ERIC | THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

BIOSIMILAR MODEL LEGISLATION

States are regulating the availability of biologics and biosimilars in a variety of ways that are inhibiting the speed and volume of uptake of biosimilars. As background, a biosimilar "is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product," according to the Food and Drug Administration (FDA). Biosimilars are generally priced lower than biologics, and they have the potential to increase competition and bring down pharmaceutical costs.

ERIC encourages state policymakers to develop biosimilar laws and regulations in accordance with the following guidelines:

Substitution allowed for biosimilars approved by the FDA

- Pharmacist may substitute automatically if biosimilar is deemed interchangeable by the FDA
- If there is no FDA interchangeable designation, pharmacist may substitute with patient's consent

Use of FDA's definitions for relevant terms (42 U.S.C. § 262)

- Biosimilar or biosimilarity
- Interchangeable or interchangeability

Prescribers may limit biosimilar substitution

- Prescriber can limit subsitution by indicating as such on the prescription (e.g., "dispense as written" or "brand medically necessary")

Pharmacist and prescriber notification requirements must be reasonable

- Prescriber notification of substitution may be required if pharmacist is given a reasonable amount of time to notify and notification is permitted through a variety of means
- Notification not required when refill is not changed from the product last dispensed

Patient notification requirements must be reasonable

- Patient notice or consent not required prior to substitution of an interchangeable biosimilar, but patient may request substitution not occur
- Do not impose additional requirements on the pharmacist to explain cost or pricing of the biological product or the biosimilar

Savings should accrue to all plan participants

- The cost of prescription drugs is borne by all participants in the plan, and savings achieved by generic and biosimilar substitution should offset premium costs to all beneficiaries. States should not mandate that savings accrue to, or be converted to cash payments to, specific beneficiaries