State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars

Updated June 1, 2016

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. These traditional drugs include familiar pills used regularly by tens of millions of Americans as well as some specialty drugs.

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. Common biologics in use today include human growth hormone, injectable treatments for arthritis, cancer and psoriasis, the Hepatitis B vaccine and stem cell therapy.

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 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.”

In the past four years at least 36 states have considered legislation establishing state standards for substitution of a “biosimilar” prescription product to replace an original biologic product.

Typical Features of State Legislation 2013-2016

The provisions of state legislation vary, but there are several features and requirements that frequently are included:

- Any biological product under consideration for substitution must first be approved as "interchangeable" by the U.S. Food and Drug Administration or FDA. (Two products have gained full FDA approval as a biosimilar (but are not yet interchangeable) in the United States, as of May 2016)
- 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.”
- 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.)
- The individual patient must be notified that a substitute or switch has been made. In some cases, state law would require patient consent before any such switch is made.
- The pharmacist and the physician must retain records of substituted biologic medications.
- Some state legislation provides immunity for pharmacists who make a substitution in compliance with biologics state law.
- The state must maintain a public or web-based list of permissible interchangeable products.
Some legislation requires the pharmacist to explain the cost or price of the biologic and the interchangeable biosimilar. The enacted laws in Colorado, Georgia, Illinois, North Carolina and Texas require that any authorized or allowable substitution must be the the lowest cost or price.

2015-16 NEWS

- **First U.S. Biosimilar Drug is Launched.** "Years after discounted versions of some of the most expensive drugs ever went on sale in other countries, they're finally coming to the world's biggest medicine market. AP reported that on Sep. 3, 2015 "Swiss drugmaker Novartis AG launched Zarxio, a biosimilar version of Amgen Inc.'s Neupogen, which boosts white blood cell production to prevent infections in certain cancer and other patients." Prices are not yet announced, but are projected to be 15-30 percent lower than the original. Market research firm GBI Research reports at least 150 "copycat" biosimilars are in development this year. [Read full article] published in Washington Post, 9/10/2015.

- **FDA Approves 2nd, Cheaper Version Of Biologics** (J&J's Top Drug Remicade): (From Washington Post 4/6/2016) Federal health officials have approved a cheaper version of Johnson & Johnson's blockbuster drug, Remicade, a high-priced biotech medicine for inflammatory diseases. The approval of Inflectra on April 5, 2016 "is only the second time that the Food and Drug Administration has approved a quasi-generic biotech drug for the U.S. market. These so-called biosimilar drugs, already available in Europe, have the potential to generate billions of dollars in savings for insurers, doctors and patients in coming years."

- **HHS/CMS Releases Guidance for the Role of Medicaid programs.** On March 30, 2015, the Centers for Medicare and Medicaid Services issued a guidance fact sheet that sets a framework by “issuing guidance to states on the classification of biosimilar biological products for rebate purposes and on strategies for states to use these products to reduce costs while improving access in terms of state Medicaid preferred drug lists.

  The CMS release emphasizes pricing and savings, saying, “State Medicaid programs should view the launch of biosimilar biological products as a unique opportunity to achieve measurable cost savings and greater beneficiary access to expensive therapeutic treatments for chronic conditions. States and managed care organizations are encouraged to provide biologics that achieve desirable, cost-effective clinical outcomes for beneficiaries using the various drug utilization and cost management tools they have available (e.g., step therapy, prior authorization, preferred drug lists). See: Biosimilars and the Medicaid Drug Rebate Program, Release 92. 3/30/2015

- **Federal Court Permits Sale of Biosimilar Drug.** From Bloomberg Business, "U.S. District Judge Richard Seeborg said in his ruling that the dispute between the drugmakers hinged on conflicting interpretations of the Biologics Price Competition and Innovation Act, the 2009 law that allows for fast-track approval of biosimilar drugs." Click here for links to articles on this topic from Kaiser Health News, March 20, 2015.

| NCSL PRESCRIPTION DRUG DATABASE - Use this updated, 2015-2016 state legislative database to learn about and analyze what states are considering and enacting in current topic areas of prescription drugs. The 1,200 bill listings for 2015 and 1,100 bills for 2016 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.

### Biologics-Biosimilars State Legislation Tally

- In 2015-16, as of June 1, 2016, there have been bills or resolutions filed in a total 36 states related to biologics and/or biosimilars. Of these, 13, in Arizona (5/12/2016), California, [Colorado](http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx), Georgia, Kentucky (4/11/2016), Idaho (3/24/2016) Illinois, Louisiana, New Jersey, North Carolina, Tennessee, Texas, Utah, Washington and Puerto Rico) have been signed into law in a 2015-2016 session.
  So far in 2016 Arizona, Idaho and Kentucky enacted a law. Oregon and Utah update their initial laws.

  ► The result is a 4-year cumulative total of 21 states and Puerto Rico.
### Biologics and Biosimilar Substitution: 2013-2016 State Laws

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<tbody>
<tr>
<td>Arizona</td>
<td>H 2310</td>
<td>Rep. Cobb (R)</td>
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<td>Allows a pharmacist to substitute a biological product for a prescribed biological if certain conditions are met, including a requirement that the pharmacy inform the patient of the substitution and a requirement that the pharmacy retain a record, requires notification of any price difference.</td>
<td>Yes</td>
<td>Yes 5 days (C)</td>
<td>Yes</td>
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<td>California</td>
<td>S 671;</td>
<td>Sen. Hill (D)</td>
<td>Authorizes a pharmacist to select an alternative biological product if the alternative biological product is designated interchangeable by the FDA and the prescriber does not personally indicate that a substitution is not to be made. Requires a pharmacist to make an electronically accessible entry in a patient record system of the specified biological product provided to the patient, also provides an alternative record method.</td>
<td>Yes</td>
<td>Yes (C)</td>
<td>Yes</td>
<td>Yes</td>
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<td>Colorado</td>
<td>S 71;</td>
<td>Sen. Jahn (D)</td>
<td>(See Rx Database, keyword &quot;Biologics&quot; for specifics.) Allows a pharmacist to substitute a biological product if the FDA has determined that the biological product is interchangeable with the prescribed biological product and if the practitioner has not indicated that the prescription must be dispensed as written, provides the dispensing pharmacist or the pharmacist’s designee must communicate to the prescribing practitioner the specific biological product dispensed to the patient, provides situations when communication is not necessary.</td>
<td>Yes</td>
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<td>Delaware</td>
<td>S 118; Ch. 238, signed 5/28/2014</td>
<td>Sen. Poole (D)</td>
<td>Authorizes pharmacists to substitute FDA-approved interchangeable biosimilar biological products for prescribed biological reference products with specified safeguards. To substitute a biosimilar product, pharmacists must notify the patient and prescriber in writing; the authorized prescriber did not state expressly that the prescription is to be dispensed only as directed; record information on the label and dispensing record. Also provides liability protections for pharmacists who substitute biosimilars.</td>
<td>Yes</td>
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<td>Florida</td>
<td>H 365; Ch. 2013-102; signed 6/3/2013</td>
<td>Rep. Matt Hudson (R)</td>
<td>Provides requirements for pharmacist to dispense substitute biological product, requiring the FDA to have determined substitute biological product is &quot;interchangeable for prescribed biological product. The prescribing provider must not &quot;express a preference against substitution.&quot; The pharmacist must notify the patient or person at the counter of the substitution and substitution record retained for two years. Also requires the state Board of Pharmacy to maintain current list of interchangeable biosimilar products. Effective July 2013.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Georgia</td>
<td>GA S 51, Signed 5/6/2015</td>
<td>Sen. Burke (R)</td>
<td>Relates to pharmacists and pharmacies, provides for the substitution of a biological product with an interchangeable biological product by a pharmacist, provides the pharmacist shall dispense the lowest retail priced interchangeable biological product in stock, requires the name of the interchangeable biological product shall appear on the prescription label, provides labeling exceptions, relates to maintaining a record of such transaction into interoperable electronic records.</td>
<td>Yes</td>
<td>Yes</td>
<td>n/a</td>
<td>Yes</td>
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<td>Idaho</td>
<td>H 483 Signed 3/24/2016</td>
<td>Health and Welfare Committee</td>
<td>Adds to existing law to provide that a pharmacist who dispenses an interchangeable biological product &quot;shall communicate to the prescriber the name and manufacturer of the drug within five business days following the dispensing of the biological product. Communication shall occur via an entry in an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system or a pharmacy record that can be accessed electronically by the prescriber.&quot;</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>n/a</td>
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<td>Illinois</td>
<td>S 455; signed 7/30/2015</td>
<td>Rep. J. Cullerton</td>
<td>Provides that a pharmacist may substitute an interchangeable biological product for a prescribed biological product only if all of the following conditions are met: (1) the U.S. FDA lists interchangeable with the prescribed biological product, (2) the prescribing physician does not designate orally, in writing, or electronically that substitution is prohibited and (3) the pharmacy informs the patient of the substitution. Within 5 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication can be by electronic, a</td>
<td>Yes</td>
<td>Yes</td>
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<td>State</td>
<td>Bill Number</td>
<td>Citation</td>
<td>Lead Sponsor</td>
<td>Summary</td>
<td>Description</td>
<td>FDA Must Certify Interchangeability</td>
<td>Prescriber / Doctor Notification</td>
<td>Patient Notification</td>
<td>Prescriptions Brand Name Blocks</td>
<td>Not Substitution</td>
<td>Pharmacy Records Must Be Retained</td>
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<td>Indiana</td>
<td>S 262; Ch. 96, signed 3/31/2014</td>
<td>Sponsor: Sen. Hershman (R)</td>
<td>Allows a pharmacist to substitute an interchangeable biosimilar product for a prescribed biosimilar product if the prescriber and patient are notified; and the prescribing practitioner has signed &quot;May substitute&quot; on the prescription. Requires the pharmacist to keep related records. Requires the Board of Pharmacy to maintain on its website a current list of all approved products that are interchangeable. Prescribed written or electronic prescriptions must comply with existing prescription form requirements.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Kentucky</td>
<td>KY S 134</td>
<td>Signed 4/11/2016</td>
<td>Sponsor: Sen. Alvarado (R)</td>
<td>Defines biological product and interchangeable biological product; requires lower-priced biological products to be dispensed when appropriate unless notified otherwise and require labeling and notification of biological product substitutions, adds biological products to inspection requirements.</td>
<td>Yes</td>
<td>Yes</td>
<td>n/a</td>
<td>Yes</td>
<td>n/a</td>
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<td>Louisiana</td>
<td>H 319</td>
<td>Signed 7/1/2015</td>
<td>Sponsor: Rep. Simon (R)</td>
<td>Provides for authorized interchangeable biological products and equivalent drug products, requires, following the dispensing of a biological product, the dispensing pharmacist to communicate, without any cause for action, to the prescriber the specific product provided to the patient, the name of the product and the manufacturer. Exception is made if the prescription is a refill or the prescription is indicated dispense as written.</td>
<td>Yes</td>
<td>Yes</td>
<td>n/a</td>
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<td>Massachusetts</td>
<td>H 3734; Ch. 143, signed 6/23/2014</td>
<td>Sponsor: Rep. Cusack (D)</td>
<td>Provides that a pharmacist may substitute an interchangeable biological product for a trade or brand name biological product unless “the prescriber instructs otherwise in writing.” If a substitution is made, the prescriber must be notified in writing within a “reasonable time,” including via an electronic health record (EHR). Also must notify the patient or patient's authorized representative of the substitution. Pharmacist, prescriber and administering practitioner must retain a record of substitutions for at least one year. Authorizes the Department of Public Health to issue regulations and specify enforcement.</td>
<td>Yes</td>
<td>Yes</td>
<td>incl. EHR</td>
<td>Yes</td>
<td>Yes</td>
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<td>New Jersey</td>
<td>A 2477; signed 11/9/2015; Spons or Assm. Lampitt (D)</td>
<td>Establishes requirements for pharmacists to dispense FDA-approved interchangeable biological products. The pharmacist must communicate with prescriber of any substitution within five days. Includes required price disclosure to the consumer and the amount of savings if any, that would result if a substitution were made.</td>
<td>Yes</td>
<td>Yes</td>
<td>n/a</td>
<td>Yes</td>
<td>5 days (C)</td>
<td>Yes</td>
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<td>North Carolina</td>
<td>H 195</td>
<td>Signed 05/21/2015</td>
<td>Sponsor: Rep. Dollar (R)</td>
<td>Amends the Pharmacy Practice Act to allow for the substitution of an interchangeable biological product.</td>
<td>Yes</td>
<td>Yes</td>
<td>n/a</td>
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<td>North Dakota</td>
<td>S 2190; Ch. 181; signed 6/26/2013</td>
<td>Provides that a pharmacy may substitute a prescription biosimilar product for a prescribed product only if the biosimilar product has been determined by the FDA to be interchangeable; the prescribing practitioner does not specifically indicate that the brand is medically necessary and the pharmacist informs the prescriber and the patient of the substitution; the patient has a right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse.</td>
<td>Yes</td>
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<td>Oregon</td>
<td>S 460; Ch. 342, signed 6/6/2013</td>
<td>Provides a pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the biological product unless certain conditions are met including the notification of the patient for whom the product is being prescribed and the practitioner or the practitioner’s staff; requires the pharmacy and pharmacist to retain a record of the substitution; requires the Board of Pharmacy to post on its website a list of interchangeable biosimilar products.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Tennessee</td>
<td>S 984</td>
<td>(See Rx Database, keyword “Biologics” for specifics). Defines a biological product and an interchangeable biological product in the Tennessee Affordable Drug Act of 2005, authorizes a prescriber to substitute a prescribed biological product for an interchangeable biological product if certain requirements and restrictions are met.</td>
<td>Yes</td>
<td>Yes</td>
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<td>Texas</td>
<td>H 751</td>
<td>(See Rx Database, keyword “Biologics” for specifics). Relates to the prescription and pharmaceutical substitution of biological products. Adds biological products to the provisions of existing law which requires the notification of the patient and the prescribing practitioner when such there has been a substitution of interchangeable biological products for certain biological products, relates to patient options, requires maintaining a record for such product change, adds provisions regarding communication of such change, updates labeling requirements.</td>
<td>Yes</td>
<td>Yes</td>
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<td>Utah</td>
<td>S 78; Ch. 423; signed 4/26/2013</td>
<td>Allows a pharmacist or pharmacy intern to substitute an interchangeable biosimilar product in the place of prescribed biological products if the FDA has determined that the biosimilar product is interchangeable; if the purchaser specifically requests or consents to the substitute; if the prescriber has not prohibited the substitute; also requires prescriber notification within three days (This provisions sunsets May 15, 2015). Also prohibits the substitution of a biosimilar product for the prescribed biological product without the prescriber’s authorization; the interchangeable biosimilar product is approved to move through interstate commerce; the prescribing practitioner has not prohibited the substitution; and the substitution is not prohibited by law; regulates out-of-state pharmacies; relates to labeling and recordkeeping.</td>
<td>Yes</td>
<td>Yes</td>
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### Biologics and Biosimilar Substitution: 2013-2016 State Laws

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<tr>
<td>Virginia</td>
<td>H 1422; Ch. 412, signed 3/16/2013</td>
<td>Sponsor: Rep. O'Bannon (R)</td>
<td>Yes</td>
<td>Yes</td>
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<td>S 1285, Ch. 544, signed 3/18/2013</td>
<td>Sponsor: Rep. Newman (R)</td>
<td>Yes</td>
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<td>Washington</td>
<td>S 5935</td>
<td>Signed 2015</td>
<td>Sponsor: Sen. Parlette (R)</td>
<td>(See Rx Database, keyword &quot;Biologics&quot; for specifics). Provides an updated definition for interchangeable biological product and apply the generic substitution state prescription form requirement to select &quot;dispense as written&quot; to prevent substitution or &quot;substitution permitted.&quot; Pharmacists must list the manufacturer of the drug dispensed electronically or manually in the patient's health records and retain a record like other prescription record retention. Also providing protection from any &quot;greater liability&quot; for selecting the interchangeable biological product, and protecting the prescribing practitioner as not liable for a pharmacist's act or omission in selecting an interchangeable biological product.</td>
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**Mandatory Prescription Drug Substitution Laws**

For a number of years before the discussion of biosimilars, at least 14 states and Puerto Rico mandatorily have required the state-regulated pharmacist to substitute a generic version of the prescribed drug if all prescription requirements are met. These laws are not invalidated by biosimilar substitution measures enacted as of May 2015. These jurisdictions include:

- Florida
- Kansas
- Kentucky
- Massachusetts
- Minnesota
- Mississippi
- Nevada
- New Jersey
- New York
- Pennsylvania
- Puerto Rico
- Rhode Island
- Washington
- West Virginia (Unless in pharmacist’s judgment; must be less expensive)


Six states allow pharmacists to prescribe categories of medications independently:

- Colorado
- Connecticut
- Florida
- Idaho
- West Virginia
- Wyoming

**The role for Medicaid programs**

On March 30, 2015, the Centers for Medicare and Medicaid Services released a guidance fact sheet that sets a framework by “issuing guidance to states on the classification of biosimilar biological products for rebate purposes and on strategies for states to use these products to reduce costs while improving access in terms of state Medicaid preferred drug lists.”

[1]
The CMS release emphasizes pricing and savings: “State Medicaid programs should view the launch of biosimilar biological products as a unique opportunity to achieve measurable cost savings and greater beneficiary access to expensive therapeutic treatments for chronic conditions. States and managed care organizations are encouraged to provide biologics that achieve desirable, cost-effective clinical outcomes for beneficiaries using the various drug utilization and cost management tools they have available (e.g., step therapy, prior authorization, preferred drug lists).”


**Recent News**

**More States Demand Notification to Use Biosimilar Drugs** - Read article by Stateline, March 30, 2015

[Excerpt] Huge Savings Anticipated. Biologics are among the most expensive drugs. As Wiles noted, some cost thousands of dollars a month. In 2010, spending on biologics in the U.S. reached $67 billion, or nearly 30 percent of the overall prescription drug market, with a much steeper growth rate than conventional, drugs. Their imitations will cost far less. In Europe, where biosimilars already are available, they have been priced 15 percent to 30 percent less than their name brand versions. (In the U.S., generic versions of conventional, non-biological drugs can be up to 90 percent cheaper than name-brand versions.)

**Federal Judge Allows Sale of Biosimilar Drug.** From Bloomberg Business, "U.S. District Judge Richard Seeborg said in his ruling that the dispute between the drugmakers hinged on conflicting interpretations of the Biologics Price Competition and Innovation Act, the 2009 law that allows for fast-track approval of biosimilar drugs.” Click here for links to articles on these topics from Kaiser Health News, March 2015.


**Differing Views and Opinions**

Not all health policy stakeholders agree on the role of state laws in regulating biological and biosimilar medications. These are some additional views expressed during the current session deliberations. As always, NCSL takes no position for or against state legislation or laws.

**Institute for Patient Access:** "Biological medications differ substantially from conventional drugs and are classified differently by the FDA; as a result, laws and regulations developed for conventional drugs cannot be applied to biologics. Under current state laws, pharmacists may substitute conventional generic drugs for name-brands without notifying the physician. However, with therapeutically interchangeable biologics, underlying differences in the medications or their manufacturing methods may cause adverse events in some patients or may lead individual patients to respond better to one biologic than another. Physicians must be able to determine exactly which biological medication was given so that they can optimize treatment for each patient. Moreover, in a transparent healthcare system, patients and physicians have a right to know exactly which medication patients receive.” Source: http://1yh21u3ciptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2014/01/tppnp1.pdf (2014)

**Pew Charitable Trusts: Biologic and Biosimilar Drugs—How Federal and State Policy Will Affect Their Use.**

Q: **Are these state provisions necessary to protect patients?** A: Biosimilars deemed interchangeable by FDA are required by statute to be as safe and effective as an FDA-approved, reference biologic, including for patients switching between drugs. Therefore, state provisions are not necessarily needed to protect patients. FDA is likely to address the risks in switching to a biosimilar when it finalizes guidance on determining interchangeability.

Q: **What are the implications of state laws restricting substitution?** A: Although it is too early to know the impact of policies restricting biosimilar substitution, research indicates that limiting the substitution of conventional generics decreases uptake and increases drug prices. For example, one study found that requiring patient consent reduces rates of generic substitution by 25 percent. The same study concluded that state Medicaid programs could save over $100 million if patient consent requirements were eliminated for three top-selling drugs. Full report. March 2016
Following information may be relevant to the patients and populations you serve. The Affordable Care Act, approved March 30, 2015, could yield measurable cost savings and greater access to therapeutic treatment for chronic conditions, the manufacturers, Express Scripts, and others. ... passing laws that create a competitive market for biosimilar products and interchangeable biologic products. Biosimilars Council: "The Generic Pharmaceutical Association (GPhA) and its Biosimilars Council applaud the enactment of legislation in five states to allow automatic substitution for Food and Drug Administration (FDA) approved interchangeable biologic products. Bills in Colorado (SB 71), Georgia (SB 51), Tennessee (SB 984), Utah (HB 279) and Washington (SB 5935) reflect core principles embraced in language agreed upon by GPhA and a wide coalition of brand manufacturers, Express Scripts, and others. ... passing laws that create a competitive market for biosimilar products and provide patient access to affordable versions of these critical medicines.” (GPhA/Biosimilars Council release, May 13, 2015). Additional information is available at www.biosimilarscouncil.org.

Update: Compromise Agreement Announced - “As state legislatures prepare for their 2015 sessions, I am pleased to announce that GPhA has agreed to support compromise automatic substitution legislation that would allow interchangeable biologics to be automatically substituted at the pharmacy. This step brings millions of Americans closer to the day when they will be able to access safe alternatives to costly biologic medicines. Indeed, Express Scripts projects savings of $250 billion in 10 years should only the 11 likeliest biosimilars enter the market.

The compromise legislation was put forward by several GPhA members and reflects our core principles: upholding the current pharmacy practice of automatic substitution; insisting on the science-based FDA determination of interchangeability; and treating all interchangeables and their corresponding brand biologics the same once an interchangeable is approved. The compromise language is a vast improvement over 2012 language that we strongly opposed, and which originally erected numerous barriers to the automatic substitution of interchangeable biologics…” (Statement by GPhA President and CEO, Dec. 9, 2014)
Biosimilars are a type of biological product that is licensed (approved) by the FDA because they are highly similar to an already FDA-approved biological product, known as the biological reference product (reference product) and have been shown to have no clinically meaningful differences from the reference product. Minor differences in clinically inactive components are allowed. But there must be no clinically meaningful differences between the biosimilar and the reference product it was compared to in terms of the safety, purity, and potency of the product.

Health care professionals can prescribe biosimilars just as they would prescribe other medications—by writing the proprietary name or nonproprietary name of the biosimilar on the prescription.

A biosimilar can be approved only for those indications and condition(s) of use previously approved for the reference product, but a biosimilar can be approved for fewer than all the indications and condition(s) of use approved for the reference product. Therefore, it is important for health care professionals to review the product labeling (prescribing information) to determine which conditions of use and routes of administration the biosimilar was approved for.

The FDA has developed a website about biosimilars specifically for providers. And, to learn more about biosimilars and Medicare Part B, please visit this website developed by the Centers for Medicare and Medicaid Services (CMS). You are encouraged to share both of these resources broadly.

Several other bills addressed use of biologics from different approaches. These measures are detailed in a separate off-line report, and include:


In 2013-14 there was an initial wave of state legislators seeking a new solution for how terminally ill patients can gain legal access to experimental drugs not yet approved by the U.S. Food and Drug Administration (FDA). This issue is not directly about biologics and biosimilars, but it has attracted a growing share of attention. NCSL has tracked activities on this approach:

- By 2015-2016, a cumulative total of 49 states had considered similar action. The results were laws signed in 24 additional states (Alabama, Arkansas, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Maine, Minnesota, Mississippi, Montana, Nevada, North Carolina, North Dakota, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia and Wyoming) between January 2015 and April 30, 2016. [List updated 6/3/2016]
- The total signed Right to Try laws now stands at 29 states. (An additional bill in New Hampshire was nearing final passage as of 6/3/2016)
- Also read an NCSL background report, describing the typical provisions and the state legislative pro-con arguments, published March 2015.

"Right to Try" Prescription Drug Laws & Legislation

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See NCSL report and bill text for details
On Feb. 4, 2015, the FDA announced a new, federally-approved "streamlined process" and a revised FDA webpage describing expanded access, sometimes called "compassionate use." An FDA blog post from Deputy Commissioner Dr. Peter Lurie summarizes the new policy.

On June 1, 2016 the FDA issued new guidance that said companies could only charge patients for the cost of manufacturing experimental treatments used under compassionate grounds, and it cannot force government or private health insurers to pay for these drugs.

State Economic Development for Biosciences. The Biotechnology Industry Organization (BIO) released “Bioscience Economic Development in the States: Legislation and Job Creation Best Practices” at the June 2015 BIO International Convention. “This report demonstrates the value of effective public policy in fostering the bioscience industry as an economic engine that provides high-wage, high-skilled jobs.” The Guide is the bioscience industry’s comprehensive analysis of state legislative and regulatory initiatives in support of economic development.

Appendix: Definitions
The following are some key definitions for policymakers to understand in considering regulations, with examples directly from state laws:

**Biological product** means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any 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. [from VA H1422 of 2013]

**Biosimilar** means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U. S. C. Section 262(k) in terms of safety, purity, and potency of the product. [from VA H1422 of 2013]

**Interchangeable** means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U. S. C. Section 262(k)(4).

[Federal law is excerpted below]

**TITLE VII—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES: Subtitle A—Biologics Price Competition and Innovation.**

**U. S. C. (United States Code) Section 262(k)(4) Safety Standards For Determining Interchangeability.**—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

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(A) the biological product—
(i) is biosimilar to the reference product; and
(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) 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 use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.
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(Full text of FDA-related federal law: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/ucm216146.pdf)

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