Legislative Analysis

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INTERCHANGEABLE BIOLOGICAL DRUG PRODUCTS

House Bill 4472 as enacted
Public Act 41 of 2018
Sponsor: Rep. John Bizon, M.D.
House Committee: Health Policy
Senate Committee: Health Policy
Complete to 6-28-18

BRIEF SUMMARY: House Bill 4472 amends 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 also requires that a pharmacist notify a prescriber within 5 days that he or she has dispensed an interchangeable biological drug product.

FISCAL IMPACT: House Bill 4472 could generate moderate long-term state fiscal savings through the Medicaid program and would likely cause a minimal increase in costs for the Department of Licensing and Regulatory Affairs. (See ***Fiscal Information***, below, for further discussion.)

THE APPARENT PROBLEM:

Most of the drugs that pharmaceutical companies manufacture consist of chemicals combined in specific ways for particular effects. They are formulaic, their ingredients are stable, and all batches are identical. When cheaper synthetic versions of these chemical combinations become available, they are called generic drugs; they are identical to their original counterparts.

Biological drugs are different. Pharmaceutical companies manufacture biological drugs in a living system—within the actual cells of plants or the cells of animals. Consequently, batches of drugs are not identical one to the other. Their cell-sources differ, their biological interactions vary, and it is possible that the drugs' effectiveness will vary. Because it is impossible to create an exact replica, the different batches of these drugs are called "biosimilar" biologics. A biosimilar drug must meet additional requirements based on further evaluation and testing of the product in order for the FDA to conclude that it is "interchangeable" with the original biologic. (See ***Background Information***, below.)

While biological drugs have been around for more than 100 years—as vaccines, for example, and insulin—only now with the mapping of the human genome to reveal countless genetic clues are biological drugs preparing to explode onto the market as twenty-first-century cures. These new and complex drugs are designed to treat very serious illnesses—diabetes, cancers, and autoimmune diseases. States across the country are adopting statutes to regulate biologics and biosimilar pharmaceuticals. According to the National Conference of State Legislatures, in the past five years at least 45 states have considered legislation to establish state standards for substitution of a biosimilar prescription product to replace an original biologic product.[1] In Michigan, legislation has been introduced to allow substitution of interchangeable biosimilars.

[1] "State Laws and Legislation Related to Biologic Medications and Substitutions of Biosimilars," http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx

THE CONTENT OF THE BILL:

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, a health information exchange, 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 Licensed 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 enactment.

MCL 333.17702, 333.17704, and 333.17755

FISCAL INFORMATION:

House Bill 4472 could generate moderate long-term state fiscal savings through the Medicaid program and would likely cause a minimal increase in costs for the Department of Licensing and Regulatory Affairs. Cost savings estimates vary from 15% to 30% for an interchangeable

biological drug product when compared to its biological drug product, meaning that for every $10.0 million in gross Medicaid expenditures on a biological drug product, an interchangeable biological drug product could save between $500,000 and $1.0 million GF/GP (based on the state's FY 2018 Medicaid match rate of 64.78%).

The bill 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.

ARGUMENTS:

For:

Proponents of the bill note that biosimilar biological drugs are the future of pharmacology. Already, interchangeable biosimilars are dispensed in Europe, saving a reported 30% in pharmacy costs. Further, more than 900 products are in development worldwide, although only nine have been approved by the United States Food and Drug Administration.[2] Proponents urge that, across the nation, all state regulatory frameworks adopted as statutes work to achieve policy coherence—complementing each other as well as federal guidelines and law—enabling research collaboration, and also competition. This bill meets these requirements. Specifically, the bill follows FDA guidelines that only interchangeable biosimilars should be substituted and requires the pharmacy to notify the prescriber after an interchangeable biosimilar is dispensed.

This legislation ensures that the physicians who prescribe the drugs to help their patients will be informed by any pharmacist who substitutes an interchangeable biosimilar biological drug. This notice is imperative, because even interchangeable biosimilars are not the same as their reference biologics, and consequently they can have different effects, including life-threatening allergic reactions.

Against:

Opponents of the legislation argue that the notice provisions of the legislation, requiring pharmacists to notify prescribers within 5 days after interchangeable biosimilar substitutions are made, will add unnecessary costs to an already costly medical system. They note that adverse reactions to interchangeable biosimilar drugs will be few and far between, because the U.S. FDA does not approve interchangeable biosimilar drugs until clinical trials demonstrate equivalent therapeutic effects.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.

[2] "FDA-Approved Biosimilar Products," https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580432.htm