Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986

House Bill 4812 (Substitute S-1)
Sponsor: Representative John Bizon, MD
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 2-16-16

CONTENT

The bill would amend the Public Health Code to authorize a pharmacist to dispense an interchangeable biological drug product in lieu of a prescribed biological drug product, and require the pharmacist to retain an electronic record of the interchangeable product dispensed for two years.

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

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 the case of such a substitution, 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.

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.

If a pharmacist dispensed an interchangeable biological drug product under the bill, he or she would have to retain for two years an electronic record of the product dispensed.

"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 (FDA) and determined to be interchangeable with the prescribed product pursuant to 42 USC 262(k)(4).

-- 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 product.

(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. Under the U.S. Code, "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 bill would incorporate this definition of "biosimilar" in the Public Health Code.

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. Section 355(b)(2) of Title 21 pertains to the application process in the case of a drug for which the investigations were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person by or for whom they were conducted.)

MCL 333.17702 et al. Legislative Analyst: Julie Cassidy

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). 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. For the sake of this analysis, a 20% differential is assumed. The key question is how much substitution of biosimilars for biologics would occur. The evidence from Europe in the Milliman, Inc. report indicates that a 25% penetration rate is a reasonable estimate. Savings thus would be 20% on 25% of the costs or about 5% of total spending. Five percent of $22 per month is $1.10 per month or about $13 per individual per year, using 2013 data. Based on current employment data, this would mean savings of $650,000 for State government (roughly half GF/GP), $800,000 for institutions of higher education, $1.3 million for local units of government, and $1.9 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.

Medicaid: There are no specific data on biologics in Medicaid. Based on the share of pharmaceutical costs in the general population, it appears that biologics represent about $200.0 million Gross of combined fee-for-service and managed care pharmaceutical costs. Savings of 5% of total spending (25% substitution times 20% cost savings) would be about $10.0 million Gross, $3.5 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
Josh Sefton

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