State	Definitions	When Is Substitution Authorized	Notification Requirements	Other Requirements
Alabama	"Biological product"	A licensed pharmacist shall be	(1) Within 24 hours, not counting the	When a pharmacist dispenses an
	has the same	permitted to select for the brand	hours of Sunday or recognized federal	interchangeable biological product
Ala.Code 1975	meaning as the term	name biological product prescribed	holidays, a pharmacist, or the designee	for the prescribed biological product,
§ 34-23-8.1;	as defined in 42	by a prescribing practitioner a less	of the pharmacist, who dispenses a	the pharmacist, or his or her
Ala.Code 1975	U.S.C. § 262	expensive interchangeable biological	different biological product than that	designee, shall inform the patient or
§ 34-23-1		product in all cases where prescriber	ordered or prescribed shall inform the	patient's designee prior to dispensing
		expressly authorizes the selection as	prescribing physician that a different	the interchangeable biological
		outlined below:	biological product was substituted for	product.
		(1) Every written prescription for a	the biological product prescribed and	
		biological product issued in by a	provide the name and manufacturer of	A pharmacist, or his or her designee,
		prescriber shall contain two signature	the biological product dispensed. The	shall record on the prescription form
		lines: one line shall indicate if the	notice to the prescribing physician or	the name and manufacturer or
		brand is meant to be dispensed, and	other practitioner shall be by any of the	distributor of any drug product, or
		the other shall indicate if a product	following:	the name and manufacturer of any
		selection is permitted. The prescriber	a. Electronic message sent to the	biological product, dispensed as
		shall communicate instructions to the	electronic prescribing system used by	authorized in this section.
		pharmacist by signing on the	the prescribing physician or other	
		appropriate line.	practitioner to transmit the prescription	Unless otherwise indicated by the
		(2) An oral or electronic	to the pharmacy.	prescriber, the prescription label on
		prescription, including an e-fax, from	b. Telephone.	the dispensing container shall
		the prescriber for a biological product	c. Facsimile.	indicate the actual biological product
		shall instruct the pharmacist whether	(2) In any instance where the prescribing	dispensed, either the brand name, or
		or not a less expensive	practitioner indicates for a pharmacist	if none, the name of the biosimilar
		interchangeable biological product	to communicate using a specific	biologic product as referred to by
		may be dispensed. The pharmacist	notification method listed in subdivision	FDA's Lists of Licensed Biological
		shall note instructions on the file	(1), the pharmacist shall utilize that	Products With Reference Product
		copy of the prescription and retain	method of communication. A voicemail	Exclusivity and Biosimilarity of
		the prescription form for the period	left for the prescribing physician or	Interchangeability Evaluations
		specified by law.	other practitioner at the telephone	(Purple Book), and the name of the
			number provided to the pharmacist or	manufacturer or a reasonable
		For prescriptions issued by out of	his or her designee shall constitute	abbreviation of the name of the
		state prescribers, an pharmacist in AL	notice under this section.	manufacturer.
		may select for the brand name		
		biological product prescribed a less	Notice to the prescribing physician is not	
		expensive interchangeable biological	required if a refill prescription is not	
July 2021		product in all cases where the out-of-	changed from the product dispensed on	

State Substitution Practices for Biological Drugs

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

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

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

			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	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		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.
	supplement of the Approved Drug Products with			

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

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

State Substitution Practices for Biological Drugs

			hospital licensed in accordance with the	
			provisions of chapter 368v.	
Delaware	"Biological product"	A pharmacist may substitute for a	If a biological product is dispensed, the	
	means a biological	prescribed biological product only if:	pharmacist or the pharmacist's designee	
24 Del.C. §	product as defined in	(1) the practitioner has not expressly	shall, within a reasonable time but not to	
2502; 24	subsection (i) of	prohibited substitution in a manner	exceed ten days following dispensing,	
Del.C. § 2549A	section 351 of the	specified in §2549;	communicate to the practitioner the name	
Del.C. 3 2343A	Public Health Service	(2) the product to be substituted has	and manufacturer of the biological product	
	Act 42 U.S.C. § 262(i)).	been designated by the Federal Food and	dispensed, by:	
		Drug Administration as interchangeable	recording such information in an	
	"Interchangeable"	with or therapeutically equivalent to the	interoperable electronic health records	
	means a biological	prescribed product;	system shared with the prescribing	
	product licensed by	(3) the pharmacist informs the patient or	practitioner, to the extent such a system is	
	the Federal Food and	the patient's adult representative that an	in place between a pharmacist and	
	Drug Administration	interchangeable biological product has	practitioner; or	
	pursuant to 42 U.S.C.	been dispensed; and	(2) in the case where electronic health	
	§ 262(k)(4).	(4) the pharmacist indicates on the	records are not in place between a	
		prescription and on the prescription label	pharmacist and a practitioner,	
		the name of the manufacturer of the	communicating such information to the	
		interchangeable biological product	practitioner using any prevailing means	
		substituted unless the practitioner	available. No communication is required	
		indicates otherwise.	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	"Biological product"	Refer to Official DC Code § 48-	Within 5 business days after dispensing	The BoP and Board of Medicine shall
Columbia	shall have the same	803.03—803.05 which substitution	a biological product, dispensing	maintain link on websites to current
columbia	meaning as	generally (both for generically	pharmacist (or designee) must	list of biological products determined
DC Official	provided in 42 USC	equivalent drug products and	communicate to prescriber the specific	by FDA to be interchangeable with a
Code § 48-	§ 262	interchangeable biological products)	biological product dispensed, including	specific biological product.
804.51; § 48-	3 202	interentingeable biological products)	the name and manufacturer of the	speeme biological product.
803—803.05	"Interchangeable		biological product; except that this	
005 005.05	biological product"		communication is not required if FDA	
	means a biological		has not approved an interchangeable	
	product that is:		biological product for the biological	
	(A) Licensed and		product prescribed to the patient or a	
	determined by the		refill prescription is not changed from	
	US FDA to meet the		the biological product dispensed on the	
	standards for		most recent filling of the prescription.	
	interchangability in			
	42 USC § 262(k)(4);		Except as provided under subsection (c)	
	or		of this section, the required	
	(B) Determined to		communication shall be provided by	
	be biosimilar to and		making an entry that is electronically	
	interchangeable		accessible to all health care providers	
	with a reference		through an interoperable EMR system,	
	product as state in		an electronic prescribing technology or a	
	the Purple Book.		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	

			through internal pharmacy operations	
			for members and patients of the HMO	
Florida	The terms "biological product,"	Pharmacist may only dispense a substitute biological product for the		BoP to maintain on its public website a current list of biological products
F.S.A. §	"biosimilar," and	prescribed biological product if:		that FDA has determined are
465.0252	"interchangeable"	(1) FDA has determined that the		biosimilar and interchangeable.
	have the same	substitute biological product is		
	meanings as defined	biosimilar to and interchangeable for		
	in s. 351 of the	the prescribed biological product.		
	federal Public	(2) Prescriber does not express a		
	Health Service Act,	preference against substitution in		
	42 U.S.C. s. 262.	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.		
Georgia	"Biological product"	A pharmacist may substitute a	Within 48 hours, excluding weekends	If a practitioner prescribes a
	means a biological	biological product with an	and holidays, following the dispensing of	biological product by its
Ga. Code Ann.,	product as defined	interchangeable biological product,	a biological product, the dispensing	nonproprietary name, the pharmacist
§ 26-4-5;	in subsection (i) of	except when:	pharmacist or the pharmacist's designee	shall dispense the lowest retail priced
Ga. Code Ann.,	section 351 of the	 a prescriber instructs the 	shall communicate to the prescriber the	interchangeable biological product
§ 26-4-81	Public Health	pharmacist not to substitute an	specific product provided to the patient,	which is in stock. Substitutions are
	Service Act, 42	interchangeable biological product in	including the name of the biological	authorized for the express purpose of
	U.S.C. Section 262.	lieu of a prescribed biological product	product and the manufacturer. The	making available to the consumer the
		by including the words 'brand	communication shall be conveyed by	lowest retail priced interchangeable
	"Interchangeable	necessary' in the body of the	making an entry into an interoperable	biological product which is in stock.
	biological product"	prescription. When a practitioner has	EMR system or through e-prescribing	
	means a biological	designated 'brand necessary', an	technology or a pharmacy record that is	Pharmacies must maintain record of
	product that the	interchangeable biological product	electronically accessible by the	substitution that includes the identity
	federal FDA has	shall not be substituted without the	prescriber. Otherwise, the pharmacist	of the interchangeable biological
	determined meets	practitioner's express consent, which	shall communicate the biological	product and its manufacturer.
	the standards set	shall be documented by the	product dispensed to the prescriber by	
	forth in subsection	pharmacist on the prescription and	using facsimile, telephone, electronic	Where substitution occurs, the name
	(k)(4) of 42 U.S.C.		transmission, or other prevailing means,	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	‴Biological product	The pharmacist shall substitute an	Within two business days following the	Every pharmacy shall prominently
	or biologic product"	equivalent generic drug product or an	dispensing of a biological product, the	display, in clear and unobstructed
HRS § 328-91;	has the same	interchangeable biological product if	dispensing pharmacist or the	public view, a sign in block letters
HRS § 328-92;	meaning as defined	the practitioner does not prohibit	pharmacist's designee shall	that shall read: "HAWAII LAW
HRS § 328-96	in Title 42 United	substitution under subsection (b),	communicate to the practitioner the	REQUIRES THAT LESS EXPENSIVE
	States Code section	and the interchangeable biological	specific provided to the patient,	GENERICALLY EQUIVALENT DRUG
	262, as the same	product results in a savings.	including the name of the product and	PRODUCTS AND INTERCHANGEABLE
	may be amended.	The shares in the line of a barrier of the	the manufacturer. The communication	BIOLOGICAL PRODUCTS BE OFFERED
	"During in the sharest"	The pharmacist shall not substitute if	shall be conveyed by making an entry	TO THE CONSUMER. CONSULT YOUR
	"Drug product"	the consumer refuses.	that is electronically accessible to the	PHYSICIAN AND PHARMACIST
	means a drug as	The pharmagict shall not substitute	practitioner through: (1) An	CONCERNING THE AVAILABILITY OF
	defined in section 328-1 other than a	The pharmacist shall not substitute an equivalent generic drug product or	interoperable electronic medical records	THE LEAST EXPENSIVE DRUG PRODUCT FOR YOUR USE." The
	biological product as	interchangeable biological product if	system; (2) An electronic prescribing technology; (3) A pharmacy benefit	letters must be at least one inch in
	defined in this part.	the practitioner indicates "brand	management system; or (4) a pharmacy	height.
	denneu in this part.	medically necessary" or words of	record. Entry into an electronic records	
	"Hawaii list of	similar meaning on the prescription.	system as described in subsection (d) is	
	i lawan nst oj	similar meaning on the prescription.	system as acsensed in subsection (a) is	

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

	a harde table h			
	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	"Biological Product	A pharmacist may substitute an	A pharmacist who dispenses a biological	
	- a virus, therapeutic	interchangeable biosimilar product	product according to board rule shall	
IDAPA	serum, toxin,	for a prescribed biological product if:	communicate to the prescriber the	
27.01.01.010;	antitoxin, vaccine,	- the biosimilar has been	name and manufacturer of the drug	
IDAPA	blood, blood	determined by the FDA to be	within five (5) business days following	
27.01.01.011;	component or	interchangeable and published in the	the dispensing of the biological product.	
IDAPA	derivative,	Purple Book;	Communication shall occur via an entry	
27.01.01.130	allergenic product,	- the prescriber does not indicate by	in an interoperable electronic medical	
	protein (except any	any means that the prescribed	records system, an electronic	
		· ·	• · · · · · · · · · · · · · · · · · · ·	

ID HB 483	chemically	biological product must be	prescribing technology, a pharmacy	
(2016)		dispensed; and		
(2010)	synthesized		benefit management system or a	
	polypeptide), or	- the name of the drug and the	pharmacy record that can be accessed	
	analogous product,	manufacturer or the NDC number is	electronically by the prescriber. Entry	
	or arsphenamine or	documented in the patient medical	into an electronic records system as	
	derivative of	record	described in this subsection shall be	
	arsphenamine (or		considered notice to the prescriber.	
	any other trivalent		Otherwise, the pharmacist shall	
	organic arsenic		communicate the biological product	
	compound), that is		dispensed to the prescriber using	
	applicable to the		facsimile, telephone, electronic	
	prevention,		transmission or other prevailing means,	
	treatment, or cure		provided that the communication shall	
	of a disease or		not be required when: (a) There is no	
	condition of human		interchangeable biological product	
	beings and licensed		approved by the federal food and drug	
	under Section		administration for the product	
	351(k) of the Public		prescribed; (b) A refill prescription is not	
	Health Service Act,		changed from the product dispensed on	
	42 U.S.C. Section		the prior filling of the prescription; or	
	262(i).		(c) The pharmacist or the pharmacist's	
			designee has already communicated to	
	" <u>Biosimilar</u> " - a		the prescriber the specific product to be	
	biological product		provided to the patient, including the	
	highly similar to a		name and manufacturer of the product,	
	specific reference		prior to dispensing; and that product is	
	biological product		the product that is actually dispensed.	
	that is licensed by		(2) Nothing in this section shall delay the	
	the FDA pursuant to		dispensing of a valid prescription for a	
	42 U.S.C. Section		biological product.	
	262(k) and		and a second products	
	published in the			
	Purple Book			
	"Interchangeable			
	Biosimilar" -a			
	licensed biosimilar			
				μ

product determined		
by the FDA to be		
therapeutically		
equivalent to the		
reference biological		
product and		
published in the		
Purple Book		
" <u>Purple Book</u> " 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	" <u>Biological product</u> " has the meaning	A pharmacist may substitute an interchangeable biological product	Within 5 business days following the dispensing of a biological product, the	The pharmacy shall retain a record of the biological product dispensed for a
225 ILCS	given to that term in	for a prescribed biological product	dispensing pharmacist or the	period of 5 years.
85/19.5	42 U.S.C. 262	only if all of the following conditions	pharmacist's designee shall make an	
	" <u>Interchangeable</u> <u>biological product</u> " 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	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.	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 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	" <u>biological product</u> " 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; 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		
" <u>biosimilar</u> " - 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.		
<i>(</i> (:		
" <u>interchangeable</u> "		
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			
lowa	"Biological product"	If an authorized prescriber prescribes	Within five business days following the	The label of any drug, biological
IOWa	means the same as	a biological product, the pharmacist	dispensing of a biological product, the	product, or device sold and
I.C.A. § 155A.3;	defined in 42 U.S.C.	may exercise professional judgment	dispensing pharmacist or the	dispensed on the prescription of a
I.C.A. §	§262.	in the economic interest of the	pharmacist's designee shall make an	practitioner shall be in compliance
155A.28; I.C.A.	3202.	patient by selecting a biological	entry of the specific biological product	with rules adopted by the board. 2.
§ 155A.32	"Interchangeable	product that is an interchangeable	provided to the patient, including the	The board shall maintain a link on its
-	biological product"	biological product for the biological	name of the biological product and the	internet site to the current list of all
	means either of the	product prescribed for dispensing	manufacturer. The entry shall be	biological products that the United
	following:	and sale to the patient. If the cost of	electronically accessible to the	States food and drug administration
	a. A biological	the prescription or any part of it will	prescriber through one of the following	has determined to be
	product that the	be paid by expenditure of public	means: (1) An interoperable electronic	interchangeable biological products.
	United States food	funds authorized under chapter	medical records system. (2) An	
	and drug	249A, the pharmacist shall exercise	electronic prescribing technology. (3) A	
	administration has	professional judgment by selecting a	pharmacy benefit management system.	
	licensed and has	biological product that is an	(4) A pharmacy record. b. An entry into	
	determined meets	interchangeable biological product	an electronic records system as	
	the standards for	for the biological product prescribed	described in this subsection is presumed	
	interchangeability	for dispensing and sale. 2. The	to provide notice to the prescriber. If	
	pursuant to 42	pharmacist shall not exercise the	the entry is not made electronically, the	
	U.S.C. §262(k)(4).	drug or biological product selection	pharmacist shall communicate the name	
	b. A biological	described in this section if either any	and manufacturer of the biological	
	product that the	of the following is true: a. The	product dispensed to the prescriber	
	United States food	prescriber specifically indicates that	using facsimile, telephone, electronic	

	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	"Biological product" is defined as a virus,	A pharmacist is allowed to exchange a biological product in order to	If the pharmacist selects an interchangeable biological product, they	The board shall maintain a link on its website to the current lists of all
K.S.A. 65-	a therapeutic	achieve a lesser cost to the purchaser	must notify the patient that they have	biological products that the FDA has
1626; K.S.A.	serum, a toxin, an	unless:	are going to receive an interchangeable	determined to be interchangeable
65-1637	antitoxin, a vaccine,	(A) The prescriber, in the case of a	biological product.	biological products.
	blood, a blood polypeptide, or an	prescription signed by a prescriber and written on a blank form	Within five business days following the	
	analogous product,	containing two signature lines, signs	dispensing of a biological product, the	
	arsphenamine or	the signature line following the	dispensing pharmacist or the	
	derivative or	statement "dispense as written";	pharmacist's designee must make an	
	arphenamine, or	(B) the prescriber, in the case of a	entry of the specific product provided to	
	any other trivalent	prescription signed by the prescriber,	the patient, including the name of the	
	organic arsenic	writes in the prescriber's own	product and the manufacturer. The	
	compound that is	handwriting "dispense as written" on	communication must be conveyed by	
	applicable to the	the prescription;	making an entry that is electronically	

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

	da an a famo an d			
	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	"Biological product"	When a pharmacist receives a	Within five (5) business days following	
	has the same	prescription for a brand name	the dispensing of a biological product,	
KRS 217.814;	meaning as in 42	biological product which is not listed	the dispensing pharmacist or the	
217.822;	U.S.C. sec. 262;	by name in the nonequivalent drug	pharmacist's designee shall	
217.216;	"Board" means the	product formulary prepared by the	communicate to the prescribing	
217.895	Kentucky Board of	board, the pharmacist shall dispense	practitioner the specific product	
	Pharmacy;	a lower priced interchangeable	provided to the patient, including the	
	"Interchangeable	biological product, if there is one in	name of the product and the	
	biological product"	stock, unless otherwise instructed by	manufacturer. (b) Communication shall	
	means: (a) A	the patient at the point of purchase	be conveyed by making an entry that is	
	biological product	or by the patient's prescribing	electronically accessible to the	
	that the United	practitioner. If an interchangeable	prescribing practitioner through: 1. An	
	States Food and	product is selected, the label on the	interoperable electronic medical records	
	Drug Administration	container shall show the name of the	system; 2. An electronic prescribing	
	has licensed and	biological product dispensed. When	technology; 3. A pharmacy benefit	
	determined meets	an equivalent drug product or	management system; or 4. A pharmacy	
	the standards for	interchangeable biological product is	record. (c) Communication entries into	
	interchangeability	dispensed in lieu of a brand name	an electronic records system as	
	pursuant to 42	drug prescribed, the price of the	described in this subsection are	
	U.S.C. sec. 262(k)(4);	equivalent drug or interchangeable	presumed to provide notice to the	
	or (b) A biological	biological product dispensed shall be	prescribing practitioner. Otherwise, the	
	product that the	lower in price to the purchaser than	pharmacist shall communicate the	
	United States Food	the drug product prescribed.	biological product dispensed to the	
	and Drug		prescribing practitioner using facsimile,	
	Administration has	A pharmacist shall not substitute a	telephone, electronic transmission, or	
	determined is	biological product for a prescribed	other prevailing means. Communication	
	therapeutically	biological product unless the	to the prescribing practitioner, or the	
	equivalent as set	substituted product is an	prescribing practitioner's office	
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	forth in the latest edition or supplement to the federal FDA's Approved Drug Products with Therapeutic	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	
	Equivalence Evaluations;		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	"Equivalent Drug Product" means	1. The pharmacist shall not select an equivalent drug product when the	No later than five business days following the dispensing of a biological	Upon the receipt of an oral prescription from an authorized
R.S. 37:1164; R.S. 37:1226.1	either of the following: (1) A drug product that has been rated as a pharmaceutical	prescriber prohibits interchange by any one of the following methods. a. On a prescription generated in written form, the prescriber shall	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	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
	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	 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 	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	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.
	to contain the same	prescription form or on a sheet of	required pursuant to this Section if the	

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

successors or rated	to, the proposed cost saving	
therapeutically	interchange.	
equivalent by the		
FDA as set forth in	4. When the pharmacist selects a	
the Approved Drug	biological product rated as	
Products with	interchangeable for the product	
Therapeutic	ordered by the prescriber, the	
Equivalence	dispensing pharmacist (or his	
Evaluations (Orange	designee) shall communicate to the	
Book). Biological	prescriber by any means, but no later	
product" has the	than five business days following the	
meaning assigned	dispensing date, the specific product	
by Section 351 of	dispensed to the patient, including	
the 13 Public Health	the name of the product and the	
Service Act, 42	manufacturer. However, no such	
U.S.C. 262.	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.	
	ming 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.	

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

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

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	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.	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. (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>I</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	(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.
	or arsphenamine or		facsimile, electronic transmission or by	

compound,	A pharmacist who utilizes an
applicable to the	interoperable electronic prescribing
prevention,	technology shall enter the substitution
treatment or cure of	into the patient's electronic health record.
a disease or	(e) Following any such substitution, the
condition of human	dispensing pharmacist or the pharmacist's
beings.	designee shall notify the patient, or the
	patient's authorized representative, of the
"Interchangeable	substitution. The notification shall be
biological product", a	written and may be conveyed by facsimile,
prescription	electronic transmission, a notation in the
biological product (i)	patients record system shared with the
that has been	prescriber or another means consistent
determined by the	with prevailing pharmacy practice in
United States Food	accordance with section 12D of chapter
and Drug	112.
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	

	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	"Biological drug	when a pharmacist receives a	Except as otherwise provided in	The pharmacist shall not dispense a
	product" means a	prescription for a brand name drug	subsection (6), within 5 days after	generically equivalent drug product
M.C.L.A.	biological product as	product or biological drug product,	dispensing an interchangeable biological	or interchangeable biological drug
333.17704;	that term is defined	the pharmacist may, or when a	drug product, the dispensing pharmacist	product under subsection (1) if any of
M.C.L.A.	in 42 USC 262.	purchaser requests a lower cost	or his or her designee shall	the following apply: (a) The
333.17755		generically equivalent drug product	communicate to the prescriber the	prescriber, in the case of a
	"Interchangeable	or interchangeable biological drug	specific interchangeable biological drug	prescription in writing signed by the
	biological drug	product, the pharmacist shall	product provided to the patient,	prescriber, writes in his or her own
	product" means	dispense a lower cost but not higher	including the name of the	handwriting "dispense as written" or
	either of the	cost generically equivalent drug	interchangeable biological drug product	"d.a.w." on the prescription. (b) The
	following, as	product or interchangeable biological	and its manufacturer. The	prescriber, having preprinted on his
	applicable: (a) A	drug product if available in the	communication required under this	or her prescription blanks the
	biological drug	pharmacy. If a drug or biological drug	subsection must be made as follows: (a)	statement "another brand of a
	product that is	product is dispensed that is not the	By making an entry that is electronically	generically equivalent product,
	licensed by the FDA	prescribed brand, the purchaser must	accessible to the prescriber through an	identical in dosage, form, and
	and that the FDA	be notified and the prescription label	interoperable electronic medical records	content of active ingredients, may be
	has determined	must indicate both the name of the	system, an electronic prescribing	dispensed unless initialed d.a.w.",
	meets the standards	brand prescribed and the name of	technology, a pharmacy benefit	writes in his or her own handwriting
	for	the brand dispensed and designate	management system, a health	the initials "d.a.w." in a space, box, or
	interchangeability	each respectively. Except as	information 3 exchange, or a pharmacy	square adjacent to the statement. (c)
	under 42 USC	otherwise provided in section 17756,	record. An entry made as described in	The prescriber, in the case of a
	262(k)(4). (b) Until	if the dispensed drug or biological	this subdivision is presumed to provide	prescription other than one in writing
	March 23, 2021, a	drug product does not have a brand	notice to the prescriber. (b) If the	signed by the prescriber, expressly
	biological drug	name, the prescription label must	methods described in subdivision (a) are	indicates that the prescription is to
	product that the	indicate the generic name of the drug	not available, then by facsimile,	be dispensed as communicated
	FDA has determined	dispensed or the proprietary name of	telephone, electronic transmission, or	
	to be	the biological drug product	other prevailing means.	If a pharmacist SUBSTITUTES A
	therapeutically	dispensed.		LOWER COST generically equivalent
	equivalent as set			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	"Biological product", the same meaning	When a pharmacist receives a paper or hard copy prescription on which	Within five business days following the dispensing of a biological product, the	
M.S.A. §	as such term is	the prescriber has not personally	dispensing pharmacist or the	
151.01; M.S.A.	defined under 42	written in handwriting "dispense as	pharmacist's designee shall	
§ 151.21	U.S.C. Section 262	written" or "D.A.W.," a prescription	communicate to the prescriber the	
		sent by electronic transmission on	name and manufacturer of the	
	"Interchangeable	which the prescriber has not	biological product dispensed. (b) The	
	biological product",	expressly indicated in a manner	communication shall be conveyed by	
	a biological product	consistent with the standards for	making an entry that is electronically	
	that the FDA: (a)	electronic prescribing under Code of	accessible to the prescriber through: (1)	
	Has licensed and	Federal Regulations, title 42, section	an interoperable electronic medical	
	determined meets	423, that the prescription is to be	records system; (2) an electronic	
	the standards for	dispensed as transmitted and which	prescribing technology; (3) a pharmacy	
	interchangeability	bears the prescriber's electronic	benefit management system; or (4) a	
	under 42 USC	signature, or an oral prescription in	pharmacy record.	
	Section 262(k)(4) or	which the prescriber has not		
	(b) determined	expressly indicated that the	A pharmacist shall notify the purchaser	
	therapeutically	prescription is to be dispensed as	if the pharmacist is dispensing a drug or	
	equivalent as set forth in the latest	communicated, and there is available	biological product other than the brand	
	edition of or	in the pharmacist's stock a less expensive generically equivalent drug	name specific drug or biological product prescribed.	
	supplement to the	or, if a biological product is		
	FDA's Approved	prescribed, a less expensive		
	Drug Products with	interchangeable biological product		
	Therapeutic	that, in the pharmacist's professional		
	Equivalence	judgment, is safely interchangeable		
	Evaluations (Orange	with the prescribed drug, then the		
	Book).	pharmacist shall, after disclosing the		

Mississippi	"Biological product"	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.	Within five (5) business days following	BoP to maintain link on its website to
Miss. Code Ann. § 73-21- 73; Miss. Code Ann. § 73-21-117; Miss. Code Ann. § 73-21- 118	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	 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, 	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.	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	"Biological product", the same meaning	A pharmacist may substitute an interchangeable biological product	Within five business days following the dispensing of a biological product, the	The pharmacist shall maintain records in a manner consistent with
V.A.M.S.	as such term is	for a prescribed product only if all of	dispensing pharmacist or the	section 338.100.
338.056;	defined under 42	the following conditions are met: (1)	pharmacist's designee shall make an	
V.A.M.S.	U.S.C. Section 262;	The substituted product has been	entry of the specific product provided to	The pharmacist shall label
338.059;	(2) "Interchangeable	determined by the Food and Drug	the patient including the name of the	prescriptions in a manner consistent
V.A.M.S.	biological product",	Administration to be an	product and manufacturer. The	with section 338.059.
338.085	a biological product	interchangeable biological product	communication shall be conveyed by	
	that the FDA: (a)	with the prescribed biological	making an entry that can be	
	Has licensed and	product; (2) The substitution occurs	electronically accessed by the prescriber	
	determined meets	according to the provisions of section	through one of the following means: (1)	
	the standards for	338.056; and (3) The pharmacy	An interoperable electronic medical	
	interchangeability	informs the patient of the	records system; (2) An electronic	
	under 42 USC	substitution.	prescribing technology; (3) A pharmacy	
	Section 262(k)(4) or		benefit management system; or (4) A	
	(b) Has determined is therapeutically		pharmacy record.	
	equivalent as set		Entry into an electronic records system	
	forth in the latest		as described in this subsection is	
	edition of or		presumed to provide notice to the	
	supplement to the		prescriber. Otherwise, if an entry	

	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	" Biological product " has the meaning	a pharmacist who receives a prescription for a specific drug	(a) Within 5 business days following the dispensing of a biological product, the	The pharmacist shall maintain a record of the biological product
MCA 37-7-	provided in 42	product by brand or proprietary	dispensing pharmacist or the	dispensed for at least 2 years
502; MCA 37-	U.S.C. 262.	name may select a less expensive	pharmacist's designee shall	dispensed for at least 2 years
7-505	0.3.C. 202.	drug product with the same generic	communicate the specific product	
7-505	"Interchangeable	name, strength, quantity, dose, and	provided to the patient, including the	
	biological product"	dosage form as the prescribed drug	name of the product and the	
	means a biological	that is, in the pharmacist's	manufacturer, to the prescriber through	
	product that the	professional opinion, therapeutically	any of the following electric records	
	federal food and		systems: (i) an interoperable electronic	
	drug administration	equivalent, bioequivalent, and bioavailable.; and (b) a pharmacist	medical records system; (ii) an	
	has: (a) licensed;	who receives a prescription for a	electronic prescribing technology; (iii) a	
	and (b) (i)	specific biological product may select	pharmacy benefit management system;	
	determined meets	a less expensive interchangeable	or (iv) a pharmacy record. (b)	
	the standards for	biological product. (2) If, in the	Communication through an electronic	
			_	
	interchangeability pursuant to 42	professional opinion of the prescriber, it is medically necessary	records system as described in subsection (3)(a) is presumed to provide	
	U.S.C. 262(k)(4); (ii)	that an equivalent drug product or	notice to the prescriber. (c) If the	
	determined is	interchangeable biological product of	pharmacist is unable to communicate	
		not be selected, the prescriber may	pursuant to an electronic records	
	therapeutically			
	equivalent as set	so indicate by certifying that the	system as provided in subsection (3)(a),	
	forth in the latest	specific brand-name drug product	the pharmacist shall communicate to	

	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	
Nebraska	Biological product	A pharmacist may drug product	the prescription If a pharmacist receives a prescription	The department shall maintain a link
	has the same	select except when: (a) A practitioner	for a biological product and chooses to	on its web site to the current list of
Neb.Rev.St. §	meaning as in 42	designates that drug product	dispense an interchangeable biological	all biological products that the
38-2818.03;	U.S.C. 262, as such	selection is not permitted by	product for the prescribed product, the	federal Food and Drug Administration
Neb.Rev.St. §	section existed on	specifying in the written, oral, or	pharmacist must advise the patient or	has determined to be
38-2825.02;	January 1, 2017.	electronic prescription that there	the patient's caregiver that drug product	interchangeable biological products.
Neb.Rev.St. §		shall be no drug product selection.	selection has occurred.	
38-28, 111-	Interchangeable	For written or electronic		
116	biological product	prescriptions, the practitioner shall	Within three business days after the	
	means a biological	specify "no drug product selection",	dispensing of a biological product, the	
	product that the	"dispense as written", "brand	dispensing pharmacist or the	
	federal Food and	medically necessary", or "no generic	pharmacist's designee shall make an	
	Drug	substitution" or the notation	entry of the specific product provided to	
	Administration: (1)	"N.D.P.S.", "D.A.W.", or "B.M.N." or	the patient, including the name of the	
	Has licensed and has	words or notations of similar import	product and the manufacturer. The	
	determined meets	to indicate that drug product	communication shall be conveyed by	
	the standards for	selection is not permitted. The	making an entry that is electronically	
	interchangeability	pharmacist shall note "N.D.P.S.",	accessible to the prescriber through an	
	pursuant to 42	"D.A.W.", "B.M.N.", "no drug product	interoperable electronic medical records	
	U.S.C. 262(k)(4), as	selection", "dispense as written",	system, electronic prescribing	
	such section existed	"brand medically necessary", "no	technology, a pharmacy benefit	
	on January 1, 2017,	generic substitution", or words or	management system, or a pharmacy	
	or as set forth in the	notations of similar import on the	record. Entry into an electronic records	
	Lists of Licensed	prescription to indicate that drug	system described in this subsection is	
Nevada	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.	The Board shall maintain a link on its
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Nevada	"Biological product" has the meaning ascribed to it in 42	Except as otherwise provided in this section, if a practitioner has	Except as otherwise provided in subsections 3 and 4, within 3 business	Internet website to the Purple Book:
N.R.S. 639.2583 -	U.S.C. § 262.	prescribed (a) Drug by brand name and the practitioner has not	days after dispensing a biological product, the dispensing pharmacist or	Lists of Licensed Biological Products with Reference Product Exclusivity
639.2597	0.3.0. y 202.	indicated, by a method set forth in	his or her designee shall make an entry	and Biosimilarity or
033.2337	"Interchangeable	subsection 5, that a substitution is	of the specific product provided to the	Interchangeability Evaluations,
	biological product"	prohibited, the pharmacist who fills	patient that includes, without limitation,	published by the Food and Drug
	means a biological	or refills the prescription shall	the name of the product and its	Administration.
	product that the	dispense, in substitution, another	manufacturer. The record must be	

Food and Drug	drug which is available to him or her	electronically accessible by the	If a generic drug or interchangeable
Administration has:	if the other drug: (1) Is less expensive	prescribing practitioner through: (a) An	biological product is substituted for a
1. Licensed and		interoperable electronic health records	0
determined meets	than the drug prescribed by brand		drug prescribed by brand name or
	name; (2) Is biologically equivalent to	system; (b) Electronic prescribing	biological product prescribed, the
the standards for	the drug prescribed by brand name;	technology; (c) A pharmacy benefit	pharmacist or practitioner shall: 1.
interchangeability	(3) Has the same active ingredient or	management system; or (d) A pharmacy	Note the name of the manufacturer,
pursuant to 42	ingredients of the same strength,	record.	packer or distributor of the drug or
U.S.C. § 262(k)(4); or	quantity and form of dosage as the	2. An electronic record of the dispensing	biological product actually dispensed
2. Determined is	drug prescribed by brand name; and	of a biological product made pursuant to	on the prescription; and 2. Indicate
therapeutically	(4) Is of the same generic type as the	subsection 1 is presumed to provide	the substitution by writing or typing
equivalent as set	drug prescribed by brand name. (b)	notice to the prescriber of the	on the label the words "substituted
forth in the most	Biological product and the	dispensing of the product.	for," or substantially similar
recent edition or	practitioner has not indicated, by a	Except as otherwise provided in	language, following the generic name
supplement of the	method set forth in subsection 5,	subsection 4, if an electronic record of	and preceding the brand name of the
Approved Drug	that a substitution is prohibited, the	the dispensing of a biological product is	drug , or following the name of the
Products with	pharmacist who fills or refills the	not made pursuant to subsection 1, the	interchangeable biological product
Therapeutic	prescription shall dispense, in	dispensing pharmacist or his or her	and preceding the brand name of the
Equivalence	substitution, another biological	designee shall, within 3 business days	prescribed biological product, as
Evaluations,	product which is available to him or	after dispensing the biological product,	applicable, unless, at the time the
published by the	her if the other biological product: (1)	give notice of the biological product to	initial substitution of the generic drug
Food and Drug	Is an interchangeable biological	the prescriber by facsimile, telephone,	or interchangeable biological product
Administration.	product for the biological product	electronic transmission or other	for a drug prescribed by brand name
	prescribed; and (2) Is less expensive	available means.	or biological product prescribed is
	than the biological product	4. Notice of the dispensing of a	made, the person for whom the drug
	prescribed by brand name. 2. If the	biological product pursuant to	or interchangeable biological product
	pharmacist has available to him or	subsection 1 or 3 is not required if: (a)	is dispensed elects not to have such
	her more than one drug or	There is no interchangeable biological	an indication written or typed on the
	interchangeable biological product	product for the biological product	label. An election to indicate or not
	that may be substituted for the drug	prescribed; or (b) A prescription for a	to indicate a substitution on the label
	prescribed by brand name or	refill is not changed from the product	pursuant to this subsection applies to
	biological product prescribed, the	dispensed on the prior filling of the	both the fill and each refill of the
	pharmacist shall dispense, in	prescription.	same prescription.
	substitution, the least expensive of	5. As used in this section, "electronic	
	the drugs or interchangeable	health record" has the meaning ascribed	
	biological products that are available	to it in 42 U.S.C. § 17921(5).	
	to him or her for substitution. 3.		
	Before a pharmacist dispenses a drug		
l	Derore a priarmacist dispenses a drug		

or biological product in substitution		
or biological product in substitution	I	
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		
uspenseu. (b) by nanuwining 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	"Biological product"	A pharmacist may substitute a	Within 3 business days following the	The label of all biological products
Hampshire	means a virus,	biological product pursuant to this	dispensing of a biological product, the	dispensed by a pharmacist shall
	therapeutic serum,	section only if it has been licensed by	dispensing pharmacist or the	include the proper name and the
	toxin, antitoxin,	the federal Food and Drug	pharmacist's designee shall make an	
L				

N.H. Rev. Stat.	vaccine, blood,	Administration as an interchangeable	entry of the specific product provided to	name of the manufacturer of the
§ 318:47-dd	blood component or	biological product for the prescribed	the patient, including the name of the	product.
3 510.47 44	derivative,	biological product.	product and the manufacturer. The	
	allergenic product,		communication shall be conveyed by	
	protein (except any	When a pharmacist dispenses an	making an entry that is electronically	
	chemically	interchangeable biological product	accessible to the prescriber through: (1)	
	synthesized	for the prescribed biological product,	An interoperable electronic medical	
	polypeptide), or	the pharmacist or his or her designee	records system; (2) An electronic	
	analogous product,	shall inform the patient. V. A	prescribing technology; or (3) A	
	or arsphenamine or	pharmacist shall not substitute an	pharmacy benefit management system;	
	derivative of	interchangeable biological product	or (4) A pharmacy record. (b) Entry into	
	arsphenamine (or	pursuant to this section if the	an electronic records system as	
	any other trivalent	prescriber indicates that substitution	described in this paragraph is presumed	
	organic arsenic	is not authorized by specifying on the	to provide notice to the prescriber.	
	compound),	prescription "medically necessary" on	Otherwise, the pharmacist shall	
	applicable to the	a paper prescription, or uses	communicate the biological product	
	prevention,	electronic indications when	dispensed to the prescriber using	
	treatment, or cure	transmitted electronically, or gives	facsimile, telephone, electronic	
	of a disease or	instructions when transmitted orally	transmission, or other prevailing means,	
	condition of human	that the biological product prescribed	provided that the communication shall	
	beings.	is medically necessary.	not be required where: (1) There is no	
			federal Food and Drug Administration-	
	"Interchangeable		approved interchangeable biological	
	biological product"		product for the biological product	
	means a biological		prescribed; or (2) A refill prescription is	
	product that the		not changed from product dispensed on	
	federal Food and		the prior filling of the prescription.	
	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			
	acternineu is			

	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,	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	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;	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.
	blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or	substitute" as set forth in N.J.S.A. 24:6E-7	 (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 	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:

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

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

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

1		
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		

New York McKinney's Education Law § 6810; McKinney's Education Law § 6816-a	products with therapeutic equivalence evaluations; "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 PRODUCT	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 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- CRIBED GEOLEICAL WA CTATEC	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
	LICENSED	STRENGTH OF THE PRODUCT AND ITS		cause disability or take life if not promptly treated, exists, then the

	BIOSIMILARITY OR INTERCHANGEABILI			the medical emergency on the back of the prescription and keep a copy of all such prescriptions
	TY 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."			
North Carolina	" <u>Biological product</u> "	A pharmacist dispensing a	Within a reasonable time following the	The Board of Pharmacy shall maintain
	- As defined in	prescription for a drug product	dispensing of a biological product	a link on its Internet Web site to the

	1		1	
N.C.G.S.A. §	section 351(i) of the	prescribed by its brand name may	requiring a prescription, the pharmacist	current list of biological products
90-85.27;	Public Health	select any interchangeable biological	or a designee shall communicate to the	determined by FDA to be
N.C.G.S.A. §	Service Act, 42	product which meets all of the	prescriber the product name and	interchangeable with a specific
90-85.28;	U.S.C. § 262(i).	following standards:	manufacturer of the specific biological	biological product.
N.C.G.S.A. §		- The manufacturer's name and the	product dispensed to the patient. This	
90-85.31	"Interchangeable	distributor's name, if different from	required communication shall be	Pharmacist may not select an
	biological product" -	the manufacturer's name, shall	conveyed by making an entry into an	equivalent drug or interchangeable
	A biological product	appear on the label of the stock	interoperable electronic medical records	biological product unless its price to
	determined by FDA	package.	system, or electronic prescribing	the purchaser is less than the price of
	to meet the	- It shall be manufactured in	technology, or a pharmacy benefit	the prescribed drug product.
	standards set forth	accordance with current good	management system, or a pharmacy	
	in 42 U.S.C. §	manufacturing practices.	record that can be electronically	The selection of an interchangeable
	262(k)(4), or	- All oral solid dosage forms shall	accessible by the prescriber. Entry into	biological product shall impose no
	deemed	have a logo, or other identification	one of the above referenced methods of	greater liability upon the pharmacist
	therapeutically	mark, or the product name to	communication is presumed to provide	for selecting the dispensed biological
	equivalent by the	identify the manufacturer or	the required communication. Otherwise,	product or upon the prescriber of the
	United States Food	distributor.	the pharmacist or a designee shall	same than would be incurred by
	and Drug	- The manufacturer shall have	provide the required communication to	either for dispensing the biological
	Administration.	adequate provisions for drug recall.	the prescriber by facsimile, telephone,	product specified in the prescription.
		- The manufacturer shall have	electronic transmission, or other	
	"Equivalent drug	adequate provisions for return of	prevailing means, provided that	
	<u>product"</u> – a drug	outdated drugs, through the	communication shall not be required	
	product which has	distributor or otherwise.	under any of the following	
	the same		circumstances:	
	established name,	A pharmacist may not select an	- There is no FDA-approved	
	active ingredient,	interchangeable biological product if	interchangeable biological product for	
	strength, quantity,	the prescriber instructs otherwise by	the product prescribed.	
	and dosage form,	one of the following methods:	- A refill prescription is not changed	
	and which is	- a prescription form shall be	from the product dispensed on the prior	
	therapeutically	preprinted or stamped with two	filling of the prescription.	
	equivalent to the	signature lines at the bottom of the	If the State mandates EMRs between a	
	drug identified in	form which read: "Product Selection	pharmacist and a prescriber, then the	
	the prescription.	Permitted" / "Dispense as Written",	pharmacist shall only be required to	
		and on this form, the prescriber shall	communicate the biological product	
		communicate instructions to the	dispensed through an EMR system when	
		pharmacist by signing the	such a system is in place and the	
		appropriate line.		

		- in the event a preprinted stamped	information is accessible by the	
		prescription form is not readily	prescriber.	
		available, the prescriber may	prescriber.	
		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.		
North Dakota	" <u>Biological product</u> ",	A pharmacy may not substitute a	Within two business days following the	The board of pharmacy shall maintain
	" <u>biosimilar</u> ",	prescription biosimilar product unless	dispensing of the biosimilar product, the	on its public website a current list, or
NDCC, 19-	"interchangeable",	each of the following requirements is	pharmacist or the pharmacist's designee	an internet link to an FDA-approved
02.1-14.3	" <u>interchangeable</u>	met:	notifies the prescribing practitioner of	list, of biosimilar biological products
	biological product",	- the biosimilar product has been	the substitution. Notification under this	determined to be interchangeable.
	" <u>license</u> ", and	determined by FDA to be	subdivision must include the name of	
	" <u>reference product</u> "	interchangeable with the prescribed	the substitution product and the name	The pharmacy and prescriber must
	mean the same as	product;	of the manufacturer, and may be made	retain a record of the
	these terms mean	- the prescriber does not specifically	using facsimile, telephone, electronic	interchangeable biosimilar
	under section 351 of	indicate "brand medically necessary"	transmission, an entry into an	substitution for a period of no less
	the Public Health	(via expressly writing on a written	interoperable electronic medical record	than five years.
	Service Act [42	prescription / expressly indicating via	accessible by the prescribing	
	U.S.C. 262].	an oral prescription / takes a specific	practitioner, or other prevailing means	
	0.0.00_j.	overt action to include the "brand	accessible by the prescribing	
		medically necessary" language with	practitioner.	
		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		

State Substitution Practices for Biological Drugs

		right to refuse the biosimilar product		Т
		selected by the pharmacist and the		1
		individual chooses not to refuse.		
Ohio	"Biological product"	Unless instructed otherwise by the	Except as provided in division (F)(1)(b) of	t
onio	means, except as	person receiving the drug pursuant to	this section, not later than five business	
R.C. §	provided in section	the prescription, a pharmacist filling a	days after a pharmacist dispenses a drug	
4729.38; R.C.	3715.011 of the	prescription for a drug prescribed by	for which an interchangeable biological	
§ 3715.01;	Revised Code, a	its brand name may, subject to the	product is available, regardless of	
8 3713.01, R.C. §	drug that is a	following conditions, select a	whether a substitution is made, the	
	U U	C	-	
3715.011	biological product, as defined on the	generically equivalent drug or, in the	pharmacist or an individual designated	
		case of a drug that is a biological	by the pharmacist shall communicate to	
	effective date of this	product, select an interchangeable	the prescriber information identifying	
	amendment in	biological product: (1) The	the specific biological product that was	
	subsection (i) of	pharmacist shall not select a	dispensed, including the name of the	
	section 351 of the	generically equivalent drug or	biological product and its manufacturer.	
	"Public Health	interchangeable biological product if	(b) Communication of the information is	
	Service Act," 42	either of the following applies: (a) In	not required when a biological product	
	U.S.C. 262(i).	the case of a written or electronic	is dispensed by refilling a prescription	
		prescription, including a computer-	and the product that is dispensed is the	
	"Interchangeable	generated prescription, the	same product that was dispensed when	
	biological product"	prescriber handwrites or actively	the same prescription was last filled or	
	means, except as	causes to display on the prescription	refilled. (2) When possible,	
	provided in section	"dispense as written," "D.A.W.," "do	communication of the information shall	
	3715.011 of the	not substitute," "brand medically	be conveyed by entering the	
	Revised Code, both	necessary," or any other statement	information into a recordkeeping system	
	of the following: (a)	or numerical code that indicates the	that can reasonably be presumed to be	
	A biological product	prescriber's intent to prevent	electronically accessible to the	
	that, on the	substitution. Such a designation shall	prescriber. Such a system may include	
	effective date of this	not be preprinted or stamped on the	any of the following: (a) An	
	amendment, has	prescription, but a reminder to the	interoperable electronic medical records	
	been determined by	prescriber of the designation	system; (b) An electronic prescribing	
	the United States	procedure may be preprinted or	system; (c) An electronic pharmacy	
	food and drug	displayed on the prescription form or	benefit management system; (d) An	
	administration to	electronic system the prescriber uses	electronic pharmacy record system. (3)	
	meet the standards	to issue the prescription. (b) In the	Entering the complete information into	
	for	case of an oral prescription, the	one of the recordkeeping systems listed	
	interchangeability	prescriber specifies that the drug as	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	" <u>Biological product</u> " means, with respect	A pharmacy or pharmacist filling a prescription order for a biological	Requires a pharmacy, pharmacist, or a pharmacist's designee, within five	The State Board of Pharmacy must post and regularly update on a
O.R.S. §	to the prevention,	product may not substitute a	calendar days communicate the specific	website maintained by the board a
689.522	treatment or cure of	biosimilar product for the prescribed	biological product dispensed a patient,	list of biosimilar products determined
	a disease or condition of human	biological product unless: - The biosimilar product has been	including the name and manufacturer of the biological product, by making an	by FDA to be interchangeable.
	beings, a virus,	determined by FDA to be	entry into an electronic records system	The pharmacy or pharmacist must
	therapeutic serum,	interchangeable with the prescribed	that the prescribing practitioner can	retains a record of the substitution
	toxin, antitoxin,	biological product	access electronically and that is:	for a period of not less than three
	vaccine, blood,		,	years.

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

product is evaluated	pharmacist re-filled the patient's
in an application	prescription.
submitted to FDA	
for licensure of a	
biological product as	
a biosimilar product	
or for determination	
that a biosimilar	
product is	
interchangeable.	
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	

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

Administration and	such substitution in the same manner	electronic prescribing technology , A	
determined to meet		PBM system or a pharmacy record , that	
the safety standards	subsection (b).	is electronically accessible by the	
for		prescriber. Entry into an electronic	
interchangeability		records system as described in this	
pursuant to the		subsection is presumed to provide	
Public Health		notice to the prescriber. Otherwise	
Service Act (58		within 72 hours, the pharmacist shall	
Stat. 682, 42 U.S.C.		communicate the interchangeable	
§ 207 et seq.) or a		biological product dispensed to the	
biological product		prescriber, using facsimile, telephone,	
APPROVED UNDER		electronic transmission or other	
SECTION 505 OF		prevailing means, provided that the	
THE FEDERAL FOOD,		communication shall not be required	
DRUG, AND		where :	
COSMETIC ACT (52		(1) there is no FDA approved	
STAT. 1040, 21		interchangeable biological product for	
U.S.C. § 355) AND		the biological	
determined by		product prescribed; or	
the United States		(2) it is a refill prescription where the	
Food and Drug		interchangeable biological product	
Administration to be		dispensed is the same interchangeable	
therapeutically		biological product which was dispensed	
equivalent to a		at the prior filling of the prescription.	
prescribed biological		(a.3) Subsections (a.1) and (a.2) may not	
product.		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	

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

interchangeable biological	administered biological product for	
product may be substituted. The	outpatients.	
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		
prescribed medication, the brand		

	January 1, 2018 "Interchangeable biological product," a biological product	interchangeable biological product by handwriting on the prescription drug order the words, brand necessary, or words of similar meaning. The	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	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
South Dakota SD Code 36-11	"Biological product," as defined in 42 U.S.C. 262(i), as of	A practitioner may prohibit a pharmacist from selecting an equivalent drug product or	A pharmacist dispensing a prescription drug order for a biological product prescribed by its brand or proper name	No nonresident pharmacy may dispense an equivalent drug product or an interchangeable biological
		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.		

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

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	product selected. A pharmacist shall, upon request of the prescribing practitioner, provide information regarding substitutions of equivalent drug products. 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.
		biological product is medically necessary, prescriber shall handwrite		

		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	" <u>Biological product</u> "	If prescriber certifies brand medically	Not later than the 3 rd business day after	If the price of a biological product to
	has the meaning	necessary on the prescription form in	the date of dispensing a biological	a patient is lower than the amount of
TX OCC §	assigned by Section	accordance with TX OCC § 562.015,	product, the dispensing pharmacist or	the patient's copayment under the
562.001;	351, Public Health	the pharmacist must dispense the	the pharmacist's designee shall	patient's prescription drug insurance
TX OCC §	Service Act (42	biological product as written by the	communicate to the prescribing	plan, the pharmacist shall offer the
562.003;	U.S.C. Section 262	practitioner. A pharmacist who	practitioner the specific product	patient the option of paying for the
TX OCC §		receives a prescription for a	provided to the patient, including the	biological product at the lower price
562.0051;	" <u>Interchangeable</u> ,"	biological product for which there is	name of the product and the	instead of paying the amount of the
TX OCC §	in reference to a	one or more interchangeable	manufacturer or national drug code	copayment.
562.006;	biological product,	biological products may dispense any	number. The communication must be	
TX OCC §	has the meaning	of the interchangeable biological	conveyed by making an entry into an	Must be labeled in accordance with
562.008;	assigned by Section	products.	interoperable EMR system or through	TX OCC § 562.006, which requires the
TX OCC §	351, Public Health		electronic prescribing technology or a	label on the dispensing container to
562.009;	Service Act (42	Before delivery of an interchangeable	pharmacy benefit management system	indicate the actual biological product
TX OCC §	U.S.C. Section 262),	biological product, a pharmacist /	or a pharmacy record, which may	dispensed (consistent with labeling
562.010;	or means a	pharmacist's agent must inform	include information submitted for the	requirements and practices for small
TX OCC §	biological product	patient / patient's agent that a less	payment of claims, that a pharmacist	molecule drugs)
562.011;	that is designated as	expensive interchangeable biological	reasonably concludes is electronically	
TX OCC §	therapeutically	product is available for the brand	accessible by the prescribing	The board shall maintain on the
562.016	equivalent to	prescribed and ask patient / patient's	practitioner. Otherwise, the pharmacist	board's Internet website a link to the
July 2021	· ·	· · · ·	· · ·	1

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

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		writing "dispanse as written" or 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." 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	"Biological product"	When a pharmacist receives a	Except as described in subdivision (4) of	When a pharmacist receives a
-	means a virus,	prescription for a drug that is listed	this subsection, within five business days	prescription for a biological product,
18 V.S.A. §	therapeutic serum,	either by generic name or brand	following the dispensing of a biological	the pharmacist shall select the lowest
4601 et. seq.	toxin, antitoxin,	name in the most recent edition of or	product, the dispensing pharmacist or	priced interchangeable biological
	vaccine, blood,	supplement to the U.S. Department	designee shall communicate the specific	product unless otherwise instructed
	blood component or	of Health and Human Services'	biological product provided to the	by the prescriber, or by the purchaser
	derivative,	publication Approved Drug Products	patient, including the biological	if the purchaser agrees to pay any
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allergenic product,	With Therapeutic Equivalence	product's name and manufacturer, by	additional cost in excess of the
protein (except any	Evaluations (the "Orange Book") of	submitting the information in a format	benefits provided by the purchaser's
chemically	approved drug products, the	that is accessible to the prescriber	health benefit plan if allowed under
synthesized	pharmacist shall select the lowest	electronically through one of the	the legal requirements applicable to
polypeptide), or	priced drug from the list which is	following: (A) an interoperable	the plan, or otherwise to pay the full
analogous product,	equivalent as defined by the "Orange	electronic medical records system; (B)	cost for the higher priced biological
or arsphenamine or	Book," unless otherwise instructed by	an electronic prescribing technology; (C)	product.
derivative of	the prescriber, or by the purchaser if	a pharmacy benefit management	
arsphenamine (or	the purchaser agrees to pay any	system; or (D) a pharmacy record.	Notwithstanding subdivisions (1) and
any other trivalent	additional cost in excess of the		(2) of this subsection, when a
organic arsenic	benefits provided by the purchaser's	Entry into an electronic records system	pharmacist receives a prescription
compound),	health benefit plan if allowed under	as described in subdivision (1) of this	from a Medicaid beneficiary, the
applicable to the	the legal requirements applicable to	subsection shall be presumed to provide	pharmacist shall select the preferred
prevention,	the plan, or otherwise to pay the full	notice to the prescriber. (3)(A) If a	brand-name or generic drug or
treatment, or cure	cost for the higher priced drug.	pharmacy does not have access to one	biological product from the
of a disease or		or more of the electronic systems	Department of Vermont Health
condition in human	Notwithstanding any provision of this	described in subdivision (1) of this	Access's preferred drug list. (b) The
beings.	subsection to the contrary, a	subsection (e), the pharmacist or	purchaser shall be informed by the
	pharmacist shall not be required to	designee shall communicate to the	pharmacist or his or her
"Interchangeable	communicate information regarding	prescriber the information regarding the	representative that an alternative
biological product"	the biological product dispensed in	biological product dispensed using	selection as provided under
means a biological	the following circumstances: (A) the	telephone, facsimile, electronic	subsection (a) of this section will be
product that the	U.S. Food and Drug Administration	transmission, or other prevailing means.	made unless the purchaser agrees to
U.S. Food and Drug	has not approved any	(B) If a prescription is communicated to	pay any additional cost in excess of
Administration has:	interchangeable biological products	the pharmacy by means other than	the benefits provided by the
(A) licensed and	for the product prescribed; or (B) the	electronic prescribing technology, the	purchaser's health benefit plan if
determined,	pharmacist dispensed a refill	pharmacist or designee shall	allowed under the legal requirements
pursuant to 42	prescription in which the product	communicate to the prescriber the	applicable to the plan, or otherwise
U.S.C. § 262(k)(4), to	dispensed was unchanged from the	information regarding the biological	to pay the full cost for the higher
be interchangeable	product dispensed at the prior filling	product dispensed using the electronic	priced drug or biological product. (c)
with the reference	of the prescription.	process described in subdivision (1) of	When refilling a prescription,
product against		this subsection (e) unless the prescriber	pharmacists shall receive the consent
which it was		requests a different means of	of the prescriber to dispense a drug
evaluated as may be		communication on the prescription.	or biological product different from
reflected in the U.S.			that originally dispensed, and shall
Food and Drug			inform the purchaser that a generic
Administration's			substitution shall be made pursuant

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

or arsphenamine or	dispensing of an interchangeable	a brand-name product, the
any derivative of	biosimilar shall be followed.	pharmacist or his designee shall label
arsphenamine or		the drug with the name of the
any other trivalent	No pharmacist may dispense a	interchangeable biosimilar followed
organic arsenic	biosimilar in place of a prescribed	by the words "Substituted for" and
compound,	biological product unless the	the name of the biological product
applicable to the	biosimilar has been licensed as	for which the prescription was
prevention,	interchangeable with the prescribed	written.
treatment, or cure	biological product by FDA	
of a disease or		Records of substitutions of
condition of human	When a pharmacist dispenses an	interchangeable biosimilars shall be
beings.	interchangeable biosimilar in the	maintained by the pharmacist and
	place of a prescribed biological	the prescriber for a period of not less
"Biosimilar" – a	product, pharmacist / designee must	than two years from the date of
biological product	inform patient prior to dispensing the	dispensing.
that is highly similar	interchangeable biosimilar	
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.		

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	" <u>Interchangeable</u> " –			
	a biosimilar that			
	meets safety			
	standards for			
	determining			
	interchangeability			
	pursuant to 42			
	U.S.C. § 262(k)(4).			
	" <u>Reference</u>			
	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	"Biological product"	Every prescription for a biological	Within 5 business days following the	Unless a prescribed biological
-	means any of the	product must contain an instruction	dispensing of a biological product, the	product is requested by the patient/
RCW	following, when	on whether or not an	dispensing pharmacist or the	patient's representative, if
69.41.110;	applied to the	interchangeable biological product	pharmacist's designee must make an	"substitution permitted" is marked
RCW	prevention,	may be substituted in its place,	entry of the specific product provided to	on the prescription, pharmacist must
69.41.120;	treatment, or cure	unless substitution is permitted	the patient, including either the name of	substitute an in-stock
RCW	of a disease or	under a prior-consent authorization	the product and the manufacturer or	interchangeable biological product
69.41.150;	condition of human	that complies with the prescription	FDA NDC, provided that the name of the	for the biological product prescribed
RCW	beings: A virus; a	format requirements outlined in RCW	product and the name of the	if the wholesale price for the
69.41.160;	therapeutic serum;	69.41.120 that enables prescribers to	, manufacturer are accessible to a	interchangeable biological product to
RCW	a toxin; an antitoxin;	communicate to dispensing	practitioner in an electronic records	the pharmacist is less than the
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69.41.196;	a vaccine; blood,	instructions to pharmacists by signing	system that can be electronically	wholesale price for the biological
RCW	blood component,	the appropriate line. No prescription	accessed by the patient's practitioner	product prescribed.
69.41.193	or derivative; an	is valid without the prescriber	through:	
	allergenic product; a	signature on one of these lines. For	- an interoperable electronic medical	The pharmacy quality assurance
	protein, other than	oral prescriptions, prescribers /	records system;	commission shall maintain a link on
	a chemically	prescribers' agents shall instruct	- an electronic prescribing technology;	its web site to the current list of all
	synthesized	pharmacist as to whether or not an	- a pharmacy benefit management	biological products determined by
	polypeptide, or an	interchangeable biological product	system; or	FDA as interchangeable. The
	analogous product;	may be substituted in its place –	- a pharmacy record.	commission shall maintain a list of all
	or arsphenamine, a	these instructions must be noted on	Entry into an electronic records system,	biological products approved as
	derivative of	the file copy of a written or oral	as described above, is presumed to	therapeutically equivalent by FDA
	arsphenamine, or	prescription. File copies of a written	provide notice to the practitioner.	through the approval process
	any trivalent organic	or oral prescription must be	Otherwise, the pharmacist must	specified in 505(b) of the federal
	arsenic compound;	maintained for the same period of	communicate to the practitioner the	FD&C act. The commission shall make
	and	time specified in RCW 18.64.245 for	specific product provided to the patient,	the 505(b) list accessible to
		retention of prescription records	including the name of the product and	pharmacies.
	"Interchangeable"		manufacturer, using facsimile,	
	means a biological		telephone, electronic transmission, or	A pharmacist who selects an
	product that is:		other prevailing means.	interchangeable biological product to
	- licensed by FDA			be dispensed pursuant to RCW
	and determined to		No entry or communication is required	69.41.100 through 69.41.180, and
	meet the safety		if:	the pharmacy for which the
	standards for		- there is no interchangeable biological	pharmacist is providing service,
	interchangeability		product for the product prescribed;	assumes no greater liability for
	pursuant to 42		- a refill prescription is not changed	selecting the interchangeable
	U.S.C. Sec.		from the product dispensed on the prior	biological product than would be
	262(k)(4); or		filling of the prescription; or	incurred in filling a prescription for
	- approved based		- the pharmacist / pharmacist's	the interchangeable biological
	on an application		designee and prescriber communicated	product when prescribed by name.
	filed under section		before dispensing and the	
	505(b) of the federal		communication included confirmation of	The prescriber is not liable for a
	FD&C Act that is		the specific product to be provided to	pharmacist's act or omission in
	determined by FDA		the patient, including the name of the	selecting, preparing, or dispensing an
	to be		product and the manufacturer.	interchangeable biological product
	therapeutically		(Notification requirements in effect with	under this section.
	equivalent to an		(Notification requirements in effect until	
	approved 505(b)		August 1, 2025)	

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

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

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

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

State Substitution Practices for Biological Drugs

	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.