MINTZ LEVIN

STATE BIOSIMILAR SUBSTITUTION LAWS

***Please note*: This chart is for informational purposes only and does not constitute legal advice or opinions regarding any specific facts relating to the substitution of biosimilars. You should seek the advice of experienced legal counsel when reviewing options and obligations in complying with biosimilar substitution laws.**

State laws and regulations concerning drug policy change quickly. This chart is current as of October 16, 2015.

States have generally used federal standards to define "interchangeable" or "interchangeability," as set forth in 42 U.S.C. § 262(k)(4). Interchangeable or Interchangeability means (1) the biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient; and (2) if administered more than once, the risk in terms of safety or diminished efficacy of alternating between the use of the biological product and reference product is not greater than the risk of using the reference product alone.

This chart provides **general information and not legal advice** regarding any specific facts or circumstances. For more information about state biosimilar substitution laws, or other pharmaceutical matters, please contact the Mintz Levin attorney with whom you work, or Theresa Carnegie (TCCarnegie@mintz.com | 202.661.8710), Ellyn Sternfield (ELSternfield@mintz.com | 202.434.7445), Joanne Hawana (JSHawana@mintz.com | 202.434.7349), or Sarah Beth Smith (SBSmith@mintz.com | 202.434.7453).

1) California	6) Idaho	11) North Dakota	16) Virginia
2) Colorado	7) Indiana	12) Oregon	17) Washington
3) Delaware	8) Louisiana	13) Tennessee	
4) Florida	9) Massachusetts	14) Texas	
5) Georgia	10) North Carolina	15) Utah	

State	Substitution Requirements	Pharmacy Notification Requirements (to prescriber, patient, or others)	Recordkeeping Requirements
California S.B. 671 Effective January 1, 2016	A pharmacist may substitute an alternative biological product for a prescribed biologic if 1. The alternative is interchangeable; 2. The prescriber did not indicate "do not substitute"; and 3. The cost to the patient of the alternative is the same as or less than the price of the prescribed biologic.	The pharmacist (or designee) must notify the prescriber: 1. Of the drug's name and manufacturer; 2. Within 5 days of dispensing the biologic; and 3. Via an interoperable electronic medical records system (with exceptions). The patient must also be notified of the substitution.	None.
Colorado S.B. 15-071 Effective April 3, 2015 (date signed by Governor)	A pharmacist may substitute a biosimilar for a prescribed biologic only if: 1. FDA has determined the biologic is interchangeable with the prescribed biologic; 2. The prescriber has not expressed a preference against substitution; and 3. The prescribed biologic costs more than the biosimilar.	The pharmacist (or designee) must notify the prescriber: 1. Of the drug's name and manufacturer; 2. Within a reasonable amount of time after dispensing the biologic; and 3. Via an interoperable electronic medical records system (with exceptions). The pharmacist also must notify the "purchaser" of the substitution in writing or orally.	The pharmacy must keep a written or electronic record of the dispensed biologic for at least 2 years after the substitution.
Delaware S.B. 118 Effective May 28, 2014 (date signed by Governor)	A pharmacist may substitute a biosimilar for a prescribed biologic if: 1. FDA has determined the biologic is interchangeable with the prescribed biologic; and 2. The prescriber has not expressed a preference against substitution.	The pharmacist (or designee) must notify the prescriber of the substitution: 1. Within 48 hours of dispensing; and 2. Via writing, fax, telephone, or electronic means. The pharmacist (or designee) also must notify the patient in writing that FDA approved the dispensed biosimilar as interchangeable with the prescribed biologic.	The pharmacist must record on the prescription label and in the dispensation record: 1. The name of the dispensed biosimilar followed by "substituted for" and the name of the prescribed biologic; and 2. The manufacturer of the dispensed biosimilar Records of the substitution must be kept for at least 3 years after dispensing.

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Florida H.B. 365 Effective July 1, 2013	A pharmacist may substitute a biosimilar for a prescribed biologic if: 1. FDA has determined the biologic is interchangeable with the prescribed biologic; and 2. The prescriber has not expressed a preference against substitution.	The pharmacist must notify the person presenting the prescription of the substitution, along with the amount of the retail price difference between the prescribed biologic and the substituted biosimilar, and the person must be informed of the right to refuse such substitution.	The pharmacist must keep written or electronic records of the substitution for at least 2 years.
Georgia S.B. 51 Effective July 1, 2015	A pharmacist may substitute a biosimilar for a prescribed biologic if: 1. FDA has determined the biologic is interchangeable with the prescribed biologic; 2. Neither the prescriber nor the patient has expressed preference against substitution; and 3. The substituted biosimilar has the lowest retail price of all interchangeable biologics in stock (when a prescriber prescribes a biologic by its nonproprietary name).	The pharmacist (or designee) must notify the prescriber: 1. Of the drug's name and manufacturer; 2. Within 48 hours (excluding weekends and holidays) after dispensing the biologic; and 3. Via an electronic means (i.e., medical records system, prescribing technology, pharmacy record) (with exceptions).	The name and an explanation of the substituted biologic must be on the prescription label (with exceptions). The pharmacist also must record on the original prescription that the substitution was made and the name of the dispensed biologic.
Idaho 27.01.01 - Rule of the Idaho Board of Pharmacy Effective April 11, 2015 (after close of 2015 regular legislative session)	A pharmacist may substitute a biosimilar for a prescribed biologic if: 1. FDA has determined the biosimilar is interchangeable with the prescribed biologic and it has been published in the *Purple Book*; 2. The prescriber does not indicate that the prescribed biologic must be dispensed; and 3. The name of the drug and manufacturer or NDC number is documented in the patient's medical record.	N/A	The name of the drug and manufacturer or NDC number must be documented in the patient's medical record if a pharmacist substitutes a biologic.

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Indiana S.B. 262 Effective July 1, 2014	A pharmacist may substitute a biosimilar for a prescribed biologic if: 1. FDA has determined the substitute is interchangeable with the prescribed biologic; and 2. The prescriber has indicated that the biologic may be substituted.	The pharmacist must inform the "customer" of the substitution. The pharmacist also must notify the prescriber: 1. Of the name and manufacture of the dispensed biologic; 2. Within 10 calendar days of dispensing; and 3. Via an interoperable EHR system (with exceptions).	The pharmacy must keep a record of the dispensed biologic, whether in written or electronic format, for at least 2 years. In addition, the prescriber must keep a record of the dispensed biologic, whether the patient's original health records or microfilms, for at least 7 years.
Louisiana H.B.319 Effective August 1, 2015	A pharmacist may substitute a biosimilar for a prescribed biologic if: 1. FDA has determined the substitute is interchangeable with the prescribed biologic; 2. The prescriber has not indicated that substitution is prohibited; and 3. The patient has consented to the substitution.	The pharmacist (or designee) must notify the prescriber: 1. Of a dispensed biological product's name and manufacturer; 2. Within 5 days of dispensation; and 3. Via any means.	No recordkeeping requirements that are specific to biological products (general pharmacy recordkeeping rules apply).
Massachusetts H.3734 Effective September 21, 2014 (90 days after date signed by Governor)	A pharmacist may substitute a biosimilar for a prescribed biologic (even when prescribed by brand name) if: 1. FDA has determined it is interchangeable with the prescribed biologic; and 2. The prescriber has not instructed in writing that substitution is not authorized.	The pharmacist (or designee) must notify the prescriber of the substitution: 1. Within a reasonable amount of time after the substitution is made; and 2. Via the patient's interoperable electronic health record (with exceptions). The pharmacist (or designee) also must notify the patient (or the patient's authorized representative) in writing of the substitution.	The pharmacist (or designee) must keep a record of each substitution for at least 1 year since the last record of dispensation. In addition, the prescriber and the administering practitioner must keep a record of each substitution for at least 1 year since the dispensation of an interchangeable biologic.

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North Carolina H.B. 195 Effective October 1, 2015	A pharmacist may substitute a biosimilar for a prescribed biologic if: 1. FDA has determined it is interchangeable with the prescribed biologic; 2. The prescriber has not instructed that substitution is not authorized; 3. The manufacturer's name and distributor's name (if different than the manufacturer's name) appear on the label of the stock package; 4. It is manufactured according to Good Manufacturing Practices; 5. On solid oral dosage forms, the manufacturer or distributor is identified by logo, identification mark, or product name; and 6. The manufacturer has adequate provisions for drug recall and for the return of outdated drugs.	The pharmacist (or designee) must notify the prescriber: 1. Of the product's name and manufacturer; 2. Within a reasonable amount of time after dispensing the biologic; and 3. Via an electronic means (i.e., medical records system, prescribing technology, pharmacy record) (with exceptions)	For prescriptions ordered orally by a prescriber, the pharmacist must note the prescriber's instructions about dispensation on the file copy of the prescription.
North Dakota S.B. 2190 Effective August 1, 2013	A pharmacy may substitute a biosimilar for a prescribed biologic only if: 1. FDA has determined it is interchangeable with the prescribed biologic; and 2. The prescriber has not indicated that the brand name biologic is medically necessary.	The pharmacy must inform the individual receiving the biologic that the biologic may be substituted with a biosimilar and that he/she has a right to refuse the biosimilar. Within 24 hours, the pharmacy also must notify the prescriber of the substitution orally, in writing, or via electronic transmission.	The pharmacy must keep a record of the substitution for at least 5 years. In addition, the prescriber must keep a record of the substitution for at least 5 years.

State	Substitution Requirements	Pharmacy Notification Requirements (to prescriber, patient, or others)	Recordkeeping Requirements
Oregon S.B. 460 Effective June 6, 2013; amendments effective January 1, 2016	A pharmacy or pharmacist may substitute a biosimilar for the prescribed biologic only if: 1. FDA has determined the biosimilar is interchangeable with the prescribed biologic; and 2. The prescriber has not indicated on the prescription that substitution is prohibited.	The pharmacy or pharmacist must inform the patient of the substitution prior to dispensing. Currently, the law requires the pharmacy or pharmacist to notify the prescriber of the substitution within 3 business days after the dispensing date. However, this requirement will be deleted via amendments to the law effective January 1, 2016.	The pharmacy or pharmacist must keep a record of the substitution for at least 3 years.
Tennessee S.B. 984 Effective May 4, 2015	Prescribers must allow pharmacists to make substitutions with interchangeable biosimilars, unless an exception applies. Available exceptions include situations in which the prescriber determines that a prescribed biologic is medically necessary.	The pharmacist must notify the patient of the substitution by noting the substitution on the prescription label. The pharmacist (or designee) must also notify the prescriber: 1. Of the product's name and manufacturer; 2. Within a reasonable amount of time after the substitution is made; and 3. Via an electronic means (i.e., medical records system, prescribing technology, pharmacy record) (with exceptions).	The pharmacist must maintain a record of any dispensed biologic for 2 years.

State	Substitution Requirements	Pharmacy Notification Requirements (to prescriber, patient, or others)	Recordkeeping Requirements
Texas H.B. 751 Effective September 1, 2015	A pharmacist may substitute a biosimilar for the prescribed biologic only if: 1. FDA has determined it is interchangeable with the prescribed biologic; 2. The prescriber has not certified on the prescription that the prescribed brand is medically necessary; 3. The patient has not indicated a choice for the band name biologic; and 4. The interchangeable biologic costs less than the prescribed biologic.	The pharmacist must notify the patient personally or through an agent or employee: 1. Prior to dispensing the biologic; 2. That a less expensive interchangeable biologic is available; and 3. The patient must be given the opportunity to choose between the biosimilar or prescribed biologic. The pharmacist also must notify the prescriber: 1. Of the product's name and manufacturer; 2. Within 3 days after dispensing the biologic; 3. Via an electronic means (i.e., medical records system, prescribing technology, pharmacy record) (with exceptions). The requirement to notify the prescriber expires on September 1, 2019.	The pharmacist must put on the container "substituted for brand prescribed" or "substituted for [brand/biologic name]." Pharmacists must keep a record on the prescription form of the dispensed biologic's name, strength, and manufacturer or distributor. Additional requirements for container labels apply to Class A and Class E pharmacies. NOTE: On September 25, 2015, the Texas State Board of Pharmacy published a proposed rule to implement H.B. 751 with regulations. Comments on the proposal are due by Oct. 30, 2015.
Utah H.B.279 Effective May 12, 2015	A pharmacist may substitute a biosimilar for the prescribed biologic only if: 1. FDA has determined it is interchangeable with the prescribed biologic and it is "permitted to move in interstate commerce"; 2. The purchaser specifically requests or consents to the substitution; 3. The pharmacist or pharmacy intern counsels the patient on the use and expected response to the biologic, whether a substitute or not; and 4. The prescriber has not prohibited substitution.	The pharmacist or pharmacy intern must notify the "purchaser" of a substitution. Out-of-state mail order pharmacies must notify the patient by telephone or in writing. The pharmacist (or designee) also must notify the prescriber: 1. Of the product's name and manufacturer; 2. Within 5 business days of dispensing the biologic; 3. Via electronic health records (with exceptions). An entry in an electronic system is presumed to provide notice to the prescriber, otherwise notification can be done through other means.	If the prescriber orders the prescription orally, the pharmacist or pharmacy intern must make a note of the prescriber's directions about substitution, as well as the prescriber's name, the words "orally by," and the initials of the pharmacist or pharmacy intern. The dispensed biosimilar's container must be labeled with the name of the product. The pharmacist, pharmacy intern, or pharmacy technician must indicate on the prescription's file copy the prescribed biologic and the dispensed biosimilar's names.

State	Substitution Requirements	Pharmacy Notification Requirements (to prescriber, patient, or others)	Recordkeeping Requirements
Virginia S.B. 1285/ H.B. 1422 Effective July 1, 2013	A pharmacist may dispense a biosimilar that the FDA has licensed as interchangeable with the prescribed biologic, unless: 1. The prescriber indicates the substitution is not authorized by specifying on prescription "brand medically necessary"; or 2. The patient insists that the prescribed product be dispensed.	The pharmacist must notify the patient prior to dispensing a substituted biosimilar. In addition, the patient must be provided the retail cost information for both the prescribed biologic and the dispensed biosimilar at the time of substitution. This second patient-notification requirement expired on July 1, 2015. The pharmacist (or designee) also must notify the prescriber of the substitution: 1. Within 5 business days of dispensing; and 2. Via writing, telephone, or electronic means. (NOTE: This provision expired on July 1, 2015.)	Records of substitutions must be kept for at least 2 years from the date of dispensing. For substitutions, the pharmacist (or designee) must indicate on the dispensation record and prescription label the name of manufacturer or distributor of the dispensed biosimilar. The pharmacist (or designee) also must label the drug with the name of the biosimilar followed by the words "substituted for [name of prescribed biologic]."
Washington S.B. 5935 Effective July 24, 2015	A pharmacist must dispense an interchangeable biosimilar if: 1. It is in stock; 2. It has a lower wholesale price than the prescribed biologic cheaper and in stock; 3. The prescriber did not specify in the prescription that substitution is prohibited; and 4. The patient or patient's representative does not ask for the prescribed biologic. Every prescription must contain an instruction as to whether or not an interchangeable biosimilar may be substituted in its place (with exceptions).	Every pharmacy must post a sign that is visible to patients regarding potential substitution of a less expensive biosimilar. The pharmacist (or designee) must notify the prescriber: 1. Of the product's name and manufacturer or NDC number; 2. Within 5 business days of dispensing the biologic; 3. Via an electronic medical record and by another means if the prescriber cannot access the record. An entry in an electronic system is presumed to provide notice to the prescriber.	For oral prescriptions, the pharmacist must record the prescriber's directions about substitution in the file copy of the prescription. The pharmacist must note the manufacturer of the dispensed drug on the file copy of a prescription, which must be maintained for 2 years.