ERIC
The ERISA Industry Committee
*Driven By and For Large Employers*
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*Adam Greathouse, Senior Associate, Health Policy*

March 5, 2019

Maine Legislature
House Committee on Health Coverage, Insurance and Financial Services

Re: LD 659 – An Act Regarding the Use of Interchangeable Biological Products

*Delivered via email to members of the Committee*

Dear Members of the Committee:

On behalf of The ERISA Industry Committee (ERIC), thank you for accepting input from interested stakeholders as you explore ways to permit pharmacists to make biological product substitutions via Legislative Document 659. ERIC is the only national association that advocates exclusively for large employers on health, retirement, and compensation public policies at the federal, state, and local levels. We speak in one voice for our members on their benefit and compensation interests, including many members with employees and retirees in Maine. As health plan sponsors, ERIC member companies have an interest in driving down the cost of prescription drugs, which is borne by all participants in a plan.

According to the Food and Drug Administration (FDA), "A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product."[1] Availability of biosimilars, which generally are priced lower than biologics, has potential to increase competition and bring down pharmaceutical prices. RAND Corporation estimated that use of biosimilars could reduce spending on biologic drugs by $54 billion from 2017-2026.[2] In the United States, which spends a high proportion of overall pharmacy spending on biologics, this represents a significant opportunity to reduce costs. ERIC applauds Maine for working to open up availability to these cost-saving drugs.

ERIC believes it is good policy to permit pharmacists to substitute a biosimilar medication for a reference biologic when it would mean a cost savings for the patient. We make note that no biosimilar product currently has an "interchangeable" designation, and as such, requiring that designation in order for substitution to occur means this legislation, as currently written, will do little to increase cost savings to the health care system. As stated above, to be approved by the FDA, a biosimilar must be proven safe and effective and have no "clinically meaningful differences from an existing FDA-approved reference product." To require an additional hurdle before substitution can occur creates an unnecessary barrier to biosimilar utilization. We suggest permitting a substitution to occur with a patient's consent if the FDA has approved a biosimilar for a given reference (branded) biologic.

[1] Food and Drug Administration website, March 4, 2019.
[2] Mulcahy, A. et. al. Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017. https://www.rand.org/pubs/perspectives/PE264.html.

We appreciate that the bill's language permits the prescriber to limit biosimilar substitution because it always should be within the health care provider's discretion what the best treatment for a patient is. We also appreciate that the time period for the pharmacist to notify the prescriber that a substitution has occurred is a reasonable five business days and permits such notice to be disclosed electronically. Additionally, not requiring notification for subsequent refills of the same medication will require less time and hassle on the part of the pharmacist.

Regarding pharmacist disclosure to the patient of the biosimilar substitution, the bill's language does not specify what is required for such notice. Patients certainly have the right to know they are receiving a substitution, but requiring excessive disclosures could lead to patient unease, which is unwarranted since biosimilars are deemed safe by the FDA. Additionally, this will add time to each prescription fill, and this added time could lead some pharmacists not to substitute a less expensive biosimilar in an effort to avoid that added time.

With the exception of requiring an interchangeable designation before a biosimilar substitution can occur, we are supportive of the goals of this bill. The cost of prescription medications is ever-escalating, especially biologic medications, and biosimilars have the promise of helping drive down those costs. Unnecessary barriers to their uptake should not be put in place.

Thank you for accepting our input on this proposed legislation. If you have any questions or if we can be of further assistance, please contact me at agreathouse@eric.org or 202-627-1914.

Sincerely,

Adam Greathouse
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