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

January 2015 - Covering 2013-2014 legislative sessions

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 both familiar pills used by tens of millions of Americans weekly and 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 desired therapeutic substances and consist of large molecules. Common biologics in use today include human growth hormone, injectable treatments for arthritis 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, biological 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 and states face regulatory issues about them.

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, or add new sections, to address the medical and chemical characteristics of these "biologics" and any future generic-style "follow-on biologics", "biosimilars", or "interchangeable biological products."

In the past two years at least 23 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 (2013-2014)

The provisions of state legislation vary, but there are several features and requirements that frequently are included. (These differ from language described as compromise legislation, and announced in Dec. 2014):

- Any biological product under consideration for substitution must first be approved as "interchangeable"* for substitution by the U.S. Food and Drug Administration (FDA). (One product has gained "recommended" approval as a biosimilar in the United States as of Jan. 7, 2015)

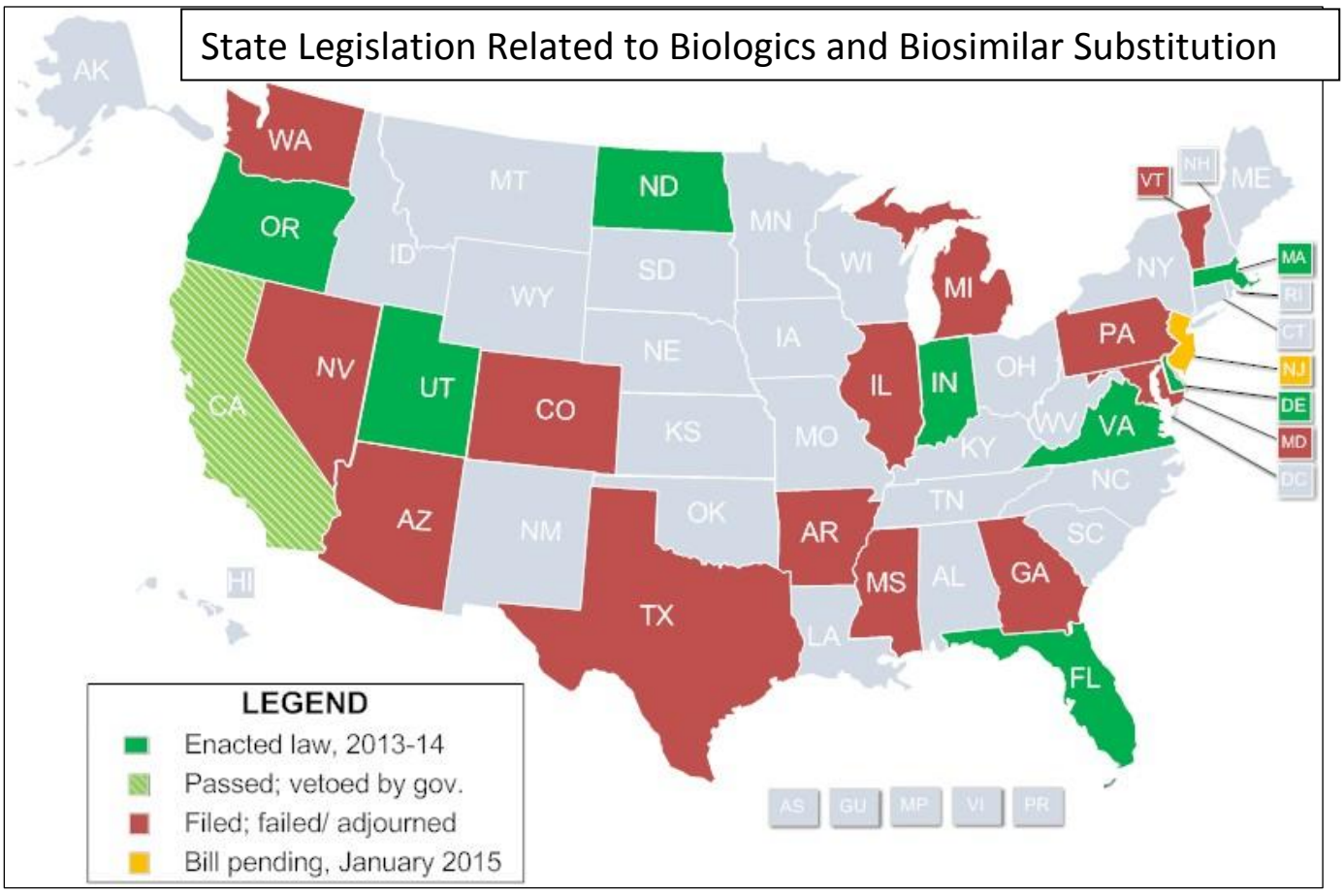
- The prescriber (such as a physician, oncologist, physician assistant, etc.) would be able to prevent substitution by stating “dispense as written” or “brand medically necessary.”
- The prescriber must be notified of any allowable substitution made at a pharmacy. (This would allow a physician to assess and compare the patient experience.)
- 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.
- The pharmacist would not be liable in any way for the dispensing of an interchangeable biological product if it complied with the listed state law provisions.
- The state must maintain a public list of permissible interchangeable products.

The state legislation tally (as of December, 2014)

- Eight states have enacted statutes;
- One state (California) passed a bill through both chambers that was vetoed and did not become law;
- 13 states had bills filed which did not pass; one state (New Jersey) has bills carried over to 2015.

Several other bills addressed use of biologics from different approaches. These other measures, not included in this report, include:

- “Right to Try” legislation, proposing to allow use of experimental drugs prior to full FDA approval.
- Economic incentive measures intended to expand Bio research and manufacturing in individual states.



Map compiled by NCSL Jan. 7, 2015 ©

2013 – 2014 State Laws and Legislation

State	Citation/ Bill # / Lead sponsor Links: blue	Summary Description (The brief summaries reproduced below are not intended to describe all statutory provisions – see full text for further information)	FDA must certify interchangeability	Doctor/prescriber notification	Patient notification	Prescriber's "Brand medically necessary" blocks substitution	Pharmacy records must be retained	Posted list of interchangeable
ENACTED LAWS		**Signed in 8 states**						
Delaware	**S 118; Ch. 238, signed 5/28/2014** Sponsor: Sen. Poole (D) (Same as S 262)	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; and maintain a three year record of such substitutions. Also provides liability protections for pharmacists who substitute biosimilars.	**Yes**	**Yes**	**Yes**	**Yes**	**Yes 3 yrs.**	**.**
Florida	**H 365; Ch. 2013-102; signed 6/3/2013** Sponsor: Rep. Matt Hudson (R)	Relates to pharmacy substitutions; provides requirements for pharmacist to dispense substitute biological product, requiring the FDA to have determined substitute biological product is "biosimilar to and interchangeable for prescribed biological product." The prescribing provider must not "express a preference against substitution; "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 as of July 1, 2013.	**Yes**		**Yes**	**Yes**	**Yes 2 yrs.**	**Yes**
Indiana	**S 262; Ch. 96, signed 3/31/2014** Sponsor: Sen. Hershman (R)	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 "May substitute" 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.	**Yes**	**Yes**	**Yes prior**	**Yes**	**Yes**	**Yes**
Massa-chusetts	**H 3734** Passed House & Senate; **Ch. 143 signed 6/23/2014** Sponsor: Rep. Cusack (D)	Provides that a pharmacist may substitute an interchange-able 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 Dept. of Public Health to issue regulations and specify enforcement.	**Yes**	**Yes incl. EHR**	**Yes**	**Yes**	**Yes 1 yr.**	
North Dakota	**S 2190; Ch. 181; signed 6/26/2013** Sponsor: Sen. Dever (R); co-chair HHS Comm.	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	**Yes**	**Yes 24 hrs.**	**Yes**	**Yes**	**Yes 5 yrs.**	**Yes**

		chooses not to refuse. Requires records retention for five years and public posting of such products.						
Oregon	**S 460; Ch. 342, signed 6/6/2013** Sponsor: Sen. Monnes Anderson (D)	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. Effective upon passage, June 6, 2013.	**Yes**	**Yes** 3 days	**Yes**	**Yes**	**Yes** 3 yrs.	**Yes**
Utah	**S 78; Ch. 423; signed 4/26/2013** Sponsor: Sen. Stuart Adams (R)	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 regulates out of state pharmacies; relates to labeling and recordkeeping.	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	
Virginia	**H 1422; Ch. 412, signed 3/16/2013** Sponsor: Rep. O'Bannon (R) **S.1285, Ch. 544, signed 3/18/2013.** Sponsor: Rep. Newman (R)	Relates to dispensing of interchangeable biosimilar biological products; permits pharmacists to dispense a biosimilar that has been licensed by the FDA as interchangeable with a prescribed biological product unless the prescriber indicates such substitution is not authorized or the patient insists on dispensing of the prescribed biological product. The pharmacist or his designee must inform the patient prior to dispensing the interchangeable biosimilar and must disclose the retail cost. The notification provisions sunset July 1, 2015.	**Yes**	**Yes** 5 days	**Yes** prior	**Yes** (MD or patient)	**Yes** 2 yrs.	
PASSED LEGISLATURE BUT VETOED (1 state)								
California	**S 598 of 2013; Passed Senate & Assembly; *Vetoed*, 10/12/2013 Did not become law** Sponsor: Sen. Hill (D)	Authorizes a pharmacist, in his or her discretion, to select a biosimilar when filing a prescription order for a prescribed biological product only if the product has federal approval and the prescriber does not personally indicate "no substitution." Requires that the pharmacy notify the prescriber or enter into a patient record the dispensed product. Prohibits a biosimilar unless the cost is less. Requires patient notification and posting interchangeable biosimilar products on a state specified Web site. Provides a pharmacist protection from liability when prescribing a biosimilar in accordance with this act.	**Yes**	**Yes** 5 days	**Yes**	**Yes**		Yes

LEGISLATION FILED, PENDING OR DID NOT PASS, 2013-2014			
State	**Bill#**	**Status**	**Summary Description**
Arkansas	S 149	2013; Failed-adjourned	Would regulate the substitution of biosimilar biological products for certain prescribed products.
Arizona	S 1438	2013; Failed-adjourned	Would provide 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 indicate that the brand is necessary and the pharmacist informs the prescriber and the patient of the substitution. Requires records retention for seven years and public posting of interchangeable products.
California	A 1139	(See passed bill above)	Would authorize a pharmacist filling a prescription order for a biological

		2013-14; Failed-adjourned	product subject to the Federal Food, Drug, and Cosmetic Act, to select a biosimilar product, as defined by federal statute, provided that product is deemed by the federal Food and Drug Administration to be interchangeable with the prescribed product.
Colorado	H 1121	2013; Failed-adjourned	Concerns the ability of a pharmacist to substitute a biosimilar product for a prescribed biological product when certain conditions are satisfied
Florida	S 732	(See enacted law H 365, above) 2013	Would authorize a pharmacist to substitute a biosimilar product for a prescribed product if certain requirements are met.
Georgia	S 370	2013-14; Senate Health & Human Services Comm., 6/14) Failed-adjourned	Relates to pharmacists and pharmacies; would provide for substitutions of interchangeable biological products; specifying requirements and limitations. Patient may block substitution by specifying original; Physician may specify brand "medically necessary."
Illinois	S 1934	2013-14; Failed-adjourned *(session ended 1/13/2015)*	Would amend the Pharmacy Practice Act, providing that a pharmacist may substitute a prescription biosimilar product for a prescribed biological product under certain circumstances, and provides that the Board shall adopt rules for compliance with these provisions.
Maryland	S 781	2013; Failed-adjourned	Would authorize pharmacists to substitute biosimilar biological products for prescribed biological reference products only under specified circumstances, requires pharmacists or their designees to give specified notices and record specified information if the pharmacist substitutes an interchangeable biosimilar biological product for a prescribed biological reference product.
Massachusetts	H 1927	2013-14. (combined with enacted law H3724, above)	Would provide 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;" 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 Dept. of Public Health to issue regulations and specify enforcement. RC
	S 2176	(See enacted law H3724, above)	
Michigan	H 5598	2014; held in Comm. on Health Policy. (Filed 5/27/14) Failed-adjourned	Would provide that a pharmacist may substitute an interchangeable product, once they notify the purchaser if a drug is dispensed that is not the prescribed brand name drug product. Requires the pharmacist to indicate both the brand name prescribed and the generic name or biosimilar name of the drug product dispensed, and list each name on the prescription label.
Mississippi	H 1268	2014; Failed-adjourned	Would authorize the substitution of interchangeable biological products for a prescribed product by a pharmacist under certain circumstances.
	H 1387	2013; Failed-adjourned	Would authorize the substitution of interchangeable biological products for a prescribed product by a pharmacist under certain circumstances.
	S 2085	2013; Failed-adjourned	Would provide for the substitution of interchangeable biological products for a prescribed product by a pharmacist
Nevada	SB 126	2013; Failed-adjourned (No action by Senate comm.)	Would authorize a pharmacist to dispense a therapeutically equivalent drug in place of a prescribed drug under certain circumstances if the pharmacist has obtained the consent of the prescribing practitioner and the person presenting the prescription. Would apply to both traditional generic drugs and biosimilars; requiring advising the person "that he or she may refuse to accept the therapeutically equivalent drug that the pharmacist intends to dispense" and require a written record at the pharmacy.
New Jersey	A 2477	2014-2015 pending (Assembly Health & Senior Services Comm.)	Would permit a pharmacist to substitute biosimilar biological product if the product is FDA "interchangeable"; the prescriber has not selected "do not substitute"; "notify the patient in writing that the substituted biological product dispensed has been FDA approved; notify the physician within 5 days of the interchange; and keep a record for five years. *(2014 session ended 1/12/15; subject to carryover to 2015 session)*
	S 1705	2014-2015 pending (In Senate Health Comm.)	

Oregon	H 2705	See Enacted law S 460 2013; (Held in committee)	Would restrict substitution of biosimilar product for prescribed biological product, would become operative on passage.
Pennsylvania	H 746	2013-14; held (House Health Comm.) Did not pass	Would amend the state Generic Equivalent Drug Law, further providing for biosimilar substitutions only if the product is determined by the FDA to be "interchangeable", the prescriber does not prohibit substitution and both prescriber and patient are notified of the substitution. Also providing for posting a list of interchangeable biological products and for immunity of pharmacists dispensing an interchangeable product in compliance with this state law. *(as amended 9/2014)*
	S 405	2013-14; passed Senate 6/24/14; Did not pass House by adjournment 11/2014	
Texas	H 542	2013; Failed-adjourned	Would specify the conditions for prescription and pharmaceutical substitution of biological products.
	S 190		
Vermont	H 837	2013-14; Failed-adjourned 6/14	Relates to generic substitution for biological products. Using the same standard as generic substitution, would provide that a prescriber can prevent substitution by specifically stating "brand necessary" or equivalent; the pharmacist must select the lowest priced FDA-approved interchangeable biological product unless otherwise instructed by the prescriber, or if the purchaser agrees to pay "any additional cost."
Washington	H 1528	2013-14; Failed-adjourned	Concerns the prescription of biological products and interchangeable biosimilar products.
	S 5469		
	H 2326	2014; Failed-adjourned	Concerns the prescription of biological products and interchangeable biosimilar products. Would add biosimilars to existing law on generic drugs, to provide that, "Every prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior-consent authorization." If a biosimilar is substituted, a pharmacist must inform prescribing practitioner and patient of the name and manufacturer of the biological product dispensed and retain a record. The state pharmacy quality commission must link its web site to the current list of all approved interchangeable biological products.
	S 6091		

NCSL research; powered by StateNet and state websites

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 June 2014. These jurisdictions include:

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

Source: NABP: 2014 Survey of Pharmacy Law, pp. 67 – 70.

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.

AHIP: "Remove barriers at the state level that restrict the use of biosimilars. While the Affordable Care Act authorized the FDA to develop an abbreviated licensure pathway for biosimilar drugs, it has yet to issue final standards that will determine when a biosimilar drugs is truly interchangeable with an already approved biologic. Ahead of these standards, some states have already adopted legislation that may restrict the availability of biosimilars before they even reach the market. These proposals will limit patient access to drugs that are not clinically different, yet cost substantially less than their brand-name counterparts." *(America's Health Insurance Plans In "Specialty Drugs - Issues and Challenges", June 2014)*

Biotechnology Industry Organization (BIO). "While the U.S. Food and Drug Administration (FDA) oversees approval of biologic medicines and designation of interchangeability, policies governing whether one product may be substituted in place of a doctor's prescription and whether a pharmacist must inform patients and doctors are covered by state law. (Indiana) SB 262 seek to properly preserve patient access to accurate prescription information, maintain incentives for innovation and promote a competitive market for biologic therapies. BIO will continue to advocate for full transparency in the substitution process as patients and their physicians should have the right to know what biologic medicine the patient receives from the pharmacy. Bills such as this, that properly addresses the important aspect of physician communication, represent model legislation necessary in all 50 states to address this cutting-edge technology." *(BIO statement in support of Indiana legislation, Feb. 26, 2014)*

Governor Brown of California: Bill 598 would effect two changes to our state's pharmacy law. First, it would allow interchangeable "biosimilar" drugs to be substituted for biologic drugs, once these interchangeable drugs are approved by the federal Food and Drug Administration (FDA). This is a policy I strongly support. Second, it requires pharmacists to send notifications back to prescribers about which drug was dispensed. This requirement, which on its face looks reasonable, is for some reason highly controversial. Doctors with whom I have spoken would welcome this information. CalPERS and other large purchasers warn that the requirement itself would cast doubt on the safety and desirability of more cost-effective alternatives to biologics. The FDA, which has jurisdiction for approving all drugs, has not yet determined what standards will be required for biosimilars to meet the higher threshold for "interchangeability." Given this fact, to require physician notification at this point strikes me as premature. For these reasons, I am returning SB 598 without my signature. *(Governor's veto message, Oct. 8, 2013)*

GPhA: " Interchangeability or substitution is the engine that drives generic competition."
(Generic Pharmaceutical Association, "Biosimilars")

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)*

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://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-

cdn.com/wp-content/uploads/2014/01/tppnp1.pdf (2014)

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—

> ‘‘(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.

(Full text of FDA-related federal law: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/ucm216146.pdf

"Interchangeable biological product" means a biological product licensed by the United States food and drug Administration and determined to meet the safety standards for interchangeability pursuant to 42 U.S.C. § 262(k)(4) (relating to regulation of biological products) or a biological product determined by the United States Food and Drug Administration to be therapeutically equivalent as set forth in the latest edition or supplement of the United States Food and Drug Administration approved drug products with therapeutic equivalence evaluations, sometimes referred to as the "Orange Book." *[from PA S405, September 2014 amendment]*

Compiled by Richard Cauchi, NCSL Health Program - Denver, Colorado.