Legislative Analysis

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INTERCHANGEABLE BIOLOGICAL DRUG PRODUCTS

House Bill 4472 (proposed substitute H-3)
Sponsor: Rep. John Bizon
Committee: Health Policy
Complete to 1-16-18

SUMMARY:

House Bill 4472 would amend the Public Health Code to allow pharmacists to substitute Food and Drug Administration (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 within 5 days that he or she has dispensed an interchangeable biological drug product.

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 5 days after dispensing an interchangeable biological drug product, the dispensing pharmacist or his or her designee must communicate to the prescriber the specific interchangeable biological drug product dispensed, including the name and manufacturer of the product.

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

Exceptions to required communication to prescriber

The communication required above would not apply if there is no FDA-licensed interchangeable biological drug product for the product prescribed or if a refill authorization does not change the product that was dispensed on the prior filling of the prescription.

List of biological drug products

The bill would require the Michigan Board of Pharmacy to maintain a link on its website to the current "purple book" (defined below).

Reporting requirement

Beginning June 1, 2018 and annually thereafter, the bill would require the Department of Licensing and Regulatory Affairs (LARA) to submit a report on all of the following to the House and Senate standing committees on health policy, the Speaker of the House of Representatives, and the Senate Majority Leader:

- A list of each biological drug product that the FDA had previously determined to be therapeutically equivalent as set forth in the "orange book" (defined below) that is now included in the purple book.
- The anticipated date that every biological drug product that the FDA has determined to be therapeutically equivalent as set forth in the orange book will be included in the purple book.

Definitions

The bill would define new terms, as follows:

Biological drug product would mean 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.

Interchangeable biological drug product would mean either of the following, as applicable:

- A biological drug product that is licensed by the FDA and that the FDA has determined meets the standards for interchangeability pursuant to the federal safety standards for determining interchangeability.
- Until March 23, 2021, a biological drug product that the FDA has determined to be therapeutically equivalent as set forth in "Approved Drug Products with Therapeutic Equivalence Evaluations," an FDA publication that is commonly referred to as the "orange book."

Orange book would mean "Approved Drug Products with Therapeutic Equivalence Evaluations," an FDA publication commonly referred to as the "orange book."

Purple book would mean "Lists of Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," an FDA publication commonly referred to as the "purple book."

The bill would take effect 90 days after its enactment.

MCL 333.17702, 333.17704, and 333.17755

FISCAL IMPACT:

House Bill 4472 would likely cause a minimal increase in costs for the Department of Licensing and Regulatory Affairs for the production of the annual report regarding biological drug products and their therapeutic equivalents. Any cost increases associated with the creation of this report would likely be borne by existing departmental appropriations.

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