For several decades, every state has regulated the use of brand-name and generic prescription drugs through statutes and agency or board rules. These state actions include when and how generics may be substituted for brand-name prescriptions, by pharmacists or others. Generic drugs typically have active ingredients that are identical to those of their brand-name counterpart.

Biologic medicines are much more complex than traditional chemically synthesized drugs. Biologics are manufactured from living organisms by programming cell lines to produce the desired therapeutic substances and consist of large molecules.

Regulating biologics raises new issues for both state and federal policymakers. Because of their complexity, biologic drugs are much more difficult to replicate than the chemically produced generics for other drugs. The cell lines used and modifications in the manufacturing process affect biologic medicines. As a result, truly identical “generic” versions are currently virtually impossible to produce. However, once patents expire for the existing brand-name biologic drugs, “biosimilar” medicines can be produced, which is an occurrence that raises regulatory issues in the states. Currently, there is concern that traditional statutes regulating “generic drugs” may be misapplied to new products that are not identical. This has led to a recent widespread move to amend older state laws to address the medical and chemical characteristics of these “biologics,” as well as any future generic-style “follow-on biologics” or “biosimilars.”

Biosimilar Substitution Requirements State Legislation Tally

- After four and a half years of legislative filing, debate and votes the cumulative total is laws in 35 states and Puerto Rico. In 2017 alone laws were signed in 10 more states: Iowa (3/5/2017), Kansas, Maryland, Minnesota, Montana (2/22/2017), Nebraska, Nevada, New Mexico, Ohio and South Carolina.
PRESCRIPTION DRUG DATABASE - Use NCSL's updated, 2015-2017 state legislative database to learn about and analyze what states are considering and enacting in 10 current topic areas of prescription drugs. The 3,200+ bill listings for 2015-2017 include a check-box search category for "biologics and biosimilars" as well as other topics of interest such as state roles in regulating safety and compounding, specialty drugs and clinical trial and 'right-to-try' measures.

Typical Features of State Legislation 2013-2017
The provisions of state legislation vary, but there are several features and requirements that frequently are included:

- **FDA Approval**: Any biological product under consideration for substitution must first be approved as "interchangeable" by the U.S. Food and Drug Administration or FDA.
- **Prescriber Decides**: The prescriber (such as a physician, oncologist, physician assistant, etc.) would be able to prevent substitution by stating "dispense as written" or "brand medically necessary."
- "Notification" vs "Communication": In bills enacted in 2013-2014, the language usually required that the prescriber "must be notified" of any allowable substitution made at a pharmacy. In 2015 bills the language commonly has been adjusted to say "communicate with," allowing a notation in an electronic medical record (EMR), PBM records or "pharmacy record that can be electronically accessible by the prescriber." (This would allow a physician to assess and compare the patient experience, but not delay the transaction.)
- **Patient Notification**: The individual patient must be notified that a substitute or switch has been made.
- **Records**: The pharmacist and the physician must retain records of substituted biologic medications.
- **Immunity**: Some states provides immunity for pharmacists who make a substitution in compliance with biologics state law.
- **Web Lists**: The state must maintain a public or web-based list of permissible interchangeable products.
- **Cost or Pricing**: Some legislation requires the pharmacist to explain the cost or price of the biologic and the interchangeable biosimilar. For example, the enacted laws in Colorado, Georgia, Illinois, North Carolina and Texas require that any authorized or allowable substitution must have the lowest cost.

2017 NEWS
- **Biosimilar US Count**: As of July 1, 2017, there are four bio-similar pharmaceuticals that have obtained full FDA approval as a biosimilar (but not yet interchangeable) in the United States. They are not currently designated as interchangeable at the prescription/retail level, so none of the state laws can be applied to dispensing decisions.

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