Legislative Analysis

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ALLOW DISPENSING OF INTERCHANGEABLE BIOLOGICAL DRUGS; REQUIRE NOTIFICATION TO PRESCRIBER AFTER DISPENSING

House Bill 4812 as introduced
Sponsor: Rep. John Bizon, MD
Committee: Health Policy
Complete to 11-2-15

SUMMARY:

House Bill 4812 would amend the Michigan Public Health Code to allow pharmacists to dispense FDA-designated interchangeable biological drug products. The bill would also require that a pharmacist notify the prescriber, within five business days after dispensing a biological product, of the product name and manufacturer.

The bill would go into effect 90 days after being enacted into law. A detailed description of the bill follows.

Now under the law, a pharmacist who receives a prescription for a brand-name drug product *may* unilaterally substitute a lower cost generically equivalent drug, and if a purchaser requests a lower cost drug, the pharmacist *must* dispense the lower cost product (if it's available in the pharmacy).

Substitution. House Bill 4812 would modify this provision described in the paragraph above, to *extend it to biological drug products and to interchangeable biological drug products*. Specifically, under the bill, when a pharmacist received a prescription for a brand name drug or a biological drug product, the pharmacist could dispense a lower cost (but not higher cost) generically equivalent drug product or an interchangeable biological drug product. If a purchaser requested a lower cost generically equivalent drug or an interchangeable biological drug product, the pharmacist would be required to dispense it.

Notification & labeling of biological drug product. Further, under the bill, the pharmacist would be required to notify the purchaser if a drug or biological drug product was dispensed that was not the prescribed brand. If the dispensed biological drug product did not have a brand name, then the prescription label would have to indicate the generic name of the drug or the biological drug product dispensed.

Pass along cost savings. Under the bill, if a pharmacist dispensed a generically equivalent drug or an interchangeable biological drug product, the pharmacist would be required to pass on the cost savings to the purchaser.

Prohibition if 'dispensed as written'. Under the 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), the

prescriber expressly indicates the prescription is to be dispensed as communicated. House Bill 4812 would retain these prohibitions, and extend them so they also apply to *an interchangeable biological drug product.*

Total charge capped. Now under the law, a pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug originally prescribed, unless agreed to by the purchaser. House Bill 4812 would retain this provision.

Biological drug product notification. Finally, the bill requires that a pharmacist must notify a prescriber within five business days after dispensing a biological drug product.

Under the bill, a pharmacist who dispensed the biological drug product, a pharmacy technician, or a pharmacist intern would be required to communicate to the prescriber the specific biological drug product dispensed, including, but not limited to, the name and manufacturer of the biological drug product. The pharmacist's communication could be made a) by making an entry in an inter-operable electronic medical records system, through the use of electronic prescribing technology, or through the use of a pharmacy record that is electronically accessible by the prescriber; or b) by facsimile, telephone, electronic transmission, or other prevailing means.

House Bill 4812 specifies that the notification requirement described above would not apply if either of the following occurred: a) there was no interchangeable biological drug product for the drug product prescribed; or b) the prescription was refilled with the same drug product that was dispensed on the prior filling of the prescription

Definitions. The bill defines two new terms—'biological drug product',' and 'interchangeable biological drug product'.

First, the term 'biological drug product' means a biological product as defined in the federal law at 42 USC 262. There, (1) 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.

Second, the bill defines 'interchangeable biological drug product' to mean either of the following: a) a biological drug product that is licensed by the FDA and determined to be interchangeable with the prescribed drug product pursuant to 42 USC 262(k)(4); or b) a biological drug product that is approved by the FDA pursuant to an application filed under 21 USC 355(b)(2) and that the FDA has determined to be therapeutically equivalent to the prescribed drug product.

MCL 333.17702, 333.17704, and 333.17755

FISCAL IMPACT:

House Bill 4812 could generate a minimal, but likely negligible, amount of short-term fiscal savings on state and local units of government, and could generate moderate long-term fiscal savings through the Medicaid program in particular. Cost savings estimates vary from 15% to 30% for a biosimilar when compared to its interchangeable biological product, meaning for every $10.0 million in gross Medicaid expenditures on a biologic product, a biosimilar could save between $500,000 and $1.0 million GF/GP (based on the state's FY 2016 Medicaid match rate of 65.60%). The first biosimilar was approved by the U.S. Food and Drug Administration in March 2015.

The bill would have no fiscal impact on the Department of Licensing and Regulatory Affairs.

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