Survey of States with Biological Product or Biosimilar Legislation

State	Citation	Summary/Description	FDA Must Certify Interchangeability	Prescriber/Doctor "Notification" (N) or "Cummunication" [C]	Patient Notification	Prescribers Can Block Substitutuion	Pharmacy Records Must be Retained	Posted List of Interchangeables	Orange Book or Purple Book
Arizona	Ariz. Rev. Stat. Ann. § 32-1963.01	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.	Yes	Yes (C 5 days)	Yes	Yes	Yes	Yes	Orange
California	Cal. Bus. & Prof. Code § 4073.5	Authorizes a pharmacist to select an alternative biological product when filling a prescription order for a prescribed 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.	Yes	Yes (C 5 days)	Yes	Yes	Unclear	Yes	Orange
Colorado	Colo. Rev. Stat. Ann. § 12-42.5-122	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.	Yes	Yes (C Within a reasonable time)	Yes	Yes	Yes (2 years)	Yes	Orange
Delaware	Del. Code Ann. tit.24, § 2549A	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 N	Yes in writing	Yes	Yes (3 years)	Yes	Neither Mentioned

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Florida	Fla. Stat. Ann. § 465.0252	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.	Yes	Unclear	Yes	Yes	Yes (2 years)	Yes	Neither Mentioned
Georgia	Ga. Code Ann. § 26-4-81	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 which in 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.	Yes	Yes (C 48 hours)	Unclear (Patient may Instruct To Not Substitute)	Yes	Unclear	Yes	Neither Mentioned
Hawaii	Haw. Rev. Stat. Ann. § 328-921 et seq.	Allows for and regulates the dispensing of interchangeable biological products. Requires pharmacists to inform consumers of interchangeable biological products from the Hawaii list when filling a prescription order and to communicate the product name and manufacturer to the practitioner after dispensing the product. Requires that less expensive "interchangeable bioloical products be offered to the consumer." Repeals the Drug Product Selection Board.	Yes	Yes (N 2 days)	Patient consent only required for anti-epileptic drugs	Yes	Yes	Not Required, but May	Both
Idaho	Idaho Code Ann. § 54-1769	Adds to existing law to provide that a pharmacist who dispenses an interchangeable biological product "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."	Yes	Yes (C 5 days)	No	Unclear	No	No	Orange

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Illinois	225 Ill. Comp. Stat. Ann. 85/19.5	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 be by electronic, a pharmacy benefit management system, or a pharmacy record.	Yes	Yes (5 days)	Yes	Yes	Yes	Yes	Orange
Indiana	Ind. Code Ann. § 16-42-25-1	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 to dispensing)	Yes (May substitute only if the word "may substitute" appear)	Yes	Yes	Orange
Iowa	2017 Ia. Legis. Serv. Ch. 5 (H.F. 305); Iowa Code Ann. § 155A.32	Creates a state process for pharmacists to substitute interchangeable biological products, requires notification to patients and within 5 days communicate with prescriber. "If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a biological product that is an interchangeable biological product for the biological product prescribed for dispensing and sale."	Yes	Yes (C 5 days)	Yes ("Shall inform")	Yes	Unclear	Yes	Orange
Kansas	2017 Kansas Laws Ch. 34 (H.B. 2055); Kan. Stat. Ann. § 65-1637	Amends the Pharmacy Practice Act to allow for the substitution of an interchangeable biological product (in addition to other pharmacy changes).	Yes	Yes (C 5 days)	Yes ("Shall inform")	Yes	Yes (5 years)	Yes	Orange

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Kentucky	2016 Kentucky Laws Ch. 73 (SB 134); Ky. Rev. Stat. Ann. § 217.822	Defines biological product and interchangeable biological product and to re-order other definitions, 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.	Yes	Yes (C 5 days)	Yes (Patient May Instruct Otherwise)	Yes	Yes (2 years)	No	Orange
Louisiana	La. Stat. Ann. § 37:1164	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.	Yes	Yes (C 5 days)	Unclear	Unclear	Unclear (BUT under 37:1229, required to maintain records for 2 years)	No	Both
Maryland	2017 Maryland Laws Ch. 726 (H.B. 1273); Md. Code Ann., Health Occ. § 12-504.1	Authorizing a pharmacist to substitute an interchangeable biological product for a certain prescribed product under certain circumstances; requiring inform to be given to consumers of the availability of an interchangeable biological product and the approximate cost difference as compared to a certain drug. Requires a pharmacist who makes a biologic substitution to notify the patient in writing and to keep records relating to the substitution. Authorizes the Department of Health and Mental Hygiene to disqualify an interchangeable biological product from being used as a substitute under certain circumstances.	Yes	Yes (C 5 days)	Yes	Yes	Yes (But Unclear as to time period)	Yes	Orange
Massachusetts	Mass. Gen. Laws Ann. ch. 112, § 12EE	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.	Yes	Yes (reasonable time following substitution)	Yes	Yes	Yes (1 year)	No	Neither Mentioned

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Minnesota	2017 Minn. Sess. Law Serv. Ch. 84 (H.F. 712); Minn. Stat. Ann. § 151.21	Establishes standards and requirements for the substitution of biological products by pharmacists.	Yes	Yes (C 5 days)	Yes	Yes	Unclear	Yes	Orange
Missouri	Mo. Ann. Stat. § 338.085	Creates a state process for pharmacists to substitute interchangeable biological products, requires notification to patients and within 5 days communicate with prescriber. The pharmacist may, unless requested otherwise by the purchaser, select a less expensive generically equivalent or interchangeable biological product.	Yes	Yes (C 5 days)	Yes	Yes	Yes	Yes	Orange
Montana	Mont. Code Ann. § 37-7-502 ; § 37-7-505	Establishes requirements for pharmacists to dispense FDA-approved interchangeable biological products. A pharmacist who receives a prescription for a specific biological product may select a less expensive interchangeable biological product.	Yes	Yes (C 5 days)	Unclear	Yes	Yes (2 years)	No	Orange
Nebraska	2017 Nebraska Laws L.B. 481 (Effective January 1, 2018)	Establishes requirements for pharmacists to dispense FDA-approved interchangeable biological products.	Yes	Yes (C 3 days)	Yes (Advise but Patient may instruct otherwise)	Yes	Unclear	Yes	Both
Nevada	N.R.S. AB 245 (Effective January 1, 2018)	Authorizes a pharmacist to dispense an interchangeable biological product in substitution for a prescribed biological product. A pharmacist is required to dispense an interchangeable biological product in substitution if the interchangeable biological product is less expensive than the prescribed biological product. Requirement to dispense an interchangeable biological product to a dispense by mail or common carrier by a certified Internet pharmacy.	Yes	Yes (C 3 days)	Yes (Prior to dispensing)	Yes	Yes	Yes	Purple exclusivity (but includes Orange in definition of interchangeable biological product)
New Jersey	N.J. Stat. Ann. § 24:6K-31 et seq.	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.	Yes	Yes (C 5 days)	Unclear	Yes	Yes (same as Rx)	Yes	Both
New Mexico	2017 New Mexico Laws Ch. 48 (H.B. 260); N.M. Stat. Ann. § 26-1-2; N.M. Stat. Ann. § 26-3-3	A pharmacist may dispense any of the listed therapeutically equivalent drugs or interchangeable biological products that is lower in cost than the prescribed drug or biological product. A licensed practitioner can "prohibit drug or biological product selection by making an entry that is electronically accessible that includes the words 'no substitution' or 'no sub' on a prescription."	Yes	Yes (C 5 days)	Yes ("Inform")	Yes	Unclear	Yes	Orange In Definitions (but includes Purple in body of statute)

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New York	2017 Sess. Law News of N.Y. Ch. 357 (A. 7509-A); N.Y. Educ. Law § 6816-a	Authorizes a pharmacist to substitute a biological product in certain circumstances. This law expires within 5 years of the effective date - on October 23, 2022 (unless renewed).	Yes	Yes (C 5 business days)	Yes (By Prescriber)	Yes	Unclear	Yes (Expires on October 23, 2022)	Both
North Carolina	N.C. Gen. Stat. Ann. § 90-85.28	Amends the Pharmacy Practice Act to allow for the substitution of an interchangeable biological product.	Yes	Yes (within reasonable time)	Unclear	Yes	Unclear (BUT under 90-85.26, required to maintain for 3 years)	Yes	Neither Mentioned
North Dakota	N.D. Cent. Code Ann. § 19-02.1-14.3	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.	Yes	Yes (within 24 hours of substitution)	Yes	Yes	Yes (5 years)	Yes	Neither Mentioned
Ohio	2016 Ohio Laws File 142 (Sub. H.B. 505) [Various statutes within the Ohio Code are affected]	Authorizes the regulation of biological products and the substitution of interchangeable biological products. Authroizes the State Board of Pharmacy to automatically update the list of biological products based on federal decisions (through rules). Establsihes certain standards for labeling and substitution of biological products and interchangeable biological products. A pharmacist may not dispense an interchangeable biological product unless its price to the patient is less than or equivalent to the drug as prescribed.	Yes	Yes (C 5 days)	Yes ("Shall inform")	Yes	Yes (3 years)	No	Orange

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Oregon	Or. Rev. Stat. Ann. § 689.522	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. In 2016, H 4105 adds: ("shall inform the patient of the substitution prior to dispensing," also communicate within 5 days the specific biological product)	Yes	Yes (C 5 days)	Yes (Prior to dispensing)	Yes	Yes (3 years)	Yes	Orange
Pennsylvania	2016 Pa. Legis. Serv. Act 2016-95 (S.B. 514); 35 Pa. Stat. Ann. § 960.3	Amends the Generic Equivalent Drug Law (P.L.1163, No.259), provides for substitutions of FDA approved interchangeable biosimilar medicines if requirements are met, for posting requirements, for powers and duties of Department of Health and for immunity of pharmacists under certain circumstances.	Yes	Yes (C 72 hours)	Yes	Yes	Yes	No	Neither Mentioned
Rhode Island	2016 Rhode Island Laws Ch. 16-193 (16-H 7816A) [In various sections of the Rhode Island code]	Adds biological products and interchangeable biological products to the medications pharmacies may dispense, regulates the procedures for dispensing and substitution of a less expensive biological product, authorizing use of an interoperable electronic medical records system and notification of interchangeability on a public state website.	Yes	Yes (C 5 days)	Yes ("Shall inform")	Yes	Yes	Yes	Both
South Carolina	2017 South Carolina Laws Act 11 (H.3438); S.C. Code Ann. § 39-24-40	An oral or written drug prescription "must provide an authorization from the practitioner as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted." Substitution may not occur unless the pharmacist advises the patient that the practitioner has authorized substitution and the patient consents. Drug label must name substituted biologic unless barred by prescriber. Patient consent not required for Medicaid.	Yes	Yes (C 5 days)	Yes (Advise plus consent)	Yes	Yes (But Unclear as to time period)	No	Neither Mentioned
Tennessee	Tenn. Code Ann. § 53-10-211	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. Communication must occur within 48 hours, excluding weekends and holidays.	Yes	Yes (C 5 days)	Yes (On Rx label)	Yes	Yes (2 years)	Yes	Orange

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Texas	2015 Tex. Sess. Law Serv. Ch. 1007 (H.B. 751); Tex. Occ. Code Ann. § 562.001 et seq.	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	Yes	Yes (C 3 days)	Yes	Yes	Yes (But Unclear as to time period)	Yes	Orange
Utah	Utah Code Ann. § 58-17b-605.5	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.	Yes	Yes (C 5 days)	Yes	Yes	Yes	No	Orange
Viriginia	Va. Code Ann. § 54.1-3408.04	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 (N 5 days), but this requirement expired on July 1, 2015	Yes (Prior to dispensing)	Yes	Yes (2 years from date of dispensing)	No	Neither Mentioned

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Washington	2015 Wash. Legis. Serv. Ch. 242 (S.B. 5935); Wash. Rev. Code Ann. § 69.41.100 et seq.	Provides an updated definition for interchangeable biological product and apply the generic substitution state prescription form requirement to select "dispense as written" to prevent substitution or "substitution permitted." 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 "greater liability" 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.	Yes	Yes (N 5 days), but this requirement expires on August 1, 2020	Unclear	Yes (Must Indicate if Allowed to Substitute)	Yes (same as Rx)	Yes	Neither Mentioned