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BILL ANALYSIS

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House Bill 4472 (Substitute H-3 as passed by the House)
Sponsor: Representative John Bizon, M.D.
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 1-30-18

CONTENT

The bill would amend the Public Health Code to do the following:

- **Authorize a pharmacist to dispense an interchangeable biological drug product in lieu of a prescribed biological drug product.**
- **Require a pharmacist to notify the prescriber within five days after dispensing an interchangeable biological drug product, unless there were no U.S. Food Drug Administration (FDA) licensed interchangeable biological drug product for the prescribed product or the prescription were refilled with a product that was dispensed on a previous filling.**
- **Require the Michigan Board of Pharmacy to maintain on its website a link to the current FDA list of interchangeable biological drug products.**
- **Require the Michigan Department of Health and Human Services to submit to the Legislature a report containing certain information on biological drug products that the FDA had determined to be therapeutically equivalent.**

The bill would take effect 90 days after it was enacted.

Drug Substitution

Under the Code, when a pharmacist receives a prescription for a brand name drug product, the pharmacist may dispense a lower-cost but not higher-cost generically equivalent drug product if available at the pharmacy. The pharmacist must dispense a lower-cost generic product, if available, upon a purchaser's request. In either case, the purchaser must be notified and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the generic name of the drug dispensed. Under the bill, a pharmacist also could substitute an interchangeable biological drug product for a prescribed biological drug product, or would be required to do so upon the purchaser's request. Additionally, if a dispensed drug or biological drug product did not have a brand name, the prescription label would have to include the generic name of drug dispensed or the proprietary name of the biological drug product.

The Code requires a pharmacist who dispenses a generically equivalent drug product to pass on the cost savings to the purchaser or, if applicable, to the third-party payment source. The Code also describes certain circumstances under which the pharmacist may not dispense a generically equivalent drug product. Under the bill, these provisions also would apply to a substitution involving an interchangeable biological drug product.

"Biological drug product" would mean a biological product as defined in 42 USC 262. (Under that section of the U.S. Code, "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.)

The bill would define "interchangeable biological drug product" as either of the following:

-- A biological drug product that is licensed by the U.S. Food and Drug Administration and the FDA has determined meets the standards of interchangeability pursuant to 42 USC 262(k)(4) (described below).
-- 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".

(Under 42 USC 262(k)(4), upon review of an application for licensure of a biological product, the U.S. Secretary for Health and Human Services (HHS) must determine the product to be interchangeable with the reference product if he or she determines that the information submitted in the application is sufficient to show that the biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient, and, for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the two products is not greater than the risk of using the reference product with such alternation or switch. "Biosimilar" means that the product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency.

The U.S. Code requires a person to apply to the HHS Secretary for approval to introduce or deliver for introduction into interstate commerce any new drug. The application must include full reports of investigations that have been made to show that the drug is safe and effective.)

Prescriber Notification

Except as provided below, the bill would require the dispensing pharmacist or his or her designee, within five business days after an interchangeable biological drug product was dispensed, to communicate to the prescriber the specific product provided to the patient, including the product's name and manufacturer. The pharmacist or designee would have to make the communication by making an entry that was electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, a health information exchange, or a pharmacy record. An entry would be presumed to provide notice to the prescriber. If those methods were not available, the communication would have to be made by facsimile, telephone, electronic transmission, or other prevailing means.

The communication requirement would not apply if there were no FDA-licensed interchangeable biological drug product for the product prescribed, or if a refill authorization did not change the product that was dispensed on the previous filling of the prescription.

Other Provisions

The Michigan Board of Pharmacy would have to maintain a link on its website to the current

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

Beginning June 1, 2018, the Michigan Department of Health and Human Services would have to submit an annual report on all of the following to the House of Representatives and Senate standing committees on health policy, the Speaker of the House, and the Senate Majority Leader:

-- A list of each biological drug product that the FDA had previously determined to be therapeutically equivalent as set for in the orange book that was previously included in the purple book.
-- The anticipated date that every biological drug product that the FDA had determined to be therapeutically equivalent as set forth in the orange book would be included in the purple book.

MCL 333.17702 et al. Legislative Analyst: Stephen Jackson

FISCAL IMPACT

Implementation of the legislation would result in reduced costs for the State and local governments as employers and for the State's Medicaid program.

State and Local Government

According to a June 2015 white paper by Milliman, Inc. (a firm that provides actuarial services and products), as of 2013, insurance companies spent about $22 per member per month on biologics (biological drugs). Indications are that per person expenditures on biologics have increased by at least 25% since 2013, so an updated baseline biologic spending estimate would be $29 per member per month. Experience from Europe indicates that the price differential between biologics and biosimilar medications ranges from 10% to 30%; that is, the price of biosimilar drugs is 10% to 30% below the price of biologics in situations where biosimilar drugs are available.

A 2017 report by RAND Corporation examined a decade's worth of studies and found that estimated biosimilar savings ranged from 10% to 51% and the market share for biosimilars as a percentage of the total biologic market ranged from 5% to 60%. RAND's estimate, based on 2016 sales data, was that the availability of biosimilars would lead to a 4.0% reduction in total biologic spending.

Four percent of $29 per month is $1.16 per month or about $14 per individual per year. Based on current employment data, this would mean savings of $700,000 for State government (roughly half GF/GP), $850,000 for institutions of higher education, $1.4 million for local units of government, and $2.0 million for schools.

The bill would have no fiscal impact on the Department of Licensing and Regulatory Affairs, which houses the Michigan Board of Pharmacy. The annual report required in the bill would lead to minor costs for the Department of Health and Human Services.

Medicaid

There are no specific data on biologics in Medicaid. Based on the share of pharmaceutical costs in the general population and changes in total pharmaceutical spending in Medicaid, it

appears that biologics represent about $250.0 million Gross of combined fee-for-service and managed care pharmaceutical costs.

Savings of 4% of total biologic spending in Medicaid would be about $10.0 million Gross, $3.6 million GF/GP.

Long-Term Trends

The above figures are static estimates based on recent health care spending. There is a clear trend toward greater use of biologics and, if the legislation were enacted, there would be greater use of biosimilars in Michigan. In future years, whether or not the legislation is enacted, it is likely that use of biologics will increase significantly. Such an increase would increase the level of potential savings tied to the legislation.

Fiscal Analyst: Steve Angelotti

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