State Substitution Practices for Biological Drugs

State	Definitions	When Is Substitution Authorized	Notification Requirements	Other Requirements
Alabama Ala.Code 1975 § 34-23-8.1; Ala.Code 1975 § 34-23-1	"Biological product" has the same meaning as the term as defined in 42 U.S.C. § 262	A licensed pharmacist shall be permitted to select for the brand name biological product prescribed by a prescribing practitioner a less expensive interchangeable biological product in all cases where prescriber expressly authorizes the selection as outlined below: (1) Every written prescription for a biological product issued in by a prescriber shall contain two signature lines: one line shall indicate if the brand is meant to be dispensed, and the other shall indicate if a product selection is permitted. The prescriber shall communicate instructions to the pharmacist by signing on the appropriate line. (2) An oral or electronic prescription, including an e-fax, from the prescriber for a biological product shall instruct the pharmacist whether or not a less expensive interchangeable biological product may be dispensed. The pharmacist shall note instructions on the file copy of the prescription and retain the prescription form for the period specified by law. For prescriptions issued by out of state prescribers, an pharmacist in AL may select for the brand name biological product prescribed a less expensive interchangeable biological product in all cases where the out-of-	(1) Within 24 hours, not counting the hours of Sunday or recognized federal holidays, a pharmacist, or the designee of the pharmacist, who dispenses a different biological product than that ordered or prescribed shall inform the prescribing physician that a different biological product was substituted for the biological product prescribed and provide the name and manufacturer of the biological product dispensed. The notice to the prescribing physician or other practitioner shall be by any of the following: a. Electronic message sent to the electronic prescribing system used by the prescribing physician or other practitioner to transmit the prescription to the pharmacy. b. Telephone. c. Facsimile. (2) In any instance where the prescribing practitioner indicates for a pharmacist to communicate using a specific notification method listed in subdivision (1), the pharmacist shall utilize that method of communication. A voicemail left for the prescribing physician or other practitioner at the telephone number provided to the pharmacist or his or her designee shall constitute notice under this section. Notice to the prescribing physician is not required if a refill prescription is not changed from the product dispensed on	When a pharmacist dispenses an interchangeable biological product for the prescribed biological product, the pharmacist, or his or her designee, shall inform the patient or patient's designee prior to dispensing the interchangeable biological product. A pharmacist, or his or her designee, shall record on the prescription form the name and manufacturer or distributor of any drug product, or the name and manufacturer of any biological product, dispensed as authorized in this section. Unless otherwise indicated by the prescriber, the prescription label on the dispensing container shall indicate the actual biological product dispensed, either the brand name, or if none, the name of the biosimilar biologic product as referred to by FDA's Lists of Licensed Biological Products With Reference Product Exclusivity and Biosimilarity of Interchangeability Evaluations (Purple Book), and the name of the manufacturer or a reasonable abbreviation of the name of the manufacturer.

		state licensed physician or other practitioner does not expressly prohibit a substitution.	the immediately prior filling of the prescription.	
Alaska AS § 08.80.294; AS § 08.80.295; AS § 08.80.480; AS § 08.80.030; 12 AAC 52.510	"biological product" means a product that is applicable to the prevention, treatment, or cure of a disease or condition of human beings, and is 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 derivative of arsphenamine or any other trivalent organic arsenic compound "interchangeable biological product" means a biological product that the United States FDA has determined (A) meets the standards	Unless the prescription indicates that it is to be dispensed only as written, the pharmacist may, with the consent of the patient, substitute an equivalent drug product or interchangeable biological product. A pharmacist who substitutes an equivalent drug product or interchangeable biological product in compliance with this section and applicable regulations incurs no greater liability in filling the prescription than would be incurred in filling the prescription by dispensing the prescribed name brand product.	If an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the biological product provided to the patient, including the name and manufacturer of the biological product. The communication must be provided within three business days after dispensing the biological product as follows: (1) by making an entry that is electronically accessible to the prescribing practitioner through (A) an interoperable electronic medical records system; (B) an electronic prescribing technology; (C) a pharmacy benefit management system; or (D) a pharmacy record; or (2) if the pharmacist or the pharmacist's designee is unable to make an entry through one of the means provided under (1) of this subsection, by facsimile transmission, telephone communication, electronic mail transmission, or transmission by other prevailing means, to the prescribing practitioner. The dispensing pharmacist or the pharmacist's designee is not required to communicate information under (c) of	In addition to other information that may be required under state or federal laws or regulations, a pharmacist, when dispensing a brand-name prescription drug order that is (1) not a biological product, shall include the generic drug name that is an equivalent drug product for the drug dispensed; (2) a biological product, shall include the dispensed product's (A) proprietary name, if available; or (B) proper name. The generic drug name or proprietary or proper biological product name required under (a) of this section shall be placed directly on the container's label near the brand name.

	for interchangeability under 42 U.S.C. 262(k)(4); or (B) is therapeutically equivalent to another biological product under the most recent edition or supplement of the United States FDA's Approved Drug Products with Therapeutic Equivalence Evaluations.		this section if the dispensed biological product is a refill of a prescription and is the same as the biological product that was dispensed on the previous filling of the prescription. Entry into an electronic records system as described under (c)(1) of this section is presumed to provide notice to the prescribing practitioner. A pharmacist shall maintain a record of a dispensed biological product for a minimum of two years after the date of the dispensing.	
Arizona A.R.S. § 32-1963.01	"BIOLOGICAL PRODUCT" HAS THE SAME MEANING PRESCRIBED IN 42 UNITED STATES CODE SECTION 262. "INTERCHANGEABLE BIOLOGICAL PRODUCT" MEANS A BIOLOGICAL PRODUCT THAT EITHER: (a) THE UNITED STATES FOOD AND DRUG ADMINISTRATION HAS LICENSED AND DETERMINED MEETS THE SAFETY STANDARDS FOR	A PHARMACIST MAY SUBSTITUTE A BIOLOGICAL PRODUCT FOR A PRESCRIBED BIOLOGICAL PRODUCT ONLY IF ALL OF THE FOLLOWING CONDITIONS ARE MET: 1. THE UNITED STATES FOOD AND DRUG ADMINISTRATION HAS DETERMINED THE SUBSTITUTED PRODUCT TO BE AN INTERCHANGEABLE BIOLOGICAL PRODUCT. 2. THE PRESCRIBING PHYSICIAN DOES NOT DESIGNATE IN WRITING OR ELECTRONICALLY THAT SUBSTITUTION IS PROHIBITED IN A MANNER PURSUANT TO SUBSECTION E OF THIS SECTION. 3. THE PHARMACY INFORMS THE PATIENT OR PERSON PRESENTING THE PRESCRIPTION OF THE	WITHIN FIVE BUSINESS DAYS AFTER DISPENSING A BIOLOGICAL PRODUCT, THE DISPENSING PHARMACIST OR THE PHARMACIST'S DESIGNEE MAKES AN ENTRY OF THE SPECIFIC PRODUCT PROVIDED TO THE PATIENT, INCLUDING THE NAME OF THE PRODUCT AND THE MANUFACTURER. THE COMMUNICATION SHALL BE CONVEYED BY MAKING AN ENTRY THAT IS ELECTRONICALLY ACCESSIBLE TO THE PRESCRIBER THROUGH AN INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM, AN ELECTRONIC PRESCRIBING TECHNOLOGY, A PHARMACY BENEFIT MANAGEMENT SYSTEM, OR A PHARMACY RECORD. ENTRY INTO AN ELECTRONIC RECORDS SYSTEM AS DESCRIBED IN THIS PARAGRAPH IS PRESUMED TO PROVIDE NOTICE TO THE PRESCRIBER.	Any pharmacy personnel shall notify the person presenting the prescription of the amount of the price difference between the brand name drug OR BIOLOGICAL PRODUCT prescribed and the generic equivalent drug OR INTERCHANGEABLE BIOLOGICAL PRODUCT, if both of the following apply: 1. The medical practitioner does not indicate an intent to prevent substitution with a generic equivalent drug OR INTERCHANGEABLE BIOLOGICAL PRODUCT. 2. The transaction is not subject to third-party reimbursement. D. The pharmacist shall place on the container the name of the drug OR BIOLOGICAL PRODUCT dispensed followed by the words "generic

	DETERMINING INTERCHANGEABILITY PURSUANT TO 42 UNITED STATES CODE SECTION 262(k)(4). (b) IS DETERMINED TO BE THERAPEUTICALLY EQUIVALENT AS SET FORTH IN THE LATEST EDITION OF THE SUPPLEMENT TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION'S APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS.	SUBSTITUTION PURSUANT TO SUBSECTION C OF THIS SECTION. 5. THE PHARMACY RETAINS A RECORD OF THE BIOLOGICAL PRODUCT DISPENSED PURSUANT TO SECTION 32-1964, SUBSECTION A.	OTHERWISE, THE PHARMACIST SHALL COMMUNICATE THE BIOLOGICAL PRODUCT DISPENSED TO THE PRESCRIBER USING FAX, TELEPHONE, ELECTRONIC TRANSMISSION OR OTHER PREVAILING MEANS, EXCEPT THAT COMMUNICATION IS NOT REQUIRED IF ONE OF THE FOLLOWING APPLIES: (a) THERE IS NO INTERCHANGEABLE BIOLOGICAL PRODUCT APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR THE PRODUCT PRESCRIBED. (b) A REFILL PRESCRIPTION IS NOT CHANGED FROM THE PRODUCT DISPENSED ON THE PRIOR FILLING OF THE PRESCRIPTION.	equivalent for "OR "INTERCHANGEABLE BIOLOGICAL PRODUCT FOR" followed by the brand or trade name of the product that is being replaced by the generic equivalent DRUG OR INTERCHANGEABLE BIOLOGICAL PRODUCT. The pharmacist shall include the brand or trade name on the container or label of any contact lenses dispensed pursuant to this chapter. E. A prescription generated in this state must be dispensed as written only if the prescriber writes or clearly displays "DAW", "dispense as written", "do not substitute" OR "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form. A prescription from out of state or from agencies of the United States government must be dispensed as written only if the prescriber writes or clearly displays "do not substitute", "dispense as written" or "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form.
Arkansas	"Biological product" means a biological product as defined by 42 U.S.C. §	Pharmacist shall not dispense interchangeable biological product if: (1) Prescriber, in the case of a prescription in writing signed by	Within 5 business days after dispensing an interchangeable biological product that has been substituted for a biological product, dispensing	Re cost savings requirement: (1) Pharmacist shall disclose cost savings amount at request of patient.

A.C.A. § 17-92-101; A.C.A. § 17-92-503	262(i)(1), as it existed on January 1, 2019 "Interchangeable biological product" means a biological product that is interchangeable as defined by 42 U.S.C. § 262(i)(3), as it existed on January 1, 2019	prescriber, indicates in his or her own handwriting by name or initial that no substitution shall be made; (2) Prescriber, in the case of prescription other than one in writing signed by prescriber, expressly indicates that prescription is to be dispensed as communicated; (3) Person for whom biological product is prescribed indicates that the prescription is to be dispensed as written or communicated; or (4) The BoP has determined that biological product should not be substituted and has notified all pharmacists of that determination. Except as provided in § 17-92-503(d), when a pharmacist receives a prescription for a brand or trade name drug product or biological product, the pharmacist may dispense an interchangeable biological product only when there will be a cost savings for the patient.	pharmacist or designee shall record specific interchangeable biological product provided to patient, including without limitation the name of interchangeable biological product and manufacturer of product. The record shall be electronically accessible to prescriber through (1) an interoperable electronic medical records system; (2) an electronic prescribing technology; (3) a pharmacy benefits management system; or (4) a pharmacy record. If requested by prescriber, pharmacist shall communicate to prescriber within 5 business days using facsimile, telephone, electronic transmission, or other prevailing means that an interchangeable biological product has been dispensed. A communication is not required when (1) an interchangeable biological product does not exist for the prescribed biological product; or (2) a refill prescription for a biological product is not substituted with an interchangeable biological product on a subsequent filling of the prescription. Dispensing pharmacist or prescriber (1) is not required to show proof that prescriber has access to record in any type of payment audit conducted by a payor or PBM; or (2) is not subject to	(2) The total amount charged for substituted interchangeable biological product or for dispensing the biological product shall not exceed amount normally and regularly charged under comparable circumstances by the pharmacist for that biological product or for the dispensing of that biological product. (3) Pharmacist may not dispense an interchangeable biological product with a total charge that exceeds the total charge of the biological product originally prescribed unless agreed to by purchaser. Pharmacist or pharmacy shall maintain a record of biological products dispensed for at least two (2) years.

			disciplinary action or civil penalties for failure to ensure that the record is accessible or for failure to access the record.	
California Cal.Bus. & Prof.Code § 4073.5	"Biological product," "biosimilar," and "interchangeable" have the same meanings that apply to those terms under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262). "Interchangeable" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in Section 262(k)(4) of Title 42 of the United States Code, or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with	A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following: (1) The alternative biological product is interchangeable. (2) The prescriber does not personally indicate "Do not substitute," or words of similar meaning, in the manner provided in subdivision	Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists' designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one or more of the following electronic records systems: (1) An interoperable electronic medical records system. (2) An electronic prescribing technology. (3) A pharmacy benefit management system. (4) A pharmacy record. (c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber.	If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist's designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply: (1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed. (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

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	Therapeutic Equivalence Evaluations.			
Colorado C.R.S.A. § 12-42.5-102; C.R.S.A. § 12-42.5-122	"Interchangeable", in reference to a biological product, means: - Interchangeable or interchangeability, as determined by FDA pursuant to 42 U.S.C. sec. 262(k)(4); or - That FDA has deemed the biological product therapeutically equivalent to another biological product, as set forth in the latest edition or supplement of the Orange Book "Biological product" has the same meaning as biological product, as defined in 42 U.S.C. sec. 262 (i)(1).	When filling prescription order for a specific biological product, may substitute interchangeable biological product for the prescribed biologic only if: - the FDA has determined the biological product to be substituted is interchangeable with the prescribed biological product; and - the practitioner has not indicated that the pharmacist shall not substitute an interchangeable biological product for the prescribed biological product by indicating "dispense as written" or DAW upon issuing the prescription	Within a reasonable time after dispensing a biological product, the dispensing pharmacist or his or her designee shall communicate to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The pharmacist or designee shall communicate the information to the prescribing practitioner by making an entry into an interoperable EMR system, through e-prescribing technology, or through a pharmacy record that the prescribing practitioner can access electronically. Otherwise, the pharmacist or his or her designee shall communicate to the prescribing practitioner the name and manufacturer of the biological product dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means except when: - there is no FDA-approved interchangeable biological product for the prescribed biological product; or - a refill prescription is not changed from the biological product dispensed on the prior filling of the prescription.	The pharmacy from which the biological product was dispensed must retain a written or electronic record of the dispensed biological product for at least two years after the substitution. Where substitution occurs, pharmacist must communicate substitution to purchaser in writing and orally, label the container with name of drug or biological product dispensed, and indicate on the file copy of the prescription both name of prescribed drug or biological product and name of drug or biological product dispensed Pharmacist may not substitute interchangeable biological product unless the substituted costs the purchaser less than the drug or biological product prescribed (except where the drug outlet only has the higher priced product in stock). The prescription shall be priced for a drug, other than a biological product, as if it had been prescribed generically.
Connecticut C.G.S.A. § 20-619; C.G.S.A. § 20-619a	"Biological product" has the same meaning as provided in 42 USC 262	Except as limited by subsections (f), (h) and (l) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a biological product for a prescribed	Upon the dispensing of an interchangeable biological product, but not later than seventy-two hours following the dispensing of such product, the pharmacist shall inform the	Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO

	"Interchangeable biological product" means a biological product that: (A) The federal Food and Drug Administration has licensed and determined to meet the standards for interchangeability pursuant to 42 USC 262(k)(4), or (B) is therapeutically equivalent to another biological product, as set forth in the latest edition of or supplement to the federal Food and Drug Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations"	biological product if: (1) It is an interchangeable biological product, and (2) the practitioner has not specified, in the manner described in subsection (f) of this section, that there shall be no substitution for the prescribed biological product. Upon the dispensing of an interchangeable biological product to a patient, the pharmacist or a duly authorized agent of the pharmacist shall inform the patient or a representative of the patient of a substitution of an interchangeable biological product for a prescribed biological product. Not later than seventy-two hours after the pharmacist has informed the patient or representative of the patient of the substitution, the pharmacist shall make an entry documenting the substitution in a manner authorized pursuant to subsection (m) of this section. (h) A pharmacist may substitute a drug product under subsection (b) or interchangeable biological product under subsection (c) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.	prescribing practitioner by facsimile, telephone or electronic transmission of the substitution of such interchangeable biological product for a prescribed biological product. Not later than forty-eight hours following the dispensing of an interchangeable 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 of the product. The entry shall be made in a manner that provides notice to the prescriber and may be made through one of the following means: (1) An interoperable electronic medical records system, (2) an electronic prescribing technology, (3) a pharmacy benefit management system, or (4) a pharmacy record. If the entry is not made by any of the means specified in subdivision (1), (2), (3) or (4) of this subsection, the pharmacist shall communicate the product dispensed to the prescriber using either facsimile, telephone or electronic transmission, provided such communication shall not be required when a refill prescription is not changed from the product dispensed on the prior filling of the prescription. The provisions of this subsection shall not apply to interchangeable biological products dispensed by a pharmacy operated by a	SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

			hospital licensed in accordance with the provisions of chapter 368v.	
Delaware 24 Del.C. § 2502; 24 Del.C. § 2549A	"Biological product" means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act 42 U.S.C. § 262(i)). "Interchangeable" means a biological product licensed by the Federal Food and Drug Administration pursuant to 42 U.S.C. § 262(k)(4).	A pharmacist may substitute for a prescribed biological product only if: (1) the practitioner has not expressly prohibited substitution in a manner specified in §2549; (2) the product to be substituted has been designated by the Federal Food and Drug Administration as interchangeable with or therapeutically equivalent to the prescribed product; (3) the pharmacist informs the patient or the patient's adult representative that an interchangeable biological product has been dispensed; and (4) the pharmacist indicates on the prescription and on the prescription label the name of the manufacturer of the interchangeable biological product substituted unless the practitioner indicates otherwise.	If a biological product is dispensed, the pharmacist or the pharmacist's designee shall, within a reasonable time but not to exceed ten days following dispensing, communicate to the practitioner the name and manufacturer of the biological product dispensed, by: (1) recording such information in an interoperable electronic health records system shared with the prescribing practitioner, to the extent such a system is in place between a pharmacist and practitioner; or (2) in the case where electronic health records are not in place between a pharmacist and a practitioner, communicating such information to the practitioner using any prevailing means available. No communication is required under this subsection where there is no interchangeable or therapeutically equivalent biological product for the prescribed biological product, or where a refill prescription is not changed from the biological product originally dispensed. (c) The pharmacy shall maintain a record of the biological product dispensed as required in §2532. (d) The Board of Pharmacy shall maintain a link on its web site to the current list of all biological products determined by the Federal Food and Drug Administration to be interchangeable with a specific biological product. (e) Hospital pharmacies shall be exempt from the requirements of subsection (b) of this section.	

District of Columbia DC Official Code § 48-804.51; § 48-803—803.05	"Biological product" shall have the same meaning as provided in 42 USC § 262 "Interchangeable biological product" means a biological product that is: (A) Licensed and determined by the US FDA to meet the standards for interchangability in 42 USC § 262(k)(4); or (B) Determined to be biosimilar to and interchangeable with a reference product as state in… the Purple Book.	Refer to Official DC Code § 48-803.03—803.05 which substitution generally (both for generically equivalent drug products and interchangeable biological products)	Within 5 business days after dispensing a biological product, dispensing pharmacist (or designee) must communicate to prescriber the specific biological product dispensed, including the name and manufacturer of the biological product; except that this communication is not required if FDA has not approved an interchangeable biological product for the biological product prescribed to the patient or a refill prescription is not changed from the biological product dispensed on the most recent filling of the prescription. Except as provided under subsection (c) of this section, the required communication shall be provided by making an entry that is electronically accessible to all health care providers through an interoperable EMR system, an electronic prescribing technology or a PBM system. Making an entry in such a system shall be presumed to provide the required communication to the prescriber. If the above notification methods are unavailable, the required communication may be provided by fax, phone, electronic transmission or other means. The communication requirements do not apply to dispensing pharmacists / their designees at an HMO that operates as a group model for services furnished	The BoP and Board of Medicine shall maintain link on websites to current list of biological products determined by FDA to be interchangeable with a specific biological product.

			through internal pharmacy operations for members and patients of the HMO	
Florida F.S.A. § 465.0252	The terms "biological product," "biosimilar," and "interchangeable" have the same meanings as defined in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.	Pharmacist may only dispense a substitute biological product for the prescribed biological product if: (1) FDA has determined that the substitute biological product is biosimilar to and interchangeable for the prescribed biological product. (2) Prescriber does not express a preference against substitution in writing, verbally, or electronically. (3) Pharmacist notifies the person presenting the prescription of substitution in the same manner as provided in s. 465.025(3)(a). (4) Pharmacist retains a written or electronic record of the substitution for at least 2 years.		BoP to maintain on its public website a current list of biological products that FDA has determined are biosimilar and interchangeable.
Georgia Ga. Code Ann., § 26-4-5; Ga. Code Ann., § 26-4-81	"Biological product" means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act, 42 U.S.C. Section 262. "Interchangeable biological product" means a biological product that the federal FDA has determined meets the standards set forth in subsection (k)(4) of 42 U.S.C.	A pharmacist may substitute a biological product with an interchangeable biological product, except when: - a prescriber instructs the pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product by including the words 'brand necessary' in the body of the prescription. When a practitioner has designated 'brand necessary', an interchangeable biological product shall not be substituted without the practitioner's express consent, which shall be documented by the pharmacist on the prescription and	Within 48 hours, excluding weekends and holidays, following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry into an interoperable EMR system or through e-prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber by using facsimile, telephone, electronic transmission, or other prevailing means,	If a practitioner prescribes a biological product by its nonproprietary name, the pharmacist shall dispense the lowest retail priced interchangeable biological product which is in stock. Substitutions are authorized for the express purpose of making available to the consumer the lowest retail priced interchangeable biological product which is in stock. Pharmacies must maintain record of substitution that includes the identity of the interchangeable biological product and its manufacturer. Where substitution occurs, the name of the interchangeable biological

	Section 262 or has been deemed therapeutically equivalent by the federal FDA	by the practitioner in the patient's medical record -a patient for whom a biological product order is intended instructs a pharmacist not to substitute an interchangeable biological product	provided that communication shall not be required where: - there is no interchangeable biological product approved by the federal Food and Drug Administration for the prescribed product; or - a refill prescription is not changed from the product dispensed on the prior filling of the prescription.	product, with an explanation of 'interchangeable biological product for (insert name of prescribed biological product)' or similar language to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the biological product may not appear upon the prescription label. (N/A to biological products dispensed in-patient hospitals.) BoP to maintain a link on its website to the current list of all biological products determined by FDA to be interchangeable with a specific biological product.
Hawaii HRS § 328-91; HRS § 328-92; HRS § 328-96	*"'Biological product or biologic product"* has the same meaning as defined in Title 42 United States Code section 262, as the same may be amended. *"Drug product"* means a drug as defined in section 328-1 other than a biological product as defined in this part. *"Hawaii list of*	The pharmacist shall substitute an equivalent generic drug product or an interchangeable biological product if the practitioner does not prohibit substitution under subsection (b), and the interchangeable biological product results in a savings. The pharmacist shall not substitute if the consumer refuses. The pharmacist shall not substitute an equivalent generic drug product or interchangeable biological product if the practitioner indicates "brand medically necessary" or words of similar meaning on the prescription.	Within two business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the practitioner the specific provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the practitioner through: (1) An interoperable electronic medical records system; (2) An electronic prescribing technology; (3) A pharmacy benefit management system; or (4) a pharmacy record. Entry into an electronic records system as described in subsection (d) is	Every pharmacy shall prominently display, in clear and unobstructed public view, a sign in block letters that shall read: "HAWAII LAW REQUIRES THAT LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG PRODUCTS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS BE OFFERED TO THE CONSUMER. CONSULT YOUR PHYSICIAN AND PHARMACIST CONCERNING THE AVAILA8ILITY OF THE LEAST EXPENSIVE DRUG PRODUCT FOR YOUR USE." The letters must be at least one inch in height.

	equivalent generic drug products and interchangeable biological products" means the list of equivalent generic drug products and interchangeable biological products, which may include references to the Orange Book, the Purple Book, and other published findings and approvals of the United States FDA, created and published by the director pursuant to the director's authority in this part to approve drug products and biological products that pharmacists may substitute with equivalent generic druq products and interchangeable biological products. *"Interchangeable biological product"* means a biological product approved by the director as	The designation "brand medically necessary" must be handwritten by the practitioner and shall not be preprinted or stamped on the written prescription. The pharmacist shall not substitute an equivalent generic drug product or an 'interchangeable biological product" for any prescription for an anti-epileptic drug, except upon the consent of the practitioner and the patient or the patient's parent or guardian. This narrow exception for epileptic patients shall not be construed as a policy decision to make for any prescription for an anti-epileptic drug, except upon the consent of the practitioner and the patient or the patient's exceptions for any other conditions.	presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where: (1) There is no interchanqeable biological product approved by the FDA for the product prescribed; or (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.	

	substitutable by pharmacists 15 and included in the Hawaii list of equivalent generic drugs and 16 interchangeable biological products. *"Purple Book"* means the United States FDA's "List of Licensed Biological Products with Interchangeability Evaluations" publication and its cumulative Reference Product Exclusivity and Biosimilarity or supplements, which include a list of licensed biological products with biosimilarity and interchangeability evaluations			
Idaho IDAPA 27.01.01.010; IDAPA 27.01.01.011; IDAPA 27.01.01.130	"Biological Product" - a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any	A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: - the biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; - the prescriber does not indicate by any means that the prescribed	A pharmacist who dispenses a biological product according to board rule shall communicate to the prescriber the name and manufacturer of the drug within five (5) business days following the dispensing of the biological product. Communication shall occur via an entry in an interoperable electronic medical records system, an electronic	

ID HB 483 (2016)	chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), that is applicable to the prevention, treatment, or cure of a disease or condition of human beings and licensed under Section 351(k) of the Public Health Service Act, 42 U.S.C. Section 262(i). "Biosimilar" - a biological product highly similar to a specific reference biological product that is licensed by the FDA pursuant to 42 U.S.C. Section 262(k) and published in the Purple Book "Interchangeable Biosimilar" -a licensed biosimilar	biological product must be dispensed; and - the name of the drug and the manufacturer or the NDC number is documented in the patient medical record	prescribing technology, a pharmacy benefit management system or a pharmacy record that can be accessed electronically by the prescriber. Entry into an electronic records system as described in this subsection shall be considered notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other prevailing means, provided that the communication shall not be required when: (a) There is no interchangeable biological product approved by the federal food and drug administration for the product prescribed; (b) A refill prescription is not changed from the product dispensed on the prior filling of the prescription; or (c) The pharmacist or the pharmacist's designee has already communicated to the prescriber the specific product to be provided to the patient, including the name and manufacturer of the product, prior to dispensing; and that product is the product that is actually dispensed. (2) Nothing in this section shall delay the dispensing of a valid prescription for a biological product.	

	product determined by the FDA to be therapeutically equivalent to the reference biological product and published in the Purple Book "Purple Book" The list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations published by the FDA under the Public Health Service Act "Biological product" shall have the same meaning as in 42 U.S.C. 262(i). (b) "Interchangeable biological product" means a biological product that the federal food and drug administration has licensed and determined meets the standards for interchangeability set forth in 42 U.S.C.			

	262(k)(4) or has been deemed therapeutically equivalent by the federal food and drug administration in the latest edition of or supplement to the publication "Approved Drug Products with Therapeutic Equivalence Evaluations."			
Illinois 225 ILCS 85/19.5	"Biological product" has the meaning given to that term in 42 U.S.C. 262 "Interchangeable biological product" means a biological product that the United States Food and Drug Administration: (1) has (A) licensed and (B) determined it to meet the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4); or (2) has determined is therapeutically equivalent as set forth in the latest	A pharmacist may substitute an interchangeable biological product for a prescribed biological product only if all of the following conditions in this subsection (b) are met: (1) the substituted product has been determined by the United States Food and Drug Administration to be interchangeable, as defined in subsection (a) of this Section, with the prescribed biological product; (2) the prescribing physician does not designate orally, in writing, or electronically that substitution is prohibited in a manner consistent with Section 25 of this Act; 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 shall be conveyed by making an entry that can be electronically accessed by the prescriber through: (1) an interoperable electronic medical records system; (2) an electronic prescribing technology; (3) a pharmacy benefit management system; or (4) a pharmacy record. Entry into an electronic records system as described in this subsection (c) is presumed to provide notice in accordance with this subsection (c). Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using	The pharmacy shall retain a record of the biological product dispensed for a period of 5 years. The Department shall maintain a link on its Internet website to the current list of all biological products determined by the United States Food and Drug Administration to be interchangeable with a specific biological product.

	edition of or supplement to the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).		facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required where: (A) there is no United States Food and Drug Administration-approved interchangeable biological product for the product prescribed; or (B) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.	
Indiana IC 16-42-25-1; IC 16-42-25-2; IC 16-42-25-3; IC 16-42-25-4; IC 16-42-25-5; IC 16-42-25-6; IC 16-42-25-7; IC 16-42-25-8	"biological product" means: a virus; a therapeutic serum; a toxin; an antitoxin; a vaccine; blood; a blood component; a blood derivative; an allergenic product; a protein (except any chemically synthesized polypeptide); a product analogous to a product described herein; arsphenamine; an arsphenamine derivative; or any other trivalent organic arsenic compound… applicable to the prevention, treatment, or cure of a disease or	A pharmacist may substitute for a prescribed biological product if the following conditions are met: - The substitute has been determined by FDA to be interchangeable with the prescribed biological product. - The prescribing practitioner has, for a written prescription, signed on the line under which the words "May substitute." appear, or for an electronically transmitted prescription, electronically transmitted the instruction "May substitute." - the pharmacist has informed the customer of the substitution.	Not later than ten (10) calendar days after dispensing a biologic product, a pharmacist shall record the name and manufacturer of the biologic product dispensed using: - an interoperable EHR system shared with the prescribing practitioner, to the extent a system is in place between the pharmacist and the practitioner; or - if an EHR system is not in place between the pharmacist and the prescribing practitioner, any prevailing means available to communicate to the prescribing practitioner the name and manufacturer of the biologic product dispensed. The pharmacist is not required to report to or communicate with the prescribing practitioner if: - there is no FDA approved interchangeable biological product for the prescribed biological product; or - the refill prescription is not changed from the product originally dispensed.	The pharmacy shall retain a record in accordance with IC 25-26-13-25(a) of the dispensed biological product. The prescriber shall retain a record in accordance with IC 16-39-7-1 of the dispensed biological product. The Indiana board of pharmacy must maintain a link on the board's Internet web site to the current list of all biological products determined by FDA to be interchangeable with a specific reference biological product

	condition for human beings "biosimilar" - a biological product that has been licensed as a biosimilar product under 41 U.S.C. 262(k) or has been approved based on an application filed under 21 U.S.C. 355(b)(2); and is highly similar to the reference product, with no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product, and only minor differences in clinically inactive components. "interchangeable" means - a determination by FDA that a biosimilar product may be substituted for a reference			

	biological product without the intervention of the health care provider that prescribed the biological product; or concerning a biological product filed under 21 U.S.C. 355(b)(2), a product that is designated as therapeutically equivalent by FDA in the Orange Book			
Iowa I.C.A. § 155A.3; I.C.A. § 155A.28; I.C.A. § 155A.32	**"Biological product"** means the same as defined in 42 U.S.C. §262. **"Interchangeable biological product"** means either of the following: a. A biological product that the United States food and drug administration has licensed and has determined meets the standards for interchangeability pursuant to 42 U.S.C. §262(k)(4). b. A biological product that the United States food	If an authorized prescriber prescribes a biological product, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a biological product that is an interchangeable biological product for the biological product prescribed for dispensing and sale to the patient. 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. 2. The pharmacist shall not exercise the drug or biological product selection described in this section if either any of the following is true: a. The prescriber specifically indicates that	Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The entry shall be electronically accessible to the prescriber through one of the following means: (1) An interoperable electronic medical records system. (2) An electronic prescribing technology. (3) A pharmacy benefit management system. (4) A pharmacy record. b. An entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. If the entry is not made electronically, the pharmacist shall communicate the name and manufacturer of the biological product dispensed to the prescriber using facsimile, telephone, electronic	The label of any drug, biological product, or device sold and dispensed on the prescription of a practitioner shall be in compliance with rules adopted by the board. 2. The board shall maintain a link on its internet site to the current list of all biological products that the United States food and drug administration has determined to be interchangeable biological products.

	and drug administration has determined to be therapeutically equivalent to another biological product as set forth in the latest edition or supplement of the United States food and drug administration approved drug products with therapeutic equivalence evaluations publication.	no drug or biological product selection shall be made. b. The person presenting the prescription indicates that only the specific drug product prescribed should be dispensed. However, this paragraph does not apply if the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A. 3. If selection of a generically equivalent drug product or an interchangeable biological product is made under this section, the pharmacist making the selection shall inform the patient and note that fact and the name of the manufacturer of the selected drug on the prescription presented by the patient or the patient's adult representative or transmitted by the prescriber or the prescriber's authorized agent.	transmission, or other prevailing means. c. Communication under this subsection shall not be required in either of the following circumstances: (1) There is no federal food and drug administration-approved interchangeable biological product for the product prescribed. (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.	
Kansas K.S.A. 65-1626; K.S.A. 65-1637	"**Biological product"** is defined as a virus, a therapeutic serum, a toxin, an antitoxin, a vaccine, blood, a blood polypeptide, or an analogous product, arsphenamine or derivative or arphenamine, or any other trivalent organic arsenic compound that is applicable to the	A pharmacist is allowed to exchange a biological product in order to achieve a lesser cost to the purchaser unless: (A) The prescriber, in the case of a prescription signed by a prescriber and written on a blank form containing two signature lines, signs the signature line following the statement "dispense as written"; (B) the prescriber, in the case of a prescription signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" on the prescription;	If the pharmacist selects an interchangeable biological product, they must notify the patient that they have are going to receive an interchangeable biological product. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee must make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication must be conveyed by making an entry that is electronically	The board shall maintain a link on its website to the current lists of all biological products that the FDA has determined to be interchangeable biological products.

	prevention, treatment or cure of a disease or condition of humans. **"Interchangeable biological product"** means a biological product that the FDA has: (1) Licensed and determined meets the standards for "interchangeability" as defined in 42 U.S.C. § 262(k), as in effect on January 1, 2017; or (2) determined to be therapeutically equivalent as set forth in the latest edition or supplement to the FDA's approved drug products with therapeutic equivalence evaluations. "Brand exchange," in the case of a drug prescribed, means the dispensing of a different drug product of the same	(C) the prescriber, in the case of a prescription other than the one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated or (D) the biological product is not an interchangeable biological product for the prescribed biological product.	accessible to the prescriber through: (1) An inter-operable electronic medical records system; (2) an electronic prescribing technology; (3) a pharmacy benefits management system or (4) a pharmacy record. Entry into an electronic records system as described in subsection (o) shall be presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other prevailing means, provided that communication shall not be required where: (1)There is no FDA-approved interchangeable biological product for the product prescribed; or (2)a refill prescription is not changed from the product dispensed on the prior filling of the prescription. (q)A pharmacist shall maintain a record of any biological product dispensed for at least five years.	

	dosage form and strength and of the same generic name as the brand name drug product prescribed, and in the case of a biological product product			
Kentucky KRS 217.814; 217.822; 217.216; 217.895	"Biological product" has the same meaning as in 42 U.S.C. sec. 262; "Board" means the Kentucky Board of Pharmacy; "Interchangeable biological product" means: (a) A biological product that the United States Food and Drug Administration has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. sec. 262(k)(4); or (b) A biological product that the United States Food and Drug Administration has determined is therapeutically equivalent as set	When a pharmacist receives a prescription for a brand name biological product which is not listed by name in the nonequivalent drug product formulary prepared by the board, the pharmacist shall dispense a lower priced interchangeable biological product, if there is one in stock, unless otherwise instructed by the patient at the point of purchase or by the patient's prescribing practitioner. If an interchangeable product is selected, the label on the container shall show the name of the biological product dispensed. When an equivalent drug product or interchangeable biological product is dispensed in lieu of a brand name drug prescribed, the price of the equivalent drug or interchangeable biological product dispensed shall be lower in price to the purchaser than the drug product prescribed. A pharmacist shall not substitute a biological product for a prescribed biological product unless the substituted product is an	Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer. (b) Communication shall be conveyed by making an entry that is electronically accessible to the prescribing practitioner through: 1. An interoperable electronic medical records system; 2. An electronic prescribing technology; 3. A pharmacy benefit management system; or 4. A pharmacy record. (c) Communication entries into an electronic records system as described in this subsection are presumed to provide notice to the prescribing practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescribing practitioner using facsimile, telephone, electronic transmission, or other prevailing means. Communication to the prescribing practitioner, or the prescribing practitioner's office	

	forth in the latest edition or supplement to the federal FDA's Approved Drug Products with Therapeutic Equivalence Evaluations;	interchangeable biological product for the prescribed biological product.	personnel, UNOFFICIAL COPY AS OF 03/30/16 16 REG. SESS. 16 RS SB 134/EN Page 5 of 6 SB013420.100 - 400 - 8094 Engrossed using facsimile, telephone, electronic transmission, or other prevailing means shall be presumed to provide notice to the prescribing practitioner. (d) Communication shall not be required where: 1. There is no United States Food and Drug Administration-approved interchangeable biological product for the product prescribed; 2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription; or 3. The prescribing practitioner indicates "Do Not Substitute" on the prescription.	
Louisiana R.S. 37:1164; R.S. 37:1226.1	"Equivalent Drug Product" means either of the following: (1) A drug product that has been rated as a pharmaceutical equivalent by the FDA and has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and which is formulated to contain the same	1. The pharmacist shall not select an equivalent drug product when the prescriber prohibits interchange by any one of the following methods. a. On a prescription generated in written form, the prescriber shall handwrite a mark in a check box labeled " Dispense as Written " , or the abbreviation " DAW " , or both, and shall manually sign the prescription form. i. For prescriptions reimbursable by the state Medicaid program, the prescriber shall handwrite the words " Brand Necessary " or " Brand Medically Necessary " on the prescription form or on a sheet of	No later than five business days following the dispensing of a biological product, the dispensing pharmacist or his designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The required communication may be done by any means. No communication shall be required if there is no interchangeable or therapeutically equivalent biological product approved by the FDA for the product prescribed, or if the prescription is a refill not changed from the product dispensed on the prior filling of the prescription. No communication shall be required pursuant to this Section if the	Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, a pharmacist may enter the prescription information directly into the pharmacy's dispensing information system. In the event a pharmacy intern or pharmacy technician transcribes such a prescription, the supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.

	amount of active ingredients in the same dosage form and to meet the same compendial or other applicable standards such as strength, quality, purity, and identity, but which may differ in characteristics such as shape, scoring, configuration, packaging, excipients including colors, flavors, preservatives, and expiration time. (2) A biological product that is either one of the following: Deemed by the FDA as meeting the standard set forth in 42 U.S.C. 262(k)(4) and rated as interchangeable in the Lists of Licensed Biologic Products with Reference Product Exclusivity and Biosimilarity and Interchangeability Evaluations (Purple Book) or its	paper attached to the prescription form. b. On a prescription generated in oral or verbal form, the prescriber (or the prescriber's agent) shall indicate a specific brand name drug or product is ordered by the practitioner, and the pharmacist shall note such information on the file copy of the prescription. c. On a prescription generated in electronic form, the prescriber shall indicate " Dispense as Written " , " DAW " , or " Brand Medically Necessary. " 2. Where the prescriber has indicated that an equivalent drug product interchange is prohibited, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange. 3. In the event the prescriber has not prohibited equivalent drug product interchange in the manner described above, the pharmacist may select an equivalent drug product for dispensing, provided the patient has been informed of, and has consented	prescriber indicates "dispense as written".	Electronic Prescriptions: The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the DEA registration number.

	successors or rated therapeutically equivalent by the FDA as set forth in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Biological product" has the meaning assigned by Section 351 of the 13 Public Health Service Act, 42 U.S.C. 262.	to, the proposed cost saving interchange. 4. When the pharmacist selects a biological product rated as interchangeable for the product ordered by the prescriber, the dispensing pharmacist (or his designee) shall communicate to the prescriber by any means, but no later than five business days following the dispensing date, the specific product dispensed to the patient, including the name of the product and the manufacturer. However, no such communication to the prescriber is required when: a. the prescriber prohibited interchange in the manner described above; b. there is no product rated as interchangeable or therapeutically equivalent; or c. the product dispensed is a refill not changed from the product dispensed on the prior filling of the prescription. C. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.		

State Substitution Practices for Biological Drugs

Maine 32 M.R.S.A. § 13781	"Biological product" has the same meaning as in 42 United States Code, Section 262 "Interchangeable biological product" means a biological product that FDA has: A. Licensed and determined meets standards for interchangeability pursuant to 42 United States Code, Section 262(k)(4); or B. Determined is therapeutically equivalent as set forth in the most recent edition of or supplement to the federal FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" or a successor publication.	A pharmacist shall substitute an interchangeable biological product for the biological product specified on the prescription if the interchangeable biological product is distributed by a business entity doing business in the United States that is subject to suit and the service of legal process in the United States and the price of the interchangeable biological product does not exceed the price of the biological product specified by the practitioner, unless a practitioner has handwritten on the prescription form, along with the practitioner's signature, "dispense as written," "DAW," "brand," "brand necessary" or "brand medically necessary"	Within 5 business days after pharmacist dispenses a biological product, the dispensing pharmacist or designee shall enter in an electronic records system that is electronically accessible to the prescriber the specific biological product dispensed, including name of biological product and manufacturer. " "Electronic records system" means an interoperable electronic medical records system, an electronic prescribing technology, a pharmacist benefit management system or an electronic pharmacy record. Entry into an electronic records system as defined is presumed to provide notice to the prescriber. If pharmacist cannot make an entry in an electronic records system, pharmacist shall notify prescriber of the specific biological product dispensed by facsimile, telephone, electronic transmission or other similar means. Notice to prescriber not required if FDA has not approved an interchangeable biological product for the product prescribed or a refill prescription is not changed from the biological product dispensed on the prior filling of the prescription. Any pharmacist who substitutes an interchangeable biological product shall	For MaineCare: When cost of a prescription is to be reimbursed under MaineCare program, the pharmacist shall substitute an interchangeable biological product only when Dept of Health and Human Services has determined that the interchangeable biological product would be a more cost-effective alternative than the drug or biological product prescribed by the practitioner. For a patient paying for a biological product with the patient's own resources, pharmacist shall inquire about the patient's preference for either the prescribed biological product or interchangeable biological product and dispense the biological product that the patient prefers. The board shall maintain a link on the board's publicly accessible website to the current list of all biological products determined by the federal Food and Drug Administration to be an interchangeable biological product.

			inform the person to whom interchangeable biological product is dispensed of the substitution.	
Maryland MD Code, Health Occupations, § 12-504; MD Code, Health Occupations, § 12-504.1	"Biological product", the same meaning as such term is defined under 42 U.S.C. Section 262 "Interchangeable biological product", a biological product that the FDA: (a) Has licensed and determined meets the standards for interchangeability under 42 USC Section 262(k)(4) or (b) determined therapeutically equivalent as set forth in the latest edition of or supplement to the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).	A pharmacist may substitute a generically equivalent drug or device product OR AN INTERCHANGEABLE BIOLOGICAL PRODUCT, of the same dosage form and strength, for any brand name drug or device product prescribed, if: (1) The authorized prescriber does not state expressly that the prescription is to be dispensed only as directed; (2) The substitution is recognized: (I) RECOGNIZED in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations; OR (II) AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE BRAND NAME DRUG OR DEVICE PRODUCT PRESCRIBED; AND (3) The consumer is charged less for the substituted drug or device OR INTERCHANGEABLE BIOLOGICAL PRODUCT than the price of the brand name drug or device.	If a drug or device product OR AN INTERCHANGEABLE BIOLOGICAL PRODUCT is substituted under this section, the pharmacist shall: (1) Notify the patient in writing that the drug or device product OR INTERCHANGEABLE BIOLOGICAL PRODUCT dispensed is a generic equivalent of OR IS INTERCHANGEABLE WITH the prescribed drug or device product; and (2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug or device product OR INTERCHANGEABLE BIOLOGICAL PRODUCT. EXCEPT AS PROVIDED IN SUBSECTION (D) OF THIS SECTION, WITHIN 5 BUSINESS DAYS AFTER DISPENSING A BIOLOGICAL PRODUCT TO A PATIENT, THE DISPENSING PHARMACIST OR THE PHARMACIST'S DESIGNEE SHALL COMMUNICATE THE SPECIFIC BIOLOGICAL PRODUCT DISPENSED, INCLUDING THE NAME AND MANUFACTURER OF THE BIOLOGICAL PRODUCT, TO THE PRESCRIBER. (B) EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION: (1) THE COMMUNICATION REQUIRED UNDER SUBSECTION (A) OF THIS SECTION SHALL BE PROVIDED BY MAKING AN ENTRY THAT IS ELECTRONICALLY ACCESSIBLE TO THE PRESCRIBER THROUGH: (I) AN	The Department may list any additional drug or device products that are determined by the Department to meet requirements that are adequate to assure product quality and therapeutic equivalence, after an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article

			INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM; (II) AN ELECTRONIC PRESCRIBING TECHNOLOGY; (III) A PHARMACY BENEFITS MANAGEMENT SYSTEM; OR (IV) A PHARMACY RECORD; AND (2) MAKING AN ENTRY THROUGH A MECHANISM LISTED IN PARAGRAPH (1) OF THIS SUBSECTION IS PRESUMED TO PROVIDE THE COMMUNICATION TO THE PRESCRIBER REQUIRED UNDER SUBSECTION (A) OF THIS SECTION. (C) IF THE MECHANISMS LISTED IN SUBSECTION (B)(1) OF THIS SECTION ARE NOT AVAILABLE, THE COMMUNICATION REQUIRED UNDER SUBSECTION (A) OF THIS SECTION MAY BE PROVIDED BY FACSIMILE, TELEPHONE, ELECTRONIC TRANSMISSION, OR OTHER MEANS.	
Massachusetts MA General Laws Part 1: Title XVI: Chapter 112, Section 12EE	"Biological product'' a virus; therapeutic serum; toxin; antitoxin; vaccine; blood; blood component or derivative; allergenic product; protein, except any chemically synthesized polypeptide, or analogous product; or arsphenamine or derivative of arsphenamine, or any other trivalent organic arsenic	Except as provided in subsection (c), a pharmacist filling a prescription for a biological product prescribed by its trade or brand name may substitute an interchangeable biological product. (c) A pharmacist shall not substitute an interchangeable biological product if the prescriber instructs otherwise in writing. The instruction shall be on a patient-specific basis.	(d) Within a reasonable time following any such substitution, the dispensing pharmacist or the pharmacist's designee shall notify the prescribing practitioner of the substitution. The notification shall be conveyed by a notation in the interoperable electronic health record of the patient, as defined by section 1 of chapter 118*I*. If the pharmacist does not have the ability to make a notation in the patient's interoperable electronic health record, then the notification shall be conveyed by facsimile, electronic transmission or by making a notation in the patient's record maintained by the pharmacy, which is accessible to the practitioner by request.	(f) The dispensing pharmacist or the pharmacist's designee, the prescribing provider and administering practitioner shall retain a record of each substitution, for not less than 1 year from the date of the last entry in the profile record, of an interchangeable biological product dispensed. Nothing in this subsection shall limit the application of the professional standards for registered pharmacists, pharmacies and pharmacy departments as promulgated by the board of registration in pharmacy.

	compound, applicable to the prevention, treatment or cure of a disease or condition of human beings. "Interchangeable biological product", a prescription biological product (i) that has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed brand name biological product pursuant to 42 U.S.C. § 262 or (ii) for which an application has been approved under subsection 21 U.S.C. § 355 (b)(2) and which has been determined by the United States Food and Drug Administration to be therapeutically equivalent to the prescribed brand name biological product. For the purposes of this		A pharmacist who utilizes an interoperable electronic prescribing technology shall enter the substitution into the patient's electronic health record. (e) Following any such substitution, the dispensing pharmacist or the pharmacist's designee shall notify the patient, or the patient's authorized representative, of the substitution. The notification shall be written and may be conveyed by facsimile, electronic transmission, a notation in the patients record system shared with the prescriber or another means consistent with prevailing pharmacy practice in accordance with section 12D of chapter 112.	

	definition the terms "biosimilar'' and "interchangeable'' shall have the same meaning as defined in section 351 of the Public Health Service Act, 42 U.S.C. § 262.			
Michigan M.C.L.A. 333.17704; M.C.L.A. 333.17755	"Biological drug product" means a biological product as that term is defined in 42 USC 262. "Interchangeable biological drug product" means either of the following, as applicable: (a) A biological drug product that is licensed by the FDA and that the FDA has determined meets the standards for interchangeability under 42 USC 262(k)(4). (b) Until March 23, 2021, a biological drug product that the FDA has determined to be therapeutically equivalent as set	when a pharmacist receives a prescription for a brand name drug product or biological drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product or interchangeable biological drug product, the pharmacist shall dispense a lower cost but not higher cost generically equivalent drug product or interchangeable biological drug product if available in the pharmacy. If a drug or biological drug product is dispensed that is not the prescribed brand, the purchaser must be notified and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. Except as otherwise provided in section 17756, if the dispensed drug or biological drug product does not have a brand name, the prescription label must indicate the generic name of the drug dispensed or the proprietary name of the biological drug product dispensed.	Except as otherwise provided in subsection (6), within 5 days after dispensing an interchangeable biological drug product, the dispensing pharmacist or his or her designee shall communicate to the prescriber the specific interchangeable biological drug product provided to the patient, including the name of the interchangeable biological drug product and its manufacturer. The communication required under this subsection must be made as follows: (a) By making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, a health information 3 exchange, or a pharmacy record. An entry made as described in this subdivision is presumed to provide notice to the prescriber. (b) If the methods described in subdivision (a) are not available, then by facsimile, telephone, electronic transmission, or other prevailing means.	The pharmacist shall not dispense a generically equivalent drug product or interchangeable biological drug product under subsection (1) if any of the following apply: (a) The prescriber, in the case of a prescription in writing signed by the prescriber, writes in his or her own handwriting "dispense as written" or "d.a.w." on the prescription. (b) The prescriber, having preprinted on his or her prescription blanks the statement "another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed d.a.w.", writes in his or her own handwriting the initials "d.a.w." in a space, box, or square adjacent to the statement. (c) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates that the prescription is to be dispensed as communicated If a pharmacist SUBSTITUTES A LOWER COST generically equivalent drug product or interchangeable

	forth in “Approved Drug Products with Therapeutic Equivalence Evaluations”, an FDA publication that is commonly referred to as the “Orange Book”			biological drug product TO A PURCHASER WHO IS NOT SUBMITTING A CLAIM TO A THIRD-PARTY PAYMENT SOURCE, the pharmacist shall CHARGE THE purchaser NOT MORE THAN THE CURRENT SELLING PRICE FOR THE LOWER COST DRUG PRODUCT.
Minnesota M.S.A. § 151.01; M.S.A. § 151.21	"Biological product", the same meaning as such term is defined under 42 U.S.C. Section 262 "Interchangeable biological product", a biological product that the FDA: (a) Has licensed and determined meets the standards for interchangeability under 42 USC Section 262(k)(4) or (b) determined therapeutically equivalent as set forth in the latest edition of or supplement to the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).	When a pharmacist receives a paper or hard copy prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has not expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug or, if a biological product is prescribed, a less expensive interchangeable biological product that, in the pharmacist's professional judgment, is safely interchangeable with the prescribed drug, then the pharmacist shall, after disclosing the	Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the name and manufacturer of the biological product dispensed. (b) The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through: (1) an interoperable electronic medical records system; (2) an electronic prescribing technology; (3) a pharmacy benefit management system; or (4) a pharmacy record. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug or biological product other than the brand name specific drug or biological product prescribed.	

		substitution to the purchaser, dispense the generic generically equivalent drug or the interchangeable biological product, unless the purchaser objects. A pharmacist may also substitute pursuant to the oral instructions of the prescriber. A pharmacist may not substitute a generically equivalent drug product unless, in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist may not substitute a biological product unless the U.S. Food and Drug Administration has determined the substituted biological product to be interchangeable with the prescribed biological product.		
Mississippi Miss. Code Ann. § 73-21-73; Miss. Code Ann. § 73-21-117; Miss. Code Ann. § 73-21-118	"Biological product" means the same as that term is defined in 42 USC Section 262. "Interchangeable biological product" means a biological product that FDA: (i) Has licensed and determined as meeting the standards for interchangeability	Pharmacist may select a interchangeable biological product only when such selection results in lower cost to the purchaser, unless product selection is expressly prohibited by the prescriber. Pharmacist shall select interchangeable biological product when (1) Purchaser requests selection of an interchangeable biological product; or (2) Prescriber has not expressly prohibited product selection; and (3) Product selection will result in lower cost to purchaser. Before product selection is made,	Within five (5) business days following dispensing of any biological product, dispensing pharmacist or designee shall make entry of specific product provided to purchaser, including product name and manufacturer, and communicate that info to prescriber. Communication shall be conveyed by making an entry that is electronically accessible to the prescriber through (1) an interoperable electronic medical records system, (2) an electronic prescribing technology, (3) a pharmacist benefit management system, or (4) a pharmacy record.	BoP to maintain link on its website to FDA's List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations. Whenever product selection is made, pharmacist to indicate on label of dispensed container the initials "I.B." The label shall include its nonproprietary name designated by FDA and name of product manufacturer.

	under 42 USC Section 262(k)(4); or (ii) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal FDA's Approved Drug Products with Therapeutic Equivalence Evaluations.	pharmacist shall advise the purchaser of his prerogatives under this subsection. When requested by purchaser to dispense biological product as ordered by the prescriber, pharmacist shall not select an interchangeable biological product.	Entry into an electronic records system as described is presumed to provide notice to prescriber. Otherwise, pharmacist shall communicate the biological product dispensed to prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where (1) there is no federal Food and Drug Administration-approved interchangeable biological product for the product prescribed, or (2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.	
Missouri V.A.M.S. 338.056; V.A.M.S. 338.059; V.A.M.S. 338.085	"Biological product", the same meaning as such term is defined under 42 U.S.C. Section 262; (2) "Interchangeable biological product", a biological product that the FDA: (a) Has licensed and determined meets the standards for interchangeability under 42 USC Section 262(k)(4) or (b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the	A pharmacist may substitute an interchangeable biological product for a prescribed product only if all of the following conditions are met: (1) The substituted product has been determined by the Food and Drug Administration to be an interchangeable biological product with the prescribed biological product; (2) The substitution occurs according to the provisions of section 338.056; and (3) The pharmacy informs the patient of the substitution.	Within five 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 manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one of the following means: (1) An interoperable electronic medical records system; (2) An electronic prescribing technology; (3) A pharmacy benefit management system; or (4) A pharmacy record. Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, if an entry	The pharmacist shall maintain records in a manner consistent with section 338.100. The pharmacist shall label prescriptions in a manner consistent with section 338.059.

	FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).		cannot be made under the provisions of subsection 3 of this section, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required if: (1) There is no Food and Drug Administration approved interchangeable biological product for the product prescribed; or (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription	
Montana MCA 37-7-502; MCA 37-7-505	"**Biological product**" has the meaning provided in 42 U.S.C. 262. "**Interchangeable biological product**" means a biological product that the federal food and drug administration has: (a) licensed; and (b) (i) determined meets the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4); (ii) determined is therapeutically equivalent as set forth in the latest	a pharmacist who receives a prescription for a specific drug product by brand or proprietary name may select a less expensive drug product with the same generic name, strength, quantity, dose, and dosage form as the prescribed drug that is, in the pharmacist's professional opinion, therapeutically equivalent, bioequivalent, and bioavailable.; and (b) a pharmacist who receives a prescription for a specific biological product may select a less expensive interchangeable biological product. (2) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product or interchangeable biological product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product	(a) Within 5 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate the specific product provided to the patient, including the name of the product and the manufacturer, to the prescriber through any of the following electric records systems: (i) an interoperable electronic medical records system; (ii) an electronic prescribing technology; (iii) a pharmacy benefit management system; or (iv) a pharmacy record. (b) Communication through an electronic records system as described in subsection (3)(a) is presumed to provide notice to the prescriber. (c) If the pharmacist is unable to communicate pursuant to an electronic records system as provided in subsection (3)(a), the pharmacist shall communicate to	The pharmacist shall maintain a record of the biological product dispensed for at least 2 years

	edition of or supplement to the federal food and drug administration's approved drug products with therapeutic equivalence evaluations.	prescribed or the specific brand-name biological product prescribed is medically necessary for that particular patient. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the specific brand-name drug product prescribed or the specific biological product prescribed is medically necessary.	the prescriber which biological product was dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means. (d) Communication is not required under this subsection (3) when: (i) there is no federal food and drug administration approved interchangeable biological product for the product prescribed; or (ii) a refill prescription is not changed from the product dispensed on the prior filling of the prescription	
Nebraska Neb.Rev.St. § 38-2818.03; Neb.Rev.St. § 38-2825.02; Neb.Rev.St. § 38-28, 111-116	Biological product has the same meaning as in 42 U.S.C. 262, as such section existed on January 1, 2017. *Interchangeable biological product* means a biological product that the federal Food and Drug Administration: (1) Has licensed and has determined meets the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4), as such section existed on January 1, 2017, or as set forth in the Lists of Licensed	A pharmacist may drug product select except when: (a) A practitioner designates that drug product selection is not permitted by specifying in the written, oral, or electronic prescription that there shall be no drug product selection. For written or electronic prescriptions, the practitioner shall specify "no drug product selection", "dispense as written", "brand medically necessary", or "no generic substitution" or the notation "N.D.P.S.", "D.A.W.", or "B.M.N." or words or notations of similar import to indicate that drug product selection is not permitted. The pharmacist shall note "N.D.P.S.", "D.A.W.", "B.M.N.", "no drug product selection", "dispense as written", "brand medically necessary", "no generic substitution", or words or notations of similar import on the prescription to indicate that drug	If a pharmacist receives a prescription for a biological product and chooses to dispense an interchangeable biological product for the prescribed product, the pharmacist must advise the patient or the patient's caregiver that drug product selection has occurred. Within three business days after 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 shall be conveyed by making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record. Entry into an electronic records system described in this subsection is	The department shall maintain a link on its web site to the current list of all biological products that the federal Food and Drug Administration has determined to be interchangeable biological products.

	Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations published by the federal Food and Drug Administration, as such publication existed on January 1, 2017; or (2) Has determined is therapeutically equivalent as set forth in the Approved Drug Products with Therapeutic Equivalence Evaluations of the federal Food and Drug Administration, as such publication existed on January 1, 2017.	product selection is not permitted if such is communicated orally by the prescribing practitioner; or (b) A patient or designated representative or caregiver of such patient instructs otherwise.	presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required if (a) there is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed or (b) a refill prescription is not changed from product dispensed on the prior filling.	
Nevada N.R.S. 639.2583 - 639.2597	"Biological product" has the meaning ascribed to it in 42 U.S.C. § 262. "Interchangeable biological product" means a biological product that the	Except as otherwise provided in this section, if a practitioner has prescribed (a) Drug by brand name and the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited, the pharmacist who fills or refills the prescription shall dispense, in substitution, another	Except as otherwise provided in subsections 3 and 4, within 3 business days after dispensing a biological product, the dispensing pharmacist or his or her designee shall make an entry of the specific product provided to the patient that includes, without limitation, the name of the product and its manufacturer. The record must be	The Board shall maintain a link on its Internet website to the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, published by the Food and Drug Administration.

	Food and Drug Administration has: 1. Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. § 262(k)(4); or 2. Determined is therapeutically equivalent as set forth in the most recent edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations, published by the Food and Drug Administration.	drug which is available to him or her if the other drug: (1) Is less expensive than the drug prescribed by brand name; (2) Is biologically equivalent to the drug prescribed by brand name; (3) Has the same active ingredient or ingredients of the same strength, quantity and form of dosage as the drug prescribed by brand name; and (4) Is of the same generic type as the drug prescribed by brand name. (b) Biological product and the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited, the pharmacist who fills or refills the prescription shall dispense, in substitution, another biological product which is available to him or her if the other biological product: (1) Is an interchangeable biological product for the biological product prescribed; and (2) Is less expensive than the biological product prescribed by brand name. 2. If the pharmacist has available to him or her more than one drug or interchangeable biological product that may be substituted for the drug prescribed by brand name or biological product prescribed, the pharmacist shall dispense, in substitution, the least expensive of the drugs or interchangeable biological products that are available to him or her for substitution. 3. Before a pharmacist dispenses a drug	electronically accessible by the prescribing practitioner through: (a) An interoperable electronic health records system; (b) Electronic prescribing technology; (c) A pharmacy benefit management system; or (d) A pharmacy record. 2. An electronic record of the dispensing of a biological product made pursuant to subsection 1 is presumed to provide notice to the prescriber of the dispensing of the product. 3. Except as otherwise provided in subsection 4, if an electronic record of the dispensing of a biological product is not made pursuant to subsection 1, the dispensing pharmacist or his or her designee shall, within 3 business days after dispensing the biological product, give notice of the biological product to the prescriber by facsimile, telephone, electronic transmission or other available means. 4. Notice of the dispensing of a biological product pursuant to subsection 1 or 3 is not required if: (a) There is no interchangeable biological product for the biological product prescribed; or (b) A prescription for a refill is not changed from the product dispensed on the prior filling of the prescription. 5. As used in this section, “electronic health record” has the meaning ascribed to it in 42 U.S.C. § 17921(5).	If a generic drug or interchangeable biological product is substituted for a drug prescribed by brand name or biological product prescribed, the pharmacist or practitioner shall: 1. Note the name of the manufacturer, packer or distributor of the drug or biological product actually dispensed on the prescription; and 2. Indicate the substitution by writing or typing on the label the words “substituted for,” or substantially similar language, following the generic name and preceding the brand name of the drug , or following the name of the interchangeable biological product and preceding the brand name of the prescribed biological product, as applicable, unless, at the time the initial substitution of the generic drug or interchangeable biological product for a drug prescribed by brand name or biological product prescribed is made, the person for whom the drug or interchangeable biological product is dispensed elects not to have such an indication written or typed on the label. An election to indicate or not to indicate a substitution on the label pursuant to this subsection applies to both the fill and each refill of the same prescription.

		or biological product in substitution for a drug prescribed by brand name or biological product prescribed, the pharmacist shall: (a) Advise the person who presents the prescription that the pharmacist intends to dispense a drug or biological product in substitution; and (b) Advise the person that he or she may refuse to accept the drug or biological product that the pharmacist intends to dispense in substitution, unless the pharmacist is being paid for the drug by a governmental agency. 4. If a person refuses to accept the drug or biological product that the pharmacist intends to dispense in substitution, the pharmacist shall dispense the drug prescribed by brand name or biological product prescribed, unless the pharmacist is being paid for the drug or biological product by a governmental agency, in which case the pharmacist shall dispense the drug or biological product in substitution. 5. A pharmacist shall not dispense a drug or biological product in substitution for a drug prescribed by brand name or biological product prescribed if the practitioner has indicated that a substitution is prohibited using one or more of the following methods: (a) By oral communication to the pharmacist at any time before the drug or biological product is dispensed. (b) By handwriting the		

		words “Dispense as Written” on the form used for the prescription, including, without limitation, any form used for transmitting the prescription from a facsimile machine to another facsimile machine. The pharmacist shall disregard the words “Dispense as Written” if they have been placed on the form used for the prescription by preprinting or other mechanical process or by any method other than handwriting. (c) By including the words “Dispense as Written” in any prescription that is given to the pharmacist by electronic transmission pursuant to the regulations of the Board or in accordance with NRS 439.581 to 439.595, inclusive, and the regulations adopted pursuant thereto, including, without limitation, an electronic transmission from a computer equipped with a facsimile modem to a facsimile machine or from a computer to another computer pursuant to the regulations of the Board. 6. The provisions of this section also apply to a prescription issued to a person by a practitioner from outside this State if the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited.		
New Hampshire	"Biological product" means a virus, therapeutic serum, toxin, antitoxin,	A pharmacist may substitute a biological product pursuant to this section only if it has been licensed by the federal Food and Drug	Within 3 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an	The label of all biological products dispensed by a pharmacist shall include the proper name and the

N.H. Rev. Stat. § 318:47-dd	vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or 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. "Interchangeable biological product" means a biological product that the federal Food and Drug Administration: (1) Has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. section 262(k)(4); or (2) Has determined is	Administration as an interchangeable biological product for the prescribed biological product. When a pharmacist dispenses an interchangeable biological product for the prescribed biological product, the pharmacist or his or her designee shall inform the patient. V. A pharmacist shall not substitute an interchangeable biological product pursuant to this section if the prescriber indicates that substitution is not authorized by specifying on the prescription "medically necessary" on a paper prescription, or uses electronic indications when transmitted electronically, or gives instructions when transmitted orally that the biological product prescribed is medically necessary.	entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through: (1) An interoperable electronic medical records system; (2) An electronic prescribing technology; or (3) A pharmacy benefit management system; or (4) A pharmacy record. (b) Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that the communication shall not be required where: (1) There is no federal Food and Drug Administration-approved interchangeable biological product for the biological product prescribed; or (2) A refill prescription is not changed from product dispensed on the prior filling of the prescription.	name of the manufacturer of the product.

	therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations			
New Jersey NJ 13:39-7.23	**"Biological product"** means a "biological product" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. s.262(i)), and refers to 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	A pharmacist may substitute a biosimilar biological product for a prescribed biological product if: (1) the biosimilar biological product has been approved by the federal Food and Drug Administration to be interchangeable with the prescribed biological reference product; and (2) the authorized prescriber has not indicated that there shall be no substitution by initialing the prescription blank next to "do not substitute" as set forth in N.J.S.A. 24:6E-7	If a pharmacist substitutes an interchangeable biosimilar biological product for a prescribed biological reference product, the pharmacist shall, within 5 days following the dispensing of the biological product: (1) notify the patient in writing that the biological product dispensed has been approved by the federal Food and Drug Administration as an interchangeable biosimilar biological product for the prescribed biological reference product; (2) provide electronic, written, or telephonic notification of the substitution to the authorized prescriber or the authorized prescriber's staff within five business days after the dispensing of the interchangeable biosimilar biological product; and (3) record, on the prescription label and record of dispensing, the product name of the interchangeable	A pharmacist who substitutes an interchangeable biosimilar biological product in compliance with this section shall incur no greater liability in filling the prescription by dispensing the interchangeable biosimilar biological product than would be incurred in filling the prescription by dispensing the prescribed biological reference product. If a pharmacist dispenses a biological product, the pharmacist or the pharmacist's designee shall, within five business days following the dispensing of the biological product, communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. No communication shall be required under this subsection when:

	any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings. **"Biosimilar"** means "biosimilar" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. s.262(i)), and refers to 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		biosimilar biological product, followed by the words: "Substituted for" and the name of the biological reference product for which the prescription was written, and the manufacturer of the interchangeable biosimilar biological product. c. Records of substitutions of interchangeable biosimilar biological products shall be maintained for at least five years after the dispensing date.	1. There is no biological product that has been determined by the FDA to be either: i. Interchangeable with the product prescribed; or ii. Therapeutically equivalent to the product prescribed; or 2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription. (c) The communication requirement under (b) above may be satisfied by making an entry in an interoperable electronic medical records system or an electronic pharmacy record that can be accessed electronically by the prescriber, or through the use of another electronic prescribing technology that can be accessed electronically by the prescriber. Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, the communication may be conveyed using other electronic means, if available, or by facsimile. (d) A pharmacist who substitutes a biological product in compliance with this section shall record, on the prescription label and record of dispensing, the product name and manufacturer of the biological product dispensed, followed by the words: "Substituted for" and the name of the biological product for which the prescription was written. (e) The recordkeeping requirements of this subchapter and N.J.A.C. 13:39-9, as applicable, which apply to the dispensing of drugs shall apply to the dispensing of biological products. (f) The Board shall maintain a link to the current list of

	biosimilar pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262) in terms of safety, purity, and potency of the product. **"Interchangeable"** means "interchangeable" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. s.262(i)). **"Reference product"** means a "reference product" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. s.262(i)), and refers to the single biological product against which a biological product is evaluated in an application for a license as a biosimilar biological product.			all biological products determined by the FDA to be interchangeable pursuant to section 351 of the Public Health Service Act (42 U.S.C. § 262) on the Board's website.

New Mexico Section 26-1-2 NMSA 1978	**"biological product"** means any of the following that is applicable to the prevention, treatment or cure of a disease or condition of human beings: (1) a virus; (2) a therapeutic serum; (3) a toxin; (4) an antitoxin; (5) a vaccine; (6) blood; (7) a blood component or derivative; (8) an allergenic product; (9) a protein, except any chemically synthesized polypeptide; (10) a product that is analogous to any of the products listed in Paragraphs (1) through (9) of this subsection; or (11) arsphenamine, a derivative of arsphenamine or any other trivalent organic arsenic compound; **"biosimilar" or "biosimilarity"**	A. Upon receipt of a prescription written by a licensed practitioner who may prescribe drugs or biological products for a drug or biological product for which one or more multiple-source drugs or interchangeable biological products are recognized, listed as final determinations and published in the federal register by the federal department of health and human services, a pharmacist may dispense any one of the drugs or interchangeable biological products that satisfies the final determinations so recognized and listed by the federal department of health and human services and is sold at a lower cost than the drug or biological product listed in the prescription. B. Upon receipt of a prescription written by a licensed practitioner for a drug or biological product that appears on the federal food and drug administration's approved prescription drug products with therapeutic equivalence evaluation list as supplemented, or for a biological product that is listed as interchangeable on the lists of the federal food and drug administration's lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations, as supplemented, a pharmacist may	Within five 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 shall be conveyed by making an entry that is electronically accessible to the prescriber through: (1) an interoperable electronic medical records system; (2) an electronic prescribing technology; (3) a pharmacy benefit management system; or (4) a pharmacy record. H. Entry into an electronic medical records system pursuant to Subsection G of this section is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate to the prescriber what biological product was dispensed, using facsimile, telephone, electronic transmission or other prevailing means; provided that communication shall not be required when: (1) there is no interchangeable biological product that has been approved by the federal food and drug administration for the product prescribed; or (2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.	The board shall maintain a link on its website to the current lists of all biological products that the federal food and drug administration has determined to be interchangeable biological products.

	means, in reference to a biological product that the federal food and drug administration has licensed, that: (1) the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (2) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product; **"interchangeable biological product"** means a biological product that the federal food and drug administration has licensed and: (1) has determined that the biological product is biosimilar to the reference product and can be expected to produce	dispense any of the listed therapeutically equivalent drugs or interchangeable biological products that is lower in cost than the prescribed drug or biological product. C. Drug and biological product selection shall be permitted only under circumstances and conditions set forth in Subsections A and B of this section unless the licensed practitioner prescribing prohibits drug or biological product selection. A licensed practitioner shall prohibit drug or biological product selection by making an entry that is electronically accessible that includes the words "no substitution" or the diminution "no sub" on a prescription.		

	the same clinical result as the reference product in any given patient; (2) for a biological product that is administered more than once to an individual and: (a) has determined to have been administered more than once to the individual; or (b) for which 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 alternation or switching; or (3) has determined to be therapeutically equivalent as set forth in the latest edition or supplement to the federal food and drug administration's approved drug			

	products with therapeutic equivalence evaluations;			
New York McKinney's Education Law § 6810; McKinney's Education Law § 6816-a	"BIOLOGICAL PRODUCT" MEANS A BIOLOGICAL PRODUCT AS DEFINED IN SUBSECTION (I) OF SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT, 42 U.S.C. SECTION 262(I) "INTERCHANGEABLE BIOLOGICAL PRODUCT" MEANS A BIOLOGICAL PRODUCT LICENSED BY THE UNITED STATES FDA PURSUANT TO 42 U.S.C. SECTION 262(K)(4) AS SET FORTH IN THE LATEST EDITION OR SUPPLEMENT OF THE UNITED STATES FDA LISTS OF LICENSED BIOLOGICAL PRODUCTS WITH REFERENCE PRODUCT EXCLUSIVITY AND	A PHARMACIST SHALL SUBSTITUTE A LESS EXPENSIVE BIOLOGICAL PRODUCT FOR A PRESCRIBED BIOLOGICAL PRODUCT PROVIDED THAT ALL OF THE FOLLOWING CONDITIONS ARE MET: (C) THE SUBSTITUTED BIOLOGICAL PRODUCT IS EITHER AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR THE PRESCRIBED PRODUCT OR THE SUBSTITUTED BIOLOG- ICAL PRODUCT IS ONE FOR WHICH THE PRESCRIBED PRODUCT IS AN INTERCHANGEA- BLE BIOLOGICAL PRODUCT; (B) THE PRESCRIBER DOES NOT DESIGNATE THAT A SUBSTITUTION IS PROHIBITED AS DESCRIBED IN SUBDIVISION SIX OF SECTION SIXTY-EIGHT HUNDRED TEN OF THIS ARTICLE; AND I THE PHARMACIST INDICATES ON THE LABEL AFFIXED TO THE IMMEDIATE CONTAINER IN WHICH THE BIOLOGICAL PRODUCT IS SOLD OR DISTRIBUTED THE NAME AND STRENGTH OF THE PRODUCT AND ITS MANUFACTURER UNLESS THE PRES- CRIBER SPECIFICALLY STATES OTHERWISE.	WITHIN FIVE BUSINESS DAYS FOLLOWING THE DISPENSING OF A SUBSTITUTED BIOLOGICAL PRODUCT, THE DISPENSING PHARMACIST OR THE PHARMACIST'S DESIGNEE SHALL COMMUNICATE TO THE PRESCRIBER THE SPECIFIC PRODUCT PROVIDED TO THE PATIENT, INCLUDING THE NAME OF THE PRODUCT AND THE MANUFACTURER. THE COMMUNICATION SHALL BE CONVEYED TO THE PRESCRIBER (I) BY MAKING AN ENTRY THAT IS ELECTRONICALLY ACCESSIBLE TO THE PRESCRIBER THROUGH AN INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM, AN ELECTRON- IC PRESCRIBING TECHNOLOGY OR A PHARMACY RECORD; OR (II) BY USING FACSIMILE, ELECTRONIC TRANSMISSION OR OTHER ELECTRONIC MEANS. IF AN ELECTRONIC MEANS DESCRIBED IN THIS PARAGRAPH IS NOT AVAILABLE TO THE PHARMACIST AT THE TIME OF COMMUNICATION, THE DISPENSING PHARMACIST OR THE PHARMACIST'S DESIGNEE MAY COMMUNICATE THE INFORMATION BY TELEPHONE.	A pharmacist may, based upon his or her professional judgment, accept an electronic prescription from a prescriber, to the pharmacy of the patient's choice, subject to the following requirements: except when the prescriber inserts an electronic direction to dispense the drug as written, the prescriber's electronic signature shall designate approval of an interchangeable biological product by a pharmacist. Notwithstanding any other provision of this section or any other law to the contrary, when an interchangeable biological product is not available and the biological product originally prescribed is available and the pharmacist agrees to dispense the prescribed biological product for a price that will not exceed the price that would have been charged for the interchangeable biological substitute had it been available, substitution of an interchangeable biological product will not be required. If the interchangeable biological product is not available and a medical emergency situation, which for purposes of this section is defined as any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated, exists, then the pharmacist may dispense the prescribed biological product at his or her regular price. In such instances, the pharmacist must record the date, hour and nature of

	BIOSIMILARITY OR INTERCHANGEABILITY EVALUATIONS, SOMETIMES REFERRED TO AS THE "PURPLE BOOK," 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 EQUIV-ALENCE EVALUATIONS, SOMETIMES REFERRED TO AS THE "ORANGE BOOK."			the medical emergency on the back of the prescription and keep a copy of all such prescriptions
North Carolina	"Biological product" - As defined in	A pharmacist dispensing a prescription for a drug product	Within a reasonable time following the dispensing of a biological product	The Board of Pharmacy shall maintain a link on its Internet Web site to the

N.C.G.S.A. § 90-85.27; N.C.G.S.A. § 90-85.28; N.C.G.S.A. § 90-85.31	section 351(i) of the Public Health Service Act, 42 U.S.C. § 262(i). "Interchangeable biological product" - A biological product determined by FDA to meet the standards set forth in 42 U.S.C. § 262(k)(4), or deemed therapeutically equivalent by the United States Food and Drug Administration. "Equivalent drug product" – a drug product which has the same established name, active ingredient, strength, quantity, and dosage form, and which is therapeutically equivalent to the drug identified in the prescription.	prescribed by its brand name may select any interchangeable biological product which meets all of the following standards: - The manufacturer's name and the distributor's name, if different from the manufacturer's name, shall appear on the label of the stock package. - It shall be manufactured in accordance with current good manufacturing practices. - All oral solid dosage forms shall have a logo, or other identification mark, or the product name to identify the manufacturer or distributor. - The manufacturer shall have adequate provisions for drug recall. - The manufacturer shall have adequate provisions for return of outdated drugs, through the distributor or otherwise. A pharmacist may not select an interchangeable biological product if the prescriber instructs otherwise by one of the following methods: - a prescription form shall be preprinted or stamped with two signature lines at the bottom of the form which read: "Product Selection Permitted" / "Dispense as Written", and on this form, the prescriber shall communicate instructions to the pharmacist by signing the appropriate line.	requiring a prescription, the pharmacist or a designee shall communicate to the prescriber the product name and manufacturer of the specific biological product dispensed to the patient. This required communication shall be conveyed by making an entry into an interoperable electronic medical records system, or electronic prescribing technology, or a pharmacy benefit management system, or a pharmacy record that can be electronically accessible by the prescriber. Entry into one of the above referenced methods of communication is presumed to provide the required communication. Otherwise, the pharmacist or a designee shall provide the required communication to the prescriber by facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required under any of the following circumstances: - There is no FDA-approved interchangeable biological product for the product prescribed. - A refill prescription is not changed from the product dispensed on the prior filling of the prescription. If the State mandates EMRs between a pharmacist and a prescriber, then the pharmacist shall only be required to communicate the biological product dispensed through an EMR system when such a system is in place and the	current list of biological products determined by FDA to be interchangeable with a specific biological product. Pharmacist may not select an equivalent drug or interchangeable biological product unless its price to the purchaser is less than the price of the prescribed drug product. The selection of an interchangeable biological product shall impose no greater liability upon the pharmacist for selecting the dispensed biological product or upon the prescriber of the same than would be incurred by either for dispensing the biological product specified in the prescription.

		- in the event a preprinted stamped prescription form is not readily available, the prescriber may handwrite "Dispense as Written" or words or abbreviations of the same meaning on a prescription form. - when ordering a prescription orally, prescriber shall specify either that the prescribed drug product be dispensed as written or that product selection is permitted, and the pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period prescribed by law.	information is accessible by the prescriber.	
North Dakota NDCC, 19-02.1-14.3	"Biological product", "biosimilar", "interchangeable", "interchangeable biological product", "license", and "reference product" mean the same as these terms mean under section 351 of the Public Health Service Act [42 U.S.C. 262].	A pharmacy may not substitute a prescription biosimilar product unless each of the following requirements is met: - the biosimilar product has been determined by FDA to be interchangeable with the prescribed product; - the prescriber does not specifically indicate "brand medically necessary" (via expressly writing on a written prescription / expressly indicating via an oral prescription / takes a specific overt action to include the "brand medically necessary" language with an electronically transmitted prescription); - the pharmacist or designee informs the recipient of the biological product that the biological product may be substituted with a biosimilar product and that the individual has a	Within two business days following the dispensing of the biosimilar product, the pharmacist or the pharmacist's designee notifies the prescribing practitioner of the substitution. Notification under this subdivision must include the name of the substitution product and the name of the manufacturer, and may be made using facsimile, telephone, electronic transmission, an entry into an interoperable electronic medical record accessible by the prescribing practitioner, or other prevailing means accessible by the prescribing practitioner.	The board of pharmacy shall maintain on its public website a current list, or an internet link to an FDA-approved list, of biosimilar biological products determined to be interchangeable. The pharmacy and prescriber must retain a record of the interchangeable biosimilar substitution for a period of no less than five years.

		right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse.		
Ohio R.C. § 4729.38; R.C. § 3715.01; R.C. § 3715.011	**"Biological product"** means, except as provided in section 3715.011 of the Revised Code, a drug that is a biological product, as defined on the effective date of this amendment in subsection (i) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(i). **"Interchangeable biological product"** means, except as provided in section 3715.011 of the Revised Code, both of the following: (a) A biological product that, on the effective date of this amendment, has been determined by the United States food and drug administration to meet the standards for interchangeability	Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug prescribed by its brand name may , subject to the following conditions, select a generically equivalent drug or, in the case of a drug that is a biological product, select an interchangeable biological product: (1) The pharmacist shall not select a generically equivalent drug or interchangeable biological product if either of the following applies: (a) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "brand medically necessary," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription. (b) In the case of an oral prescription, the prescriber specifies that the drug as	Except as provided in division (F)(1)(b) of this section, not later than five business days after a pharmacist dispenses a drug for which an interchangeable biological product is available, regardless of whether a substitution is made, the pharmacist or an individual designated by the pharmacist shall communicate to the prescriber information identifying the specific biological product that was dispensed, including the name of the biological product and its manufacturer. (b) Communication of the information is not required when a biological product is dispensed by refilling a prescription and the product that is dispensed is the same product that was dispensed when the same prescription was last filled or refilled. (2) When possible, communication of the information shall be conveyed by entering the information into a recordkeeping system that can reasonably be presumed to be electronically accessible to the prescriber. Such a system may include any of the following: (a) An interoperable electronic medical records system; (b) An electronic prescribing system; (c) An electronic pharmacy benefit management system; (d) An electronic pharmacy record system. (3) Entering the complete information into one of the recordkeeping systems listed in division (F)(2) of this section is	

	set forth in subsection (k) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), as amended, and has been licensed under that subsection; (b) A biological product that, prior to the effective date of this amendment, was determined by the United States food and drug administration to be therapeutically equivalent as set forth in its publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."	prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.	presumed to provide notice to the prescriber. (4) When it is not possible to communicate the information by using one of the recordkeeping systems listed in division (F) (2) of this section, communication of the information shall be conveyed by telephone, facsimile, another form of electronic communication, or any other prevailing means of communication.	
Oklahoma				
Oregon O.R.S. § 689.522	"Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood,	A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biosimilar product for the prescribed biological product unless: - The biosimilar product has been determined by FDA to be interchangeable with the prescribed biological product	Requires a pharmacy, pharmacist, or a pharmacist's designee, within five calendar days communicate the specific biological product dispensed a patient, including the name and manufacturer of the biological product, by making an entry into an electronic records system that the prescribing practitioner can access electronically and that is:	The State Board of Pharmacy must post and regularly update on a website maintained by the board a list of biosimilar products determined by FDA to be interchangeable. The pharmacy or pharmacist must retains a record of the substitution for a period of not less than three years.

	blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound. "Biosimilar product" means a biological product licensed by FDA pursuant to 42 U.S.C.262(k)(3)(A)(i). "Interchangeable" means, in reference to a biological product, that FDA has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4). "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) against which a biological	- The prescriber has not designated on the prescription that substitution is prohibited - The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product	(1) An interoperable electronic medical records system; (2) An electronic prescribing technology; (3) A pharmacy benefit management system or (4) A pharmacy records States that if a pharmacy or pharmacist, or their designee, does not have not have access to the electronic records system, the pharmacy or pharmacist, or their designee, will communicate within five calendar days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. Stipulates that the communication may be in writing, electronic, telephone or another method. Stipulates that a pharmacy or pharmacist, or their designee, is not required to communicate to the prescribing practitioner the specific biological product dispensed to the patient if: (1) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product or (2) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or	Stipulates that these new provisions do not prohibit an insurer or other health care payer from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product. Requires that if a biological product is dispensed to a patient in an community-based care facility, clinic, hospital or long term care facility that an entry must be made into the patient's record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, thereby satisfying the communication requirements of this act.

	product is evaluated in an application submitted to FDA for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable. Requires that for the rule defining the term "interchangeable" (A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4) and (B) For biological products approved by the United States Food and Drug Administration under the Federal		pharmacist re-filled the patient's prescription.	

	Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.			
Pennsylvania 35 P.S. § 960.1 et. seq.	"Biological product" shall have the same meaning as "biological product" in the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 207 et seq.). "Interchangeable biological product" means a biological product licensed by the United States Food and Drug	A pharmacist may substitute a biological product for a prescribed biological product only if: (1) the biological product is an interchangeable biological product and has been determined by the FDA to be interchangeable with the prescribed product; (2) the prescriber does not designate verbally or in writing on the prescription that substitution is prohibited; and (3) the person presenting the prescription receives notification of	Within 72 hours following the dispensing of an interchangeable biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in the electronic health record of the patient, as defined in the act of July 5, 2012 (P.L.1042, No.121), known as the "Pennsylvania eHealth Information Technology Act," or through an	

	Administration and determined to meet the safety standards for interchangeability pursuant to the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 207 et seq.) or a biological product APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (52 STAT. 1040, 21 U.S.C. § 355) AND determined by the United States Food and Drug Administration to be therapeutically equivalent to a prescribed biological product.	such substitution in the same manner provided in subsection (b).	electronic prescribing technology , A PBM system or a pharmacy record , that is electronically accessible by the prescriber. Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise within 72 hours, the pharmacist shall communicate the interchangeable biological product dispensed to the prescriber, using facsimile, telephone, electronic transmission or other prevailing means, provided that the communication shall not be required where : (1) there is no FDA approved interchangeable biological product for the biological product prescribed; or (2) it is a refill prescription where the interchangeable biological product dispensed is the same interchangeable biological product which was dispensed at the prior filling of the prescription. (a.3) Subsections (a.1) and (a.2) may not apply to a biological product which may be dispensed without a prescription. (c) Any pharmacist substituting a less expensive drug product or interchangeable biological product shall charge the purchaser the regular and customary retail price for the generically equivalent drug or interchangeable biological product. (d) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product or	

			interchangeable biological product for a prescribed brand name drug.	
Rhode Island Gen.Laws 1956, § 5-19.1-2; § 5-19.1-19.1; Gen.Laws 1956, 21-31-16.1;	"Biological product" means a "biological product" as defined 4 in the "Public Health Service Act", 42 U.S.C. §262. "Interchangeable biological product" means a biological product that the United States FDA has: (1) Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. §262(k)(4) or lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations; or (2) Determined is therapeutically equivalent as set forth in the latest edition of or supplement to the United States FDA's Approved Drug	Pharmacists when dispensing a prescription for any biological product shall, unless requested otherwise by the individual presenting the prescription in writing, substitute such product with an interchangeable biological product in accordance with the provisions of §21-31-16.1(g). No substitution under this section shall be allowed if the prescribing physician orders the pharmacist to dispense as brand name necessary on the prescription form, or if the prescriber gives oral direction to that effect to the dispensing pharmacist. The requirements of this section shall not apply to an order to dispense a biological product for immediate administration to a licensed hospital, nursing facility, or hospice facility in-patient. The pharmacist will make a biological product selection from approved interchangeable prescription biological products in accordance with §21-31-16.1(g). When a biological product selection is made, the pharmacist shall inform the patient of the selection made and shall indicate the product dispensed on the written prescription or on the oral prescription, which has been reduced to writing, or product information may be maintained on a	Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. (c) The communication shall be conveyed by making an entry electronically accessible to the prescriber through: (1) An interoperable electronic medical records system; (2) An electronic prescribing technology; (3) A pharmacy benefit management system; or (4) A pharmacy record. (d) Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that the communication shall not be required where: (1) There is no interchangeable biological product for the product prescribed approved by the United States FDA; or (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.	Biological product selection: The director shall permit substitution of a less expensive biological product, as defined in §5-19.1-2, for a prescribed biological product only if said less expensive biological product is an interchangeable biological product as defined in §5-19.1-2. 19 The director shall maintain on the Rhode Island state department of health website, a link to the current list of each biological product determined by the United States FDA to be an interchangeable biological product.

	Products with Therapeutic Equivalence Evaluations.	computerized system if information is readily retrievable.		
South Carolina Code 1976 § 39-24-20; Code 1976 § 39-24-30; Code 1976 § 39-24-40; Code 1976 § 40-43-30; Code 1976 § 40-43-86	'Biological Product' has the same meaning as defined in 42 U.S.C. Sec. 262. 'Interchangeable biological product' means a biological product that the federal Food and Drug Administration has: (a) licensed and determined to meet the standards of 'interchangeability' pursuant to 42 U.S.C. Section 262(k)(4); or (b) determined to be therapeutically equivalent by the federal Food and Drug Administration.	Upon receiving a prescription for a brand name drug or for a specific biological product, a registered pharmacist may in his professional judgment substitute an equivalent drug or interchangeable biological product as provided in this subsection. (2) Every oral or written drug prescription shall provide an authorization from the practitioner as to whether or not an equivalent drug or interchangeable biological product may be substituted. (3) A written prescription shall have two signature lines at opposite ends on the bottom of the form. Under the line at the left side shall be clearly printed the words 'Dispense As Written'. Under the line at the right side shall be clearly printed the words 'Substitution Permitted'. The practitioner shall communicate the instructions to the pharmacist by signing on the appropriate line. No written prescription is valid without the signature of the practitioner on one of these lines. (4)An oral prescription from the practitioner shall instruct the pharmacist as to whether or not an equivalent drug product or	Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication must be conveyed by making an entry that is electronically accessible to the prescriber through: (i) an interoperable electronic medical records system; (ii) an electronic prescribing technology; (iii) a pharmacy benefit management system; or (iv) a pharmacy record. Entry into an electronic records system as described in this section is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required when: (a) there is no federal Food and Drug Administration approved interchangeable biological product for the product prescribed; or (b) a refill prescription is not changed from the product dispensed on the prior filling of the prescription; or (c) a biological product is dispensed for inpatient hospital services or is a hospital-	

		interchangeable biological product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period as prescribed by law. (5)The pharmacist shall note the brand name or the manufacturer of the substituted drug or brand or proper name and manufacturer of the biological product dispensed on the file copy of a written or oral prescription or record this information electronically, or both. If a pharmacist substitutes a generic drug or interchangeable biological product for a name brand prescribed drug or specific biological product prescribed: (a)In the case of a drug product described, when dispensing a prescribed medication, the brand name and the generic name of the drug and its manufacturer or brand name, if any, with an explanation of 'generic for' or similar language in the case of a drug dispensed, to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless in the case of a drug product prescribed, the prescribing practitioner indicated that the name of the drug may not appear upon the prescription label. (b) In the case of a biological product described, when dispensing a prescribed medication, the brand	administered biological product for outpatients.	

		name, if any, and the proper name of the biological product and its manufacturer, with an explanation of 'interchangeable with' or similar language, in the case of a biological product dispensed, to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless in the case of a drug product prescribed, the prescribing practitioner indicated that the name of the drug may not appear upon the prescription label. (6)Substitution may not occur unless the pharmacist advises the patient or the patient's agent that the practitioner has authorized substitution and the patient, or patient's agent, consents. A Medicaid recipient whose prescription is reimbursed by the South Carolina Medicaid Program is deemed to have consented to the substitution of a less costly equivalent generic drug product or interchangeable biological product.		
South Dakota SD Code 36-11	"Biological product," as defined in 42 U.S.C. 262(i), as of January 1, 2018 "Interchangeable biological product," a biological product	A practitioner may prohibit a pharmacist from selecting an equivalent drug product or interchangeable biological product by handwriting on the prescription drug order the words, brand necessary, or words of similar meaning. The prohibition may not be preprinted or	A pharmacist dispensing a prescription drug order for a biological product prescribed by its brand or proper name may select an interchangeable biological product of the prescribed product. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the	No nonresident pharmacy may dispense an equivalent drug product or an interchangeable biological product if a brand name has been prescribed, unless the dispensing is done in compliance with the laws of this state nor may dispense an equivalent drug product or an

	that the U.S. FDA either has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4), as of January 1, 2018, or has determined is therapeutically equivalent as set forth in the latest edition of, or any supplement to, the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations publication as adopted by the board pursuant to chapter 1-26	stamped on the prescription drug order. This selection does not preclude a reminder of the procedure required for the practitioner to prohibit selection by a pharmacist from being preprinted on the prescription drug order. If an oral prescription is given to a pharmacist, the practitioner or practitioner's authorized agent shall instruct the pharmacist if selection of an equivalent drug product or interchangeable biological product is prohibited. The pharmacist shall note the instructions on the file copy of the prescription drug order.	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 shall be conveyed by making an entry that is electronically accessible to the prescriber through: (1) An interoperable electronic medical records system; (2) An electronic prescribing technology; (3) A pharmacist benefit management system; or (4) A pharmacy record. Any entry into an electronic records system as described in section 9 of this Act is presumed to provide notice to the practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the practitioner using facsimile, telephone, electronic transmission, or other prevailing means, if communication is not required where: (1) There is no interchangeable biological product approved by the U.S. Food and Drug Administration for the product prescribed; or (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription. The pharmacist or the pharmacist's agent shall inform the person receiving the drug or biological product pursuant to the prescription drug order of the selection of an equivalent drug product or interchangeable biological product and of the person's right to refuse the	interchangeable biological product to a resident of this state without informing the patient of the selection and the right to refuse the product selected either by telephone or in writing.

			product selected. A pharmacist shall, upon request of the prescribing practitioner, provide information regarding substitutions of equivalent drug products.	
Tennessee TN Code Annotated, Section 53-10-203; TN Code Annotated, Section 53-10-211	"Biological product" has the same meaning as defined in 42 U.S.C. § 262(i) "Interchangeable biological product" means: - a biological product licensed by FDA and determined to meet the safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4); or - a biological product determined by FDA to be therapeutically equivalent as set forth in the latest edition or supplement the Orange Book	A prescriber shall allow for substitution with an interchangeable biological product of a prescribed biological product under all circumstances unless: - the prescriber determines the medical necessity of a prescribed biological product due to an adverse reaction previously experienced by the patient to an interchangeable biological product, an interchangeable biological product has previously been demonstrated as ineffective for the patient, or any other clinically-based, prescriber-determined need; or - an interchangeable biological product is not available. Pharmacist must notify patient of the substitution with an interchangeable biological product by noting the substitution on the prescription label. If prescriber determines a prescribed biological product is medically necessary, prescriber shall handwrite instructions showing intent upon the prescription at the time it is prepared and issued by conveying "Brand name medically necessary", "dispense as written", "medically	Within a reasonable time following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in an interoperable EMR system or through an electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber, using facsimile, telephone, electronic transmission, or other prevailing means; provided, that communication shall not be required where: - there is no FDA-approved interchangeable biological product for the product prescribed; or - a refill prescription is not changed from the product dispensed on the prior filling of the prescription.	A pharmacist who selects an interchangeable biological product for substitution has the same responsibility for the selected product as the pharmacist would in dispensing a prescription for the product prescribed. The board of pharmacy shall maintain a link on its web site to the current list of all biological products determined by FDA to be interchangeable biological products. The pharmacist shall maintain a record of the biological product dispensed as required pursuant to § 53-14-110.

		necessary", "brand name", or "no generic"; any abbreviation of this language; or any other prescriber handwritten notation, such as circling a preprinted instruction to dispense as written on the prescription order, that clearly conveys the intent that a brand name is necessary for a patient. Upon issuing an oral prescription where brand is medically necessary, prescriber shall alert the pharmacist that use of the prescribed biological product is medically necessary for the patient. Similar proper instruction required for electronic and faxed prescription. (See statutory language for specifics)		
Texas TX OCC § 562.001; TX OCC § 562.003; TX OCC § 562.0051; TX OCC § 562.006; TX OCC § 562.008; TX OCC § 562.009; TX OCC § 562.010; TX OCC § 562.011; TX OCC § 562.016	"Biological product" has the meaning assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262 "Interchangeable," in reference to a biological product, has the meaning assigned by Section 351, Public Health Service Act (42 U.S.C. Section 262), or means a biological product that is designated as therapeutically equivalent to	If prescriber certifies brand medically necessary on the prescription form in accordance with TX OCC § 562.015, the pharmacist must dispense the biological product as written by the practitioner. A pharmacist who receives a prescription for a biological product for which there is one or more interchangeable biological products may dispense any of the interchangeable biological products. Before delivery of an interchangeable biological product, a pharmacist / pharmacist's agent must inform patient / patient's agent that a less expensive interchangeable biological product is available for the brand prescribed and ask patient / patient's	Not later than the 3rd business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number. The communication must be conveyed by making an entry into an interoperable EMR system or through electronic prescribing technology or a pharmacy benefit management system or a pharmacy record, which may include information submitted for the payment of claims, that a pharmacist reasonably concludes is electronically accessible by the prescribing practitioner. Otherwise, the pharmacist	If the price of a biological product to a patient is lower than the amount of the patient's copayment under the patient's prescription drug insurance plan, the pharmacist shall offer the patient the option of paying for the biological product at the lower price instead of paying the amount of the copayment. Must be labeled in accordance with TX OCC § 562.006, which requires the label on the dispensing container to indicate the actual biological product dispensed (consistent with labeling requirements and practices for small molecule drugs) The board shall maintain on the board's Internet website a link to the

	another product by the FDA in the most recent edition or supplement of the Orange Book	agent to choose between the interchangeable biological product and the brand prescribed, except that this is not required in the following situations: - refills for which the pharmacy previously complied with this requirement; or - where patient's physician / physician's agent has determined patient's / patient's agent preference for brand vs. less expensive interchangeable biological product If patient / patient 's agent fails to indicate otherwise to a pharmacy on the prescription, the pharmacy may dispense an interchangeable biological product. A pharmacist may not select an interchangeable biological product unless the interchangeable biological product selected costs the patient less than the prescribed drug or biological product.	or the pharmacist's designee shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if: - there is no interchangeable biological product approved by FDA for the product prescribed; or - a refill prescription is not changed from the product dispensed on the prior filling of the prescription (Notification requirements in effect until September 1, 2019)	FDA's list of approved interchangeable biological products. A pharmacist who selects an interchangeable biological product assumes the same responsibility for selecting the interchangeable biological product as the pharmacist does in filling a prescription for a drug prescribed by biological product name. Prescriber is not liable for a pharmacist's act or omission in selecting, preparing, or dispensing a drug or biological product under this subchapter. A pharmacist may not charge for dispensing an interchangeable biological product a professional fee higher than the fee the pharmacist customarily charges for dispensing the brand name biological product prescribed.
Utah U.C.A. 1953 § 58-17b-605.5	"biological product" means the same as that term is defined in 42 U.S.C. Sec. 262 "Interchangeable biological product" means a biological product that FDA has licensed and determined meets	A pharmacist / intern dispensing a prescription order for a specific biological product by brand or proprietary name may substitute an interchangeable biological product for the prescribed biological product only if: - purchaser specifically requests or consents to the substitute of an interchangeable biological product;	Within five 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 shall be conveyed by making an entry into an interoperable electronic medical records system, through an electronic prescribing	Each out-of-state mail service pharmacy dispensing an interchangeable biological product as a substitute for another biological product must notify the patient of the substitution either by telephone or in writing, and must comply with UT's requirements with respect to an interchangeable biological product substituted for another biological

	the standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4), or that FDA has determined is therapeutically equivalent as set forth in the latest edition of or supplement of the Orange Book	- the interchangeable biological product is permitted to move in interstate commerce; - the pharmacist / intern counsels the patient on use and expected response to the prescribed biological product, whether a substitute or not, and the substitution is not otherwise prohibited by this chapter; - prescriber has not prohibited the substitution of an interchangeable biological product for the prescribed biological product by either by writing "dispense as written" or by signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted" to indicate dispense as written; and - substitution is not otherwise prohibited by law Pharmacists / interns may not substitute biological product prescriptions without prescriber's authorization unless the product has been determined by FDA to be interchangeable with the prescribed biological product If the prescriber determines it's in the best interest of a patient that an interchangeable biological product not be substituted for a prescribed biological product, the prescriber may prohibit substitution either by	technology, a pharmacy benefit management system, or a pharmacy record that is electronically accessible by the prescriber. Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where: - there is no FDA-approved interchangeable biological product for the product prescribed; - a refill prescription is not changed from the product dispensed on the prior filling of the prescription; or - the product is paid for using cash or cash equivalent.	product, including labeling and record keeping. A pharmacist / intern who dispenses a prescription with an interchangeable biological product assumes no greater liability than would be incurred had he or she dispensed the prescription with the biological product prescribed The Legislative Management Committee is to appoint an interim committee to study whether to require a pharmacist to notify the prescriber when a biological product is dispensed if an interchangeable biological product is available and to establish the methods of notifying a prescriber (2nd Sub. H.B. 279).

		writing "dispense as written" or by signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted." For oral prescriptions communicated to the pharmacist / intern, prescribers shall direct the prohibition or substitution, and in such cases, the pharmacist / intern must make written note of the prescribers direction by writing the name of the practitioner and the words "orally by" and the initials of the pharmacist or intern written after it. A pharmacist / intern who substitutes an interchangeable biological product for a prescribed biological product shall communicate the substitution to the purchaser and label the product with the name of the interchangeable biological product dispensed, and indicate on the file copy of the prescription both the name of the prescribed biological product and the name of the interchangeable biological product dispensed in its place.		
Vermont 18 V.S.A. § 4601 et. seq.	"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative,	When a pharmacist receives a prescription for a drug that is listed either by generic name or brand name in the most recent edition of or supplement to the U.S. Department of Health and Human Services' publication Approved Drug Products	Except as described in subdivision (4) of this subsection, within five business days following the dispensing of a biological product, the dispensing pharmacist or designee shall communicate the specific biological product provided to the patient, including the biological	When a pharmacist receives a prescription for a biological product, the pharmacist shall select the lowest priced interchangeable biological product unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any

	allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition in human beings. "Interchangeable biological product" means a biological product that the U.S. Food and Drug Administration has: (A) licensed and determined, pursuant to 42 U.S.C. § 262(k)(4), to be interchangeable with the reference product against which it was evaluated as may be reflected in the U.S. Food and Drug Administration's	With Therapeutic Equivalence Evaluations (the "Orange Book") of approved drug products, the pharmacist shall select the lowest priced drug from the list which is equivalent as defined by the "Orange Book," unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug. Notwithstanding any provision of this subsection to the contrary, a pharmacist shall not be required to communicate information regarding the biological product dispensed in the following circumstances: (A) the U.S. Food and Drug Administration has not approved any interchangeable biological products for the product prescribed; or (B) the pharmacist dispensed a refill prescription in which the product dispensed was unchanged from the product dispensed at the prior filling of the prescription.	product's name and manufacturer, by submitting the information in a format that is accessible to the prescriber electronically through one of the following: (A) an interoperable electronic medical records system; (B) an electronic prescribing technology; (C) a pharmacy benefit management system; or (D) a pharmacy record. Entry into an electronic records system as described in subdivision (1) of this subsection shall be presumed to provide notice to the prescriber. (3)(A) If a pharmacy does not have access to one or more of the electronic systems described in subdivision (1) of this subsection (e), the pharmacist or designee shall communicate to the prescriber the information regarding the biological product dispensed using telephone, facsimile, electronic transmission, or other prevailing means. (B) If a prescription is communicated to the pharmacy by means other than electronic prescribing technology, the pharmacist or designee shall communicate to the prescriber the information regarding the biological product dispensed using the electronic process described in subdivision (1) of this subsection (e) unless the prescriber requests a different means of communication on the prescription.	additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced biological product. Notwithstanding subdivisions (1) and (2) of this subsection, when a pharmacist receives a prescription from a Medicaid beneficiary, the pharmacist shall select the preferred brand-name or generic drug or biological product from the Department of Vermont Health Access's preferred drug list. (b) The purchaser shall be informed by the pharmacist or his or her representative that an alternative selection as provided under subsection (a) of this section will be made unless the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug or biological product. (c) When refilling a prescription, pharmacists shall receive the consent of the prescriber to dispense a drug or biological product different from that originally dispensed, and shall inform the purchaser that a generic substitution shall be made pursuant

	Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (the Purple Book); or (B) determined to be therapeutically equivalent as set forth in the latest edition of or supplement to the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).			to this section unless the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug or biological product. (d) Any pharmacist substituting a generically equivalent drug or interchangeable biological product shall charge no more than the usual and customary retail price for that selected drug or biological product. This charge shall not exceed the usual and customary retail price for the prescribed brand. The Board of Pharmacy shall maintain a link on its website to the current lists of all biological products that the U.S. Food and Drug Administration has determined to be interchangeable biological products
Virginia VA Code Ann. § 54.1-3401; VA Code Ann. § 54.1-3408.04	"Biological product" – a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product,	A pharmacist may dispense a biosimilar that has been licensed by FDA as interchangeable with the prescribed product unless: - prescriber indicates such substitute is not authorized by specifying on the prescription "brand medically necessary"; or - patient insists on the dispensing of the prescribed biological product. For oral prescriptions, prescriber's oral dispensing instructions regarding		Unless otherwise directed by the prescriber, pharmacist / designee must indicate the brand name or, in case of interchangeable biosimilar, the product name and the name of the manufacturer or distributor of the interchangeable biosimilar on both the record of dispensing and the prescription label. Whenever a pharmacist substitutes an interchangeable biosimilar pursuant to a prescription written for

	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. "Biosimilar" – 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. § 262(k) in terms of safety, purity, and potency of the product.	dispensing of an interchangeable biosimilar shall be followed. No pharmacist may dispense a biosimilar in place of a prescribed biological product unless the biosimilar has been licensed as interchangeable with the prescribed biological product by FDA When a pharmacist dispenses an interchangeable biosimilar in the place of a prescribed biological product, pharmacist / designee must inform patient prior to dispensing the interchangeable biosimilar		a brand-name product, the pharmacist or his designee shall label the drug with the name of the interchangeable biosimilar followed by the words "Substituted for" and the name of the biological product for which the prescription was written. Records of substitutions of interchangeable biosimilars shall be maintained by the pharmacist and the prescriber for a period of not less than two years from the date of dispensing.

	"Interchangeable" – a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4). "Reference biological product" – the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to FDA for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).			
Washington RCW 69.41.110; RCW 69.41.120; RCW 69.41.150; RCW 69.41.160; RCW	"Biological product" means any of the following, when applied to the prevention, treatment, or cure of a disease or condition of human beings: A virus; a therapeutic serum; a toxin; an antitoxin;	Every prescription for a biological product must contain an instruction on whether or not an interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior-consent authorization that complies with the prescription format requirements outlined in RCW 69.41.120 that enables prescribers to communicate to dispensing	Within 5 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee must make an entry of the specific product provided to the patient, including either the name of the product and the manufacturer or FDA NDC, provided that the name of the product and the name of the manufacturer are accessible to a practitioner in an electronic records	Unless a prescribed biological product is requested by the patient/ patient's representative, if "substitution permitted" is marked on the prescription, pharmacist must substitute an in-stock interchangeable biological product for the biological product prescribed if the wholesale price for the interchangeable biological product to the pharmacist is less than the

69.41.196; RCW 69.41.193	a vaccine; blood, blood component, or derivative; an allergenic product; a protein, other than a chemically synthesized polypeptide, or an analogous product; or arsphenamine, a derivative of arsphenamine, or any trivalent organic arsenic compound; and "Interchangeable" means a biological product that is: - licensed by FDA and determined to meet the safety standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4); or - approved based on an application filed under section 505(b) of the federal FD&C Act that is determined by FDA to be therapeutically equivalent to an approved 505(b)	instructions to pharmacists by signing the appropriate line. No prescription is valid without the prescriber signature on one of these lines. For oral prescriptions, prescribers / prescribers' agents shall instruct pharmacist as to whether or not an interchangeable biological product may be substituted in its place – these instructions must be noted on the file copy of a written or oral prescription. File copies of a written or oral prescription must be maintained for the same period of time specified in RCW 18.64.245 for retention of prescription records	system that can be electronically accessed by the patient's practitioner through: - an interoperable electronic medical records system; - an electronic prescribing technology; - a pharmacy benefit management system; or - a pharmacy record. Entry into an electronic records system, as described above, is presumed to provide notice to the practitioner. Otherwise, the pharmacist must communicate to the practitioner the specific product provided to the patient, including the name of the product and manufacturer, using facsimile, telephone, electronic transmission, or other prevailing means. No entry or communication is required if: - there is no interchangeable biological product for the product prescribed; - a refill prescription is not changed from the product dispensed on the prior filling of the prescription; or - the pharmacist / pharmacist's designee and prescriber communicated before dispensing and the communication included confirmation of the specific product to be provided to the patient, including the name of the product and the manufacturer. (Notification requirements in effect until August 1, 2025)	wholesale price for the biological product prescribed. The pharmacy quality assurance commission shall maintain a link on its web site to the current list of all biological products determined by FDA as interchangeable. The commission shall maintain a list of all biological products approved as therapeutically equivalent by FDA through the approval process specified in 505(b) of the federal FD&C act. The commission shall make the 505(b) list accessible to pharmacies. A pharmacist who selects an interchangeable biological product to be dispensed pursuant to RCW 69.41.100 through 69.41.180, and the pharmacy for which the pharmacist is providing service, assumes no greater liability for selecting the interchangeable biological product than would be incurred in filling a prescription for the interchangeable biological product when prescribed by name. The prescriber is not liable for a pharmacist's act or omission in selecting, preparing, or dispensing an interchangeable biological product under this section.

	biological product and is included in the 505(b) list maintained by the pharmacy quality assurance commission			Every pharmacy shall post a sign in a location at the prescription counter that is readily visible to patrons stating, "Under Washington law, a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information."
West Virginia WV Code § 30-5-12c	"Biological product" means the same as that term is defined in 42 U.S.C.§ 262 "Interchangeable biological product" means a biological product that the federal FDA has: (1) Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C § 262(k)(4); (2) Determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal FDA's Approved Drug	"Substitute" means to dispense without the prescriber's express authorization an interchangeable biological product in the place of the drug ordered or prescribed. (b) Except as limited by subsection (c) and unless instructed otherwise by the patient, a pharmacist who receives a prescription for a specific biological product shall select a less expensive interchangeable biological product unless in the exercise of his or her professional judgment the pharmacist believes that the less expensive drug is not suitable for the particular patient. The pharmacist shall provide notice to the patient or the patient's designee regarding the selection of a less expensive interchangeable biological product. (c) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product or interchangeable biological	Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate the specific product provided to the patient, including the name of the product and the manufacturer, to the prescriber through any of the following electronic records systems: (A) An interoperable electronic medical records system; (B) An electronic prescribing technology; (C) A pharmacy benefit management system; or D) A pharmacy record. (2) Communication through an electronic records system as described in §30-5-12c(d)(1) of this code is presumed to provide notice to the prescriber. (3) If the pharmacist is unable to communicate pursuant to an electronic records system the pharmacist shall communicate to the prescriber which biological product was dispensed to the patient using facsimile, telephone,	The pharmacist shall maintain a record of the biological product dispensed for at least two years. Such record shall include the manufacturer and proper name of the interchangeable biological product selected

	Products with Therapeutic Equivalence Evaluations.	product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product prescribed, or the specific brand-name biological product prescribed, is medically necessary. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the specific brand-name drug product prescribed, or the specific biological product prescribed is medically necessary.	electronic transmission, or other prevailing means.	
Wisconsin W.S.A. 450.135; W.S.A. 450.11; W.S.A. 450.13	"Biological product" has the meaning given in 42 USC 262 (i). "interchangeable biological product" means a biological product that the federal food and drug administration has licensed and has determined meets the standards for interchangeability pursuant to 42 USC 262 (k) (4) or has determined is therapeutically equivalent as set forth in the latest edition of or	a pharmacist shall dispense every prescription using either the biological product prescribed or an interchangeable biological product, if the interchangeable biological product is lower in price to the consumer than the biological product prescribed and shall inform the consumer of the options available in dispensing the prescription. **(3)** EXCEPTION. A prescribing practitioner may indicate, by writing on the face of the prescription order or, with respect to a prescription order transmitted electronically, by designating in electronic format the phrase "No substitutions" or words of similar meaning or the initials "N.S.," that no substitution of the biological product prescribed may be made under sub. (2). If such indication is made, the pharmacist shall dispense	Within 5 business days after the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall do one of the following: (a) Make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescribing practitioner. The communication shall be conveyed by making an entry that is electronically accessible to the prescribing practitioner through one of the following: 1. An interoperable electronic medical records system. 2. An electronic prescribing technology. 3. A pharmacist benefit management system. 4. A pharmacy record.	

	supplement to the federal FDA's Approved Drug Products with Therapeutic Equivalence Evaluations. "drug product equivalent" means a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration as set forth in the latest edition of or to the federal food and drug administration's Approved Drug Products with Therapeutic Equivalence Evaluations.	the prescription with the specific biological product prescribed. No preprinted statement regarding biological product substitution may appear on the face of the prescription order. **(4)** REFILLED PRESCRIPTIONS. Prescriptions dispensed with an interchangeable biological product may be refilled with a different interchangeable biological product only if the pharmacist informs the consumer of the change.	(b) If a pharmacist is unable to make an entry as provided in par. (a), communicate the biological product dispensed to the prescribing practitioner using facsimile, telephone, electronic transmission, or another prevailing means, except that communication under this paragraph is not required if any of the following applies: 1. There is no interchangeable biological product for the product prescribed. 2. A refill of the biological product is not changed from the product dispensed on the prior filling of the prescription.	
Wyoming W.S.1977 § 33-24-147; W.S.1977 § 33-24-148;	"Substitute" means to dispense a generically equivalent drug or interchangeable biological product in place of the	A pharmacist who receives a prescription for a brand name prescription drug may dispense any interchangeable biological product or generically equivalent drug of the brand name prescription drug prescribed, unless the prescribing	Except as otherwise provided in subsections (g) and (j) of this section, not later than five (5) business days after dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product dispensed	The national drug code number or the name of the manufacturer or distributor of the interchangeable biological product or generically equivalent drug dispensed shall be noted on the prescription record or entry by the pharmacist.

W.S.1977 § 33-24-149	prescription ordered or prescribed "Biological product" means as defined in 42 U.S.C. 262(i)(1) "Interchangeable biological product" means a biological product that the United States food and drug administration has: (A) Licensed and determined meets the standards for interchangeability under 42 U.S.C. 262(k)(4); or (B) Determined is therapeutically equivalent to the prescription ordered or prescribed, as set forth in the latest edition or supplement to the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) issued by the United States food and drug administration.	practitioner has clearly indicated substitution is not permitted. (b) If a practitioner prescribes a prescription drug by its generic name or by the nonproprietary name of an interchangeable biological product, the pharmacist may dispense the generically equivalent drug or the interchangeable biological product as defined in this act. (c) Except as provided in subsection (e) of this section, when a pharmacist dispenses an interchangeable biological product or generically equivalent drug as authorized by this act, he shall label the prescription container with the name of the dispensed biological product or drug. If the dispensed drug or product does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed or the nonproprietary name of the interchangeable biological product dispensed.	to the patient, including the name and manufacturer of the product. The entry shall be electronically accessible to the practitioner through one (1) of the following electronic records systems: (i) An interoperable electronic medical records system; (ii) Electronic prescribing technology; (iii) A pharmacy benefit management system; or (iv) A pharmacy record. (g) Except as otherwise provided in subsection (j) of this section, if an electronic records system under subsection (f) of this section is not available, the dispensing pharmacist shall, not later than five (5) business days after dispensing a biological product, communicate to the practitioner the specific product dispensed to the patient, including the name and manufacturer of the product, using facsimile, telephone, electronic transmission or any other prevailing means of communication. (h) An entry made into an electronic records system under subsection (f) of this section or a communication made under subsection (g) of this section shall establish a presumption that the practitioner received notice of the biological product dispensed to the patient. (j) The requirements of subsections (f) and (g) of this section shall not apply if: (i) There is no interchangeable biological product for the product prescribed by the practitioner; or (ii) A prescription for a	

			refill is not changed from the product dispensed on the prior filling of the prescription. (k) The dispensing pharmacist shall notify a patient of the biological product which was dispensed, which may be carried out through the prescription label required pursuant subsection (c) of this section.	