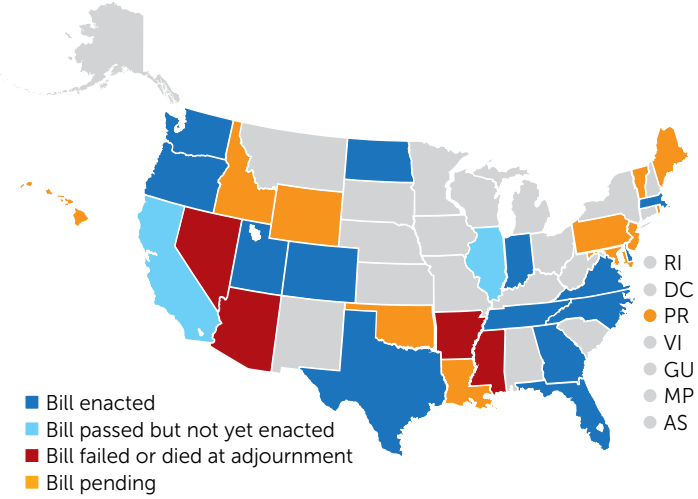
Biologic Medicines Under the Microscope

Biologic medicines provide needed relief to millions of Americans with arthritis, psoriasis, Crohn's and other diseases. The medicines, also known as biologics and biopharmaceuticals, are derived from living organisms by programming cell lines to produce therapeutic substances.

Common biologics include human growth hormone, injectable treatments for arthritis and psoriasis, the hepatitis B vaccine and stem cell therapy. They work for many patients like no other drugs have, but often are more expensive. They account for about 2 percent of U.S. prescriptions but include life extending products for cancer treatment and rare diseases.

Enter biosimilars. These "highly similar" versions of biologics are just starting to hit the market. Although prices are not yet set, they are calculated to be less expensive. Regulating biologics raises new issues for state and federal policymakers alike. Because of their complexity, biologic drugs are more difficult to replicate than the chemically produced generics for other drugs. And, because biologics are derived from unique cell lines, truly identical generic versions are virtually impossible to produce. Once patents for existing brand-name biologics expire, however, biosimilars may be more readily produced.



Source: NCSL

The U.S. Food and Drug Administration must deem generics "interchangeable" before they can be used as substitutes for brand-name biologics. In early March, the FDA approved the first biosimilar, a version of the drug Neupogen, which is used mostly for patients whose ability to make white blood cells has been compromised by chemotherapy or bone marrow transplantation.

The FDA confirms that at least three other biosimilars are awaiting approval. Many others are in development.

But patient advocates worry the new copies will be substituted for the already proven successful original medications, without their knowledge.

All of this recent activity is prompting states to consider laws that require patients and doctors to be informed when biosimilars are substituted for name brands.

So-called notification bills began popping up in states two years ago, but most were deferred or defeated in the face of opposition from biosimilar manufacturers and organizations representing pharmacists, who object to the extra work that notification requirements can entail.

The landscape, however, has shifted in the past six months partly due to agreements over wording, initiated by legislators in Georgia, Massachusetts, Utah and Washington. With required "notification" changed to required "communication," which includes electronic records, interest has expanded. The number of enacted laws has increased from seven states last year to 14 states as of mid-June this year.

—Richard Cauchi

COMMON PROVISIONS

Concern that existing statutes regulating generic drugs may be misapplied to new products has prompted a move to amend state laws to address biologics and biosimilars. Legislation varies by state, but several common elements have emerged:

- Biosimilars must be FDA approved as "interchangeable" before being used as a substitute.
- Prescribers (physicians, oncologists, physician assistants, etc.) can prevent substitutions by stating "dispense as written" or "brand medically necessary."
- Prescribers must be notified or sent a "communication" when substitutions are made at a pharmacy.
- Patients must be notified or given a separate advance consent about substitutions.
- Pharmacists who make a substitution in compliance with state law are granted immunity.
- States must maintain a public or web-based list of permissible substitutes.
- Pharmacists must explain cost differences between biologics and biosimilars to patients.