable, the bill would require the communication to take place by facsimile, telephone, electronic transmission, or other prevailing means. The prescriber must include this information in the patient's medical record.

**Exceptions to required communication to prescriber**

The communication required above would not apply if there is no interchangeable biological drug product for the drug product prescribed or if the prescription was refilled with the same drug product that was dispensed on the prior filling of the prescription.

**List of biological drug products**

Finally, the bill would require the Michigan Board of Pharmacy to maintain a link on its website to the current list of all biological drug products that the FDA has determined to be interchangeable biological drug products.

**Definitions**

The bill defines three new terms—biological drug product, biosimilar, and interchangeable biological drug product, as follows.

***Biological drug product*** means a biological product as defined in the federal U.S. Code at 42 USC 262. There, the term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

***Biosimilar*** means that term as defined in 42 USC 262. There, the term "biosimilar" or "biosimilarity," in reference to a biological product that is the subject of an application under subsection (k), means—(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

***Interchangeable biological drug product*** means either of the following:

- A biological drug product that is licensed by the FDA and determined to be interchangeable with the prescribed drug product pursuant to the federal safety standards for determining interchangeability.

- A biological drug product that is approved by the FDA pursuant to an application filed under the U.S. Code's provisions for introducing new drugs and that the FDA has determined to be therapeutically equivalent to the prescribed drug product.

The bill would take effect 90 days after enactment.

MCL 333.17702, 333.17704, and 333.17755

**FISCAL IMPACT:**

House Bill 4472 does not appear to have any fiscal impact on the Department of Licensing and Regulatory Affairs, or on other units of state or local government.

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