Legislative Analysis

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ALLOW SUBSTITUTION OF INTERCHANGEABLE BIOLOGICAL DRUGS; REQUIRE NOTIFICATION BEFORE DISPENSING BIO-SIMILAR DRUGS

House Bill 4437 as introduced
Sponsor: Rep. Ken Yonker
Committee: Health Policy
Complete to 10-19-15

SUMMARY:

House Bill 4437 would amend the Michigan 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 before dispensing a *biosimilar* drug in place of a biological drug.

The bill would go into effect 90 days after it was 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). House Bill 4437 would modify this provision, to *extend it to interchangeable biological drug products*.

Substitution. Under the bill, a pharmacist who received a prescription for a brand-name drug product *or a biological drug product* would be allowed (but would not be required) to dispense a lower cost generically equivalent drug product or *lower cost interchangeable biological drug product* (if available in the pharmacy). Upon the request of a purchaser, a pharmacist who received a prescription for a brand-name drug product or a biological drug product would be required to dispense a lower cost generically equivalent drug product or lower cost interchangeable biological drug product (if available in the pharmacy).

Notification & labeling of biological drug product & interchangeable biological drug product. Further, under the bill, the pharmacist would be required to notify the purchaser if a drug were dispensed that was not the prescribed brand-name drug product or the prescribed biological drug product. In notifying the purchaser, the pharmacist would be required to indicate both the brand-name of the drug product or the biological drug product prescribed, and the generic name or interchangeable biological drug product name of the drug product dispensed, and designate each on the prescription label. (If the dispensed drug did not have a brand-name, then the pharmacist would indicate the generic name or interchangeable biological drug product name on the prescription label.)

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

Record interchangeable biological drug on prescription file copy. The bill specifies that if a pharmacist dispensed an interchangeable biological drug product, the pharmacist would be required to indicate on the file copy of the prescription the interchangeable biological drug product name, and the full name of the manufacturer (if available).

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 4437 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 4437 would modify this provision to establish a clear prohibition, by specifying that a pharmacist shall 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).

Biosimilar drug notification. Finally, the bill requires that a pharmacist must notify the prescriber before dispensing a biosimilar drug product in place of a biological drug product.

Definitions. The bill defines five new terms—'biological drug product', 'biosimilar', 'biosimilar drug product', 'interchangeable,' 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 the term 'biosimilar' to mean that terms as defined in 42 USC 262. There, (2) 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.

Third, the bill defines 'biosimilar drug product' to mean a biological drug product that the FDA has determined to be biosimilar to a reference product.

Fourth, the bill defines 'interchangeable' to mean that term as defined in 42 USC 262. There, (3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without [emphasis added] the intervention of the health care provider who prescribed the reference product.

Fifth, the bill defines 'interchangeable biological drug product' to mean a biological drug product that has met the safety standards for determining interchangeability under 42 USC 262 and is therefore determined to be interchangeable with a reference product by the FDA.

Note: The Food and Drug Administration defines 'reference product' as follows: (4) the term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

MCL 333.17702, 333.17704, 333.17709, and 333.17755

FISCAL IMPACT:

House Bill 4437 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.

Legislative Analyst: J. Hunault
Fiscal Analyst: Kevin Koorstra
Paul B. A. Holland