	Table 1: State Regulations for Generic Drug Substitution	
Name of State	**State Law**	**Mandated or Permitted**
Alabama (AL)	AL Code § 34-23-8 (Current as of 2024)[1] Title 34 - Professions and Businesses. Chapter 23 - Pharmacists and Pharmacies. Article 1 - General Provisions. Section 34-23-8 - Substitution of Drugs or Brands of Drugs. (1) A licensed pharmacist in this state **shall be <u>permitted</u>** to select for the brand name drug product prescribed by a licensed physician or other practitioner who is located in this state and authorized by law to write prescriptions, hereinafter referred to as "practitioner," a less expensive pharmaceutically and therapeutically equivalent drug product containing the same active ingredient or ingredients, and of the same dosage form strength, in all cases where the practitioner expressly authorizes such selection in accordance with subdivision (4).	Permitted
Alaska (AK)	AK Stat § 08.80.295 (Current as of 2024)[2] Section 08.80.295 - Substitution of equivalent drug products or interchangeable biological products (a) Unless the prescription indicates that it is to be dispensed only as written, **<u>the pharmacist may</u>, with the consent of the patient, <u>substitute</u>** an equivalent drug product or interchangeable biological product.	Permitted (with additional requirement; requires patient consensus)
Arizona (AZ)	AZ Rev Stat § 32-1963.01 (Current as of 2023)[3] 32-1963.01. Substitution for prescription drugs or biological products; requirements; label; definitions A. If a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution as prescribed in subsection E of this section, a **<u>pharmacist may fill</u>** the prescription with a generic equivalent drug. … E. A prescription generated in this state must be dispensed as written only if the prescriber writes or clearly displays " DAW" , " dispense as written" , " do not substitute" or " medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form. A prescription from out of state or from agencies of the United States government must be dispensed as written only if the prescriber writes or clearly displays " do not substitute" , " dispense as written" or " medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution on the face of the prescription form.	Permitted
Arkansas (AR)	AR Code § 17-92-503 (Current as of 2024)[4]	Permitted

	Arkansas Code Title 17. Professions, Occupations, and Businesses § 17-92-503. Generic drug product and biological product substitutions (a) (1) (A) Except as provided in subsection (b) of this section, when a pharmacist receives a prescription for a brand or trade name drug product or biological product, the **pharmacist may dispense a generically equivalent drug product** or interchangeable biological product only when there will be a cost savings for the patient.	
California (CA)	Cal. Bus. & Prof. Code § 4073 (Current as of 2024)[5] 4073. Substitution of Generic Drug —Requirements and Exceptions (a) **A pharmacist** filling a prescription order for a drug product prescribed by its trade or brand name **may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name** as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients	Permitted
Colorado (CO)	CO Rev Stat § 12-280-125 (Current as of 2023)[6] Colorado Revised Statutes Title 12. Professions and Occupations § 12-280-125. Substitution of prescribed drugs and biological products authorized--when—conditions (1) (a) **A pharmacist** filling a prescription order for a specific drug by brand or proprietary name **may substitute an equivalent drug product if the substituted drug product is the same generic drug type and, in the pharmacist's professional judgment, the substituted drug product is therapeutically equivalent**, is interchangeable with the prescribed drug, and is permitted to be moved in interstate commerce. A pharmacist making a substitution shall assume the same responsibility for selecting the dispensed drug product as he or she would incur in filling a prescription for a drug product prescribed by a generic name; except that the pharmacist is charged with notice and knowledge of the FDA list of approved drug substances and manufacturers that is published periodically.	Permitted
Connecticut (CT)	CT Gen Stat § 20-619 (Formerly Sec. 20-185a). (Current as of 2023)[7] Connecticut General Statutes Title 20. Professional and Occupational Licensing, Certification, Title Protection and Registration. Examining Boards Chapter 400j – Pharmacy Section 20-619. (Formerly Sec. 20-185a) - Substitution of generic drugs and biological products. Definitions. Interchangeable biological products. Prescribing practitioners. Pharmacy signs. Dispensing. Records. Regulations (b) Except as limited by subsections (f), (h) and (l) of this section, unless the purchaser instructs otherwise, **the pharmacist may substitute a generic drug product** with the same strength,	Permitted

	quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.	
Delaware (DE)	24 DE Code § 2549 (Current as of 2023)[8] Delaware Code Title 24 - Professions and Occupations CHAPTER 25. PHARMACY Subchapter VI Prohibited Acts; Penalties Generally; Enforcement § 2549. Substitution of drugs. (a) When a pharmacist receives a prescription drug order from a practitioner for a brand or trade name drug, the **pharmacist may dispense a therapeutically equivalent drug** if the following conditions are met: (1) The practitioner, in the case of a written prescription, places that practitioner's own signature on the signature line along side or above the words "substitution permitted" pursuant to subsection (c) of this section; or, in the case of a verbal prescription or a verbal prescription reduced to writing, the practitioner states that the substitution may be made; or, in the case of an order written in an institution licensed by the Department of Health and Social Services pursuant to Chapter 10 or Chapter 11 of Title 16, the practitioner has given written authorization to fill all prescription drug orders with therapeutically equivalent drugs unless otherwise indicated; (2) The pharmacist informs the patient or the patient's adult representative that a therapeutically equivalent drug has been dispensed; (3) The pharmacist indicates on the prescription and on the prescription label the name of the manufacturer or distributor of the therapeutically equivalent drug substituted unless the practitioner indicates otherwise.	Permitted
Florida (FL)	Florida Statues, 465.025 Substitution of drugs (Current as of 2024)[9] (2) **A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive**, generically equivalent drug product that is:	Mandated

	(a) Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and (b) Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed.	
Georgia (GA)	GA Code § 26-4-81 (Current as of 2023)[10] Georgia Code Title 26 - Food, Drugs, and Cosmetics Chapter 4 - Pharmacists and Pharmacies Article 5 - Prescription Drugs § 26-4-81. Substitution of generic drugs or interchangeable biological products for brand name drugs and prescribed biological products (a) In accordance with this Code section, **a pharmacist may substitute:** (1) A drug with the same generic name in the same strength, quantity, dose, and dosage form as the prescribed brand name drug product which is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent; or (2) A biological product with an interchangeable biological product.	Permitted
Hawaii (HI)	HI Rev Stat § 328-92 (Current as of 2023)[11] Hawaii Revised Statutes Title 19. Health 328. Food, Drugs, and Cosmetics 328-92 Drug product and biological product selection §328-92 Drug product and biological product selection. (a) When filling a prescription order for a drug prescribed by its brand name, a pharmacist or the pharmacist's authorized agent shall: (1) Offer to the consumer an equivalent generic drug product or an interchangeable biological product from the Hawaii list of equivalent generic drug products and interchangeable biological products adopted pursuant to section 328-96; (2) Upon the request of the consumer, inform the consumer of the savings; and (3) Inform the consumer of the consumer's right to refuse substitution. **The pharmacist shall substitute an equivalent generic drug product or an interchangeable biological product** if the practitioner does not prohibit substitution under subsection (b), and the substitute equivalent generic drug product or interchangeable biological product results in a savings. The pharmacist shall not substitute if the consumer refuses.	Mandated (Additional requirement: If patient refuses, do not dispense generic)
Idaho (ID)	Section 24.36.01.404 - FILLING PRESCRIPTION DRUG ORDERS: DRUG PRODUCT SUBSTITUTION (Current as of 2023)[12]	Permitted

	Drug product substitutions in which a pharmacist dispenses a drug product other than that prescribed are allowed only as follows: (7-1-21)T 01.Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; (7-1-21)T 02.Institutional Facility. At the direction of the quality assessment and assurance committee of an institutional facility; (7-1-21)T 03.Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: (7-1-21)T a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; (7-1-21)T b. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. (7-1-21)T 04.Therapeutic Interchange. **A pharmacist may substitute a drug with another drug in the same therapeutic class, provided the substitution lowers the cost to the patient** or occurs during a drug shortage. (7-1-21)T Idaho Admin. Code r. 24.36.01.404	
Illinois (IL)	Section 410 ILCS 620/3.14 - Dispensing or causing to be dispensed a different drug in place of the drug or brand of drug ordered or prescribed without the express permission of the person ordering or prescribing (Current as of 2024)[13] Except as set forth in Section 26 of the Pharmacy Practice Act, **this Section does not prohibit the interchange of different brands of the same generically equivalent drug product,** when the drug products are not required to bear the legend "Caution: Federal law prohibits dispensing without prescription", provided that the same dosage form is dispensed and there is no greater than 1% variance in the stated amount of each active ingredient of the drug products. A generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration (FDA) shall be available for substitution in Illinois in accordance with this Act and the Pharmacy Practice Act.	Permitted
Indiana (IN)	Ind. Code § 16-42-22-8 (Current through 2024)[14] Section 16-42-22-8 - Requirements for substitution (a) **For substitution to occur** for a prescription other than a prescription filled under the Medicaid program (42 U.S.C. 1396 et seq.), the children's health insurance program established	Permitted (But the physician must sign on the line under which the words “May substitute” appear)

	under IC 12-17.6-2, the biosimilar biological products requirements under IC 16-42-25, or the Medicare program (42 U.S.C. 1395 et seq.): (1) the practitioner must: (A) sign on the line under which the words "May substitute" appear; or (B) for an electronically transmitted prescription, electronically transmit the instruction "May substitute."; and (2) the pharmacist must inform the customer of the substitution. (b) This section **does not authorize any substitution other than substitution of a generically equivalent drug product.** IN Code § 16-42-22-11 (Current through 2024)[15] IC 16-42-22-11 Substitution of generic drugs; identification of brand name drug Sec. 11. If under this section a **pharmacist substitutes** a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label must identify the brand name drug for which the substitution is made and the generic drug. The identification required under this subsection must take the form of the following statement on the drug container label, with the generic name and the brand name inserted on the blank lines: "_____ Generic for _____". [Pre-1993 Recodification Citation: 16-6-8.1-2(f).] As added by P.L.2-1993, SEC.25. Amended by P.L.186-1993, SEC.1.	
Iowa (IA)	155A.32 Drug product selection — restrictions. (Current as of 2024)[16] 1. a. If an authorized prescriber prescribes, in writing, electronically, by facsimile, or orally, a drug by its brand or trade name, **the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated bioavailability as the drug product prescribed for dispensing and sale to the patient.** If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a drug product with the same generic name and demonstrated bioavailability as the drug product prescribed for dispensing and sale. b. If an authorized prescriber prescribes a biological product, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a biological product	Permitted

	that is an interchangeable biological product for the biological product prescribed for dispensing and sale to the patient. If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a biological product that is an interchangeable biological product for the biological product prescribed for dispensing and sale. IA Code § 510B.6 (enacted in 2007 and current as of 2024)[17] 510B.6 Dispensing of substitute prescription drug for prescribed drug. 1. The following provisions shall apply when a pharmacy benefits manager requests the dispensing of a substitute prescription drug for a prescribed drug to a covered individual: a. **The pharmacy benefits manager may request the substitution of a lower priced generic and therapeutically equivalent drug for a higher priced prescribed drug.** b. If the substitute prescription drug's net cost to the covered individual or covered entity exceeds the cost of the prescribed drug, the substitution shall be made only for medical reasons that benefit the covered individual. 2. A pharmacy benefits manager shall obtain the approval of the prescribing practitioner prior to requesting any substitution under this section. 3. A pharmacy benefits manager shall not substitute an equivalent prescription drug contrary to a prescription drug order that prohibits a substitution.	
Kansas (KS)	KS Stat § 65-1637 (Current as of 2024)[18] (g) All prescriptions shall be filled or refilled in strict conformity with any directions of the prescriber, except that: (1) **A pharmacist** who receives a prescription order for a brand name drug product **may exercise brand exchange** with a view toward achieving a lesser cost to the purchaser unless: (A) The prescriber indicates "dispense as written" on the prescription or when communicating a prescription by oral order; (B) the FDA has determined that a biological product is not an interchangeable biological product for the prescribed biological product; or (C) the FDA has determined that a drug product of the same generic name is not bioequivalent to the prescribed brand name prescription medication;	Permitted
Kentucky (KY)	KY Rev Stat § 217.822 (Current as of 2024)[19] 217.822 Substitution of equivalent drug or interchangeable biological product --Substitute must be lower in price than prescribed drug or biological product --Selection by pharmacist not	Mandated

	practice of medicine --Liability of pharmacist --Pharmacist to communicate to prescribing practitioner the specific biological product dispensed. (1) When a **pharmacist** receives a prescription for a brand name drug which is not listed by generic name in the nonequivalent drug product formulary prepared by the board, the **pharmacist shall select a lower-priced therapeutically equivalent drug** which the pharmacist has in stock, unless otherwise instructed by the patient at the point of purchase or by the patient's practitioner. If a lower-priced selection is made, the label on the container of the drug shall show the name of the drug dispensed.	
Louisiana (LA)	Chapter 25. Prescriptions, Drugs, and Devices. Subchapter B. Prescriptions. $2517. Prescription Dispensing; Equivalent Drug Product Interchange; Drug Returns; Drug Disposal (Current as of 2024)[20] B. Equivalent Drug Product Interchange 3. In the event the prescriber has not prohibited equivalent drug product interchange in the manner described above, **the pharmacist may select an equivalent drug product for dispensing**, provided the <u>patient has been informed of, and has consented to</u>, the proposed cost saving interchange.	Permitted (requires patient consent prior to dispensing)
Maine (ME)	32 ME Rev Stat § 13781 (Current as of 2023)[21] §13781. Generic and therapeutically equivalent substitution A written prescription issued by a practitioner in this State may contain a box in the lower right-hand corner of the prescription form. The following words must appear to the left of this box: "Any drug that is the generic and therapeutic equivalent of the drug or any biological product that is an interchangeable biological product of the biological product specified above in this prescription must be dispensed, provided that no check mark ( ) has been handwritten in the box in the lower right-hand corner." [PL 2019, c. 34, §4 (AMD).] Except with regard to a patient who is paying for a drug or biological product with the patient's own resources, **<u>any pharmacist</u>** receiving a prescription in which <u>no handwritten check mark ( ) is found in the box</u> provided **<u>shall substitute a generic and therapeutically equivalent drug</u>** <u>for the drug or an interchangeable biological product</u> for the biological product specified on the prescription if the substituted drug or interchangeable biological product is distributed by a business entity doing business in the United States that is subject to suit and the service of legal process in the United States and the price of the substituted drug or interchangeable biological product does not exceed the price of the drug or biological product specified by the practitioner;	Mandated

	except that, when the cost of a prescription is to be reimbursed under the MaineCare program pursuant to Title 22, chapter 855, the pharmacist shall substitute a generic and therapeutically equivalent drug or an interchangeable biological product only when the Department of Health and Human Services has determined that the substitute drug or interchangeable biological product would be a more cost-effective alternative than the drug or biological product prescribed by the practitioner. Except for prescribed drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 United States Code, Section 812, as amended, as Schedule II drugs, with regard to a patient who is paying for a drug or biological product with the patient's own resources, a pharmacist shall inquire about the patient's preference for either the brand-name drug or generic and therapeutically equivalent drug or for either the prescribed biological product or interchangeable biological product and dispense the drug or biological product that the patient prefers. [PL 2019, c. 34, §4 (AMD).]	
Maryland (MD)	MD Health Occ Code § 12-504 (Current as of 2024)[22] Section 12-504 - Substitution of generic equivalent for brand name drug products (d) (1) **A pharmacist may substitute a generically equivalent drug** or device product, a therapeutically equivalent brand name drug or device product to the originally prescribed generically equivalent drug or device product, or an interchangeable biological product, of the same dosage form and strength, for the drug or device product originally prescribed, if: (i) The authorized prescriber does not state expressly that the prescription is to be dispensed only as directed; (ii) The substitution is: (1) Recognized in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations; or (2) An interchangeable biological product for the drug or device product originally prescribed; and (iii) The consumer is charged less for the substituted drug or device or interchangeable biological product than the price of the brand name drug or device.	Permitted
Massachusetts (MA)	105 Mass. Reg. 720.200 (Current as of 2024)[23] INTERCHANGEABLE (GENERIC) DRUG LAW In 1976 the Massachusetts Legislature passed an Act Further Regulating the Establishment of a Formulary of Interchangeable Drug Products (St. 1976, c. 470, § 13), commonly known as the Generic Drug Law. This law, enacted to promote and regulate the use of generic drugs, created the Drug Formulary Commission to develop a list of interchangeable drug products and also	Mandated

	required the use of a standard prescription form to encourage practitioners to prescribe generic drugs. PRESCRIPTION FORM M.G.L. c. 112, § 12D mandates prescription forms with one signature line. Ifthe prescriber signs the prescription form and writes the words "no substitution" in his/her own handwriting in the space provided below the signature line, the pharmacist must fill the prescription exactly as indicated, with no interchange permitted. However, if the prescriber signs the prescription and does not write "no substitution" under his/her signature, **the pharmacist is legally required** to dispense a **less expensive, equivalent interchangeable drug product** listed in the Massachusetts List of Interchangeable Drugs if one is reasonably available.	
Michigan (MI)	333.17755 Dispensing lower cost generically equivalent drug product or interchangeable biological drug product; notice; contents of prescription label; limitation; restrictions; limitation on total charge; communication to be provided prescriber; exception; link on website to Purple Book; report; definitions. (Current as of 2024)[24] (1) Except as provided in subsection (3), when a pharmacist receives a prescription for a brand name drug product or biological drug product, **the pharmacist may,** or when a purchaser requests a lower cost generically equivalent drug product or interchangeable biological drug product, **the pharmacist shall dispense** a lower cost but not higher cost generically equivalent drug product or interchangeable biological drug product if available in the pharmacy. If a drug or biological drug product is dispensed that is not the prescribed brand, the purchaser must be notified and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. Except as otherwise provided in section 17756, if the dispensed drug or biological drug product does not have a brand name, the prescription label must indicate the generic name of the drug dispensed or the proprietary name of the biological drug product dispensed.	Permitted (If the patient or purchaser requests lower cost generic, mandated. Otherwise, “may” dispense generics)
Minnesota (MN)	2023 Minnesota Statutes 151.21 SUBSTITUTION. Subd 3. Other prescription drug orders. (Current as of 2024)[25] Subd. 3.Other prescription drug orders. When a pharmacist receives a paper or hard copy prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has not expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed	Permitted with lots of restrictions. (must have less expensive drugs in stock + requires patient notification and consent)

	as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug or, if a biological product is prescribed, a less expensive interchangeable biological product, then the **pharmacist shall, after disclosing the substitution to the purchaser, dispense the 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 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. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug or biological product other than the specific drug or biological product prescribed.	
Mississippi (MS)	MS Code § 73-21-117 (Current as of 2024)[26] (1) **A pharmacist may select a generic equivalent drug product** or an interchangeable biological product only when such selection results in lower cost to the purchaser, unless product selection is expressly prohibited by the prescriber.	Permitted
Missouri (MO)	Mo. Code Regs. tit. 20 § 2220-3.011 (Current as of 2024)[27] Section 20 CSR 2220-3.011 - Generic Drug Substitution (1) Except as otherwise provided by Chapter 338, RSMo, **a pharmacist** who receives a prescription for a brand name drug or biological product **may select a less expensive generically equivalent** or inter-changeable biological product unless the patient requests a brand named drug or biological product or the prescribing practitioner indicates that substitution is prohibited or displays "brand medically necessary", "dispense as written", "do not substitute", "DAW", or words of similar import on the prescription.	Permitted
Montana (MT)	Montana Code Annotated 2023 TITLE 37. PROFESSIONS AND OCCUPATIONS CHAPTER 7. PHARMACY Part 5. Drug Product Selection. 37-7-505. Product selection permitted – limitation (Current as of 2024)[28] (1) Except as limited by subsection (2) and unless instructed otherwise by the purchaser: (a) **A pharmacist** who receives a prescription for a specific drug product by brand or proprietary name **may select** a less expensive drug product with the same generic name, strength, quantity, dose, and dosage form as the prescribed drug that is, in the pharmacist's professional opinion, therapeutically equivalent, bioequivalent, and bioavailable; and	Permitted

	(b) A pharmacist who receives a prescription for a specific biological product may select a less expensive interchangeable biological product.	
Nebraska (NE)	Nebraska Revised Statutes Chapter 38. Health Occupations and Professions § 38-28,111. Drug product selection; when; pharmacist; duty (Current as of 2024)[29] (1) **A pharmacist may drug product select** except when: (a) A practitioner designates that drug product selection is not permitted by specifying in the written, oral, or electronic prescription that there shall be no drug product selection. For written or electronic prescriptions, the practitioner shall specify "no drug product selection", "dispense as written", "brand medically necessary", or "no generic substitution" or the notation "N.D.P.S.", "D.A.W.", or "B.M.N." or words or notations of similar import to indicate that drug product selection is not permitted. The pharmacist shall note "N.D.P.S.", "D.A.W.", "B.M.N.", "no drug product selection", "dispense as written", "brand medically necessary", "no generic substitution", or words or notations of similar import on the prescription to indicate that drug 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.	Permitted (unless DAW or patient refusal to generic)
Nevada (NV)	NV Rev Stat § 639.2583 (Current as of 2023)[30] 1. Except as otherwise provided in this section, if a practitioner has prescribed a: (a) Drug by brand name and the practitioner has not indicated, by a method set forth in subsection 5, that a substitution is prohibited, **the pharmacist who fills or refills the prescription shall dispense**, in substitution, another drug which is available to him or her if the other drug: (1) Is less expensive than the drug prescribed by brand name; (2) Is biologically equivalent to the drug prescribed by brand name; …. 2. If the pharmacist has available to him or her more than one drug or interchangeable biological product that may be substituted for the drug prescribed by brand name or biological product prescribed, **the pharmacist shall dispense, in substitution, the least expensive of the drugs** or interchangeable biological products that are available to him or her for substitution.	Mandated
New Hampshire (NH)	N.H. Rev. Stat. § 318:47-d (Current as of 2024)[31] Section 318:47-d - Pharmacies; Substituting Generic Drugs **Pharmacies,** including mail-order pharmacies, **may substitute generically equivalent drug products** for all legend and non-legend prescriptions unless the prescribing practitioner	Permitted

	handwrites "medically necessary'' on each paper prescription, or uses electronic indications when transmitted electronically, or gives instructions when transmitted orally that the brand name drug product is medically necessary. In this section, "drug product" does not include a biological product.	
New Jersey (NJ)	N.J. Stat. Ann. § 24:6E-7 (Current as of 2023)[32] New Jersey Revised Statutes Title 24 - FOOD AND DRUGS Section 24:6E-7 - Prescriptions; dispensation of lowest cost interchangeable drug product; exceptions; notice of substitution "..Notwithstanding any other law, unless the physician or other authorized prescriber explicitly states that there shall be no substitution when transmitting an oral prescription or, in the case of a written prescription, indicates that there shall be no substitution by initialing the prescription blank next to "do not substitute," a different brand name or nonbrand name drug product of the same established name **shall be dispensed by a pharmacist** if such different brand name or nonbrand name drug product shall reflect a lower cost to the consumer and is contained in the latest list of interchangeable drug products published by the council;	Mandated
New Mexico (NM)	NM Stat § 26-3-3 (Current as of 2023)[33] New Mexico Statutes Chapter 26 - Drugs and Cosmetics Article 3 - Drug Product Selection Section 26-3-3 - Drug and biological product selection permitted; conditions; exception for prohibition; labeling. A. Upon receipt of a prescription written by a licensed practitioner who may prescribe drugs or biological products for a drug or biological product for which one or more multiple-source drugs or interchangeable biological products are recognized, listed as final determinations and published in the federal register by the federal department of health and human services, **a pharmacist may dispense** any one of **the drugs or interchangeable** biological products that satisfies the final determinations so recognized and listed by the federal department of health and human services and is **sold at a lower cost** than the drug or biological product listed in the prescription.	Permitted
New York (NY)	N.Y. Educ. Law § 6816-a (Current as of 2023)[34] § 6816-a. When substitution is required 1. **A pharmacist shall substitute a less expensive drug product** containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met:	Mandated

	(a) The prescription is written on a form which meets the requirements of subdivision six of section sixty-eight hundred ten of this article and the prescriber does not prohibit substitution, or in the case of oral prescriptions, the prescriber must expressly state whether substitution is to be permitted or prohibited. Any oral prescription that does not include such an express statement shall not be filled; and (b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law; and (c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.	
North Carolina (NC)	NC Gen Stat § 90-85.28 (Current as of 2023)[35] 90-85.28. Selection by pharmacists permissible; prescriber may permit or prohibit selection; price limit on selected drugs; communication of dispensed biological products under specified circumstances. **(a) A pharmacist** dispensing a prescription for a drug product prescribed by its brand name **may select** any equivalent drug or interchangeable biological product which meets all of the following standards: (1) The manufacturer's name and the distributor's name, if different from the manufacturer's name, shall appear on the label of the stock package. (2) It shall be manufactured in accordance with current good manufacturing practices. (3) All oral solid dosage forms shall have a logo, or other identification mark, or the product name to identify the manufacturer or distributor. (4) The manufacturer shall have adequate provisions for drug recall. (5) The manufacturer shall have adequate provisions for return of outdated drugs, through the distributor or otherwise.	Permitted
North Dakota (ND)	N.D. Cent. Code § 19-02.1-14.1 (Current as of 2024)[36] Section 19-02.1-14.1 - Definitions - Label of prescription drugs - Selecting and dispensing generic name drugs - Identification of prescription drugs 3. If a practitioner prescribes a drug by its brand name, the **pharmacist may** exercise professional judgment in the economic interest of the patient by **selecting a drug product with the same generic name** and demonstrated therapeutical equivalency as the one prescribed for dispensing and sale to the patient unless the practitioner specifically indicates in the practitioner's own	Permitted

	handwriting "brand medically necessary" on a written prescription or expressly indicates that an oral prescription is to be dispensed as communicated.	
Ohio (OH)	Section 4729.38 | Selecting generically equivalent drugs or interchangeable biological products. (Current as of 2024)[37] (B) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, **a pharmacist** filling a prescription for a drug prescribed by its brand name **may,** subject to the following conditions, **select a generically equivalent drug**, or, in the case of a drug that is a biological product, select an interchangeable biological product: (1) The pharmacist shall not select a generically equivalent drug or interchangeable biological product if either of the following applies: (a) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "brand medically necessary," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription. (b) In the case of an oral prescription, the prescriber specifies that the drug as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution. (2) The pharmacist shall not select a generically equivalent drug or interchangeable biological product unless its price to the patient is less than or equal to the price of the drug as prescribed.	Permitted
Oklahoma (OK)	Section 317:30-5-76 - Generic drugs (current as of 2024)[38] **All eligible providers are required to substitute generic medications for prescription name brand medications** with the exception of prescriptions in which a brand necessary certification as provided in OAC 317:30-5-77 is made by a prescribing provider or when the agency has notified pharmacy providers that the net cost of the brand name medication is lower than the net cost of the generic medication.	Mandated
Oregon (OR)	ORS 689.515 Regulation of generic drugs (Current as of 2024)[39] (2) Except as limited by subsections (3) and (5) of this section, unless the purchaser instructs otherwise, **a pharmacist may substitute as follows:**	Permitted (unless patient objects)

	(a) A drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent. (b) When the prescriber is not reasonably available for consultation and the prescribed drug does not utilize a unique delivery system technology, an oral tablet, capsule or liquid form of the prescribed drug so long as the form dispensed or administered has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed.	
Pennsylvania (PA)	35 Pa. Stat. § 960.3 (Current as of 2024)[40] Section 960.3 - Substitution for brand name drugs; oral prescription; notice to purchaser; refusal of substitution; prices; records; labels (a) Whenever a pharmacist receives a prescription for a brand name drug, **the pharmacist shall substitute a less expensive generically equivalent drug** unless requested otherwise by the purchaser or indicated otherwise by the prescriber.	Mandated
Rhode Island (RI)	RI Gen L § 5-19.1-19 (Current as of 2024)[41] § 5-19.1-19. Pharmacists - Substitution of drugs. **Pharmacists when dispensing a prescription shall**, unless requested otherwise by the individual presenting the prescription in writing, **substitute drugs containing** all the same active chemical ingredients of the same strength, quantity, and dosage form as the drug requested by the prescriber from approved prescription drug products in accordance with the provisions of § 21-31-16, unless ordered by the prescribing physician to dispense as brand name necessary on the prescription form, or if the prescriber gives oral direction to that effect to the dispensing pharmacist.	Mandated
South Carolina (SC)	SC Code § 39-24-40 (current as of 2024)[42] Section 39-24-40 - Prescription shall state whether substitution proper; form; consent of patient (A) An oral or written drug prescription must provide an authorization from the practitioner as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted. (B) A written prescription must have two signature lines at opposite ends on the bottom of the form. Under the line at the left side must be clearly printed the words "DISPENSE AS WRITTEN". Under the line at the right side shall be clearly printed the words "SUBSTITUTION PERMITTED", unless the prescription is to be paid for with Medicaid funds. The practitioner shall communicate the instructions to the pharmacist by signing on the appropriate line. A written prescription is not valid without the signature of the practitioner on one of these lines.	Permitted (But with strict physician authorization ("Substitution permitted" if written prescription or verbal permission by physician; have to be recorded; On top of it, patient consent required)

	(C) An oral prescription from the practitioner must instruct the pharmacist as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless the prescription is to be paid for with Medicaid funds. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period as prescribed by law. (D) The pharmacist shall note the brand name or the manufacturer of the substituted drug or biological product dispensed on the file copy of a written or oral prescription or record this information electronically, or both. (E) **Substitution may not occur unless the pharmacist advises the patient that the practitioner has authorized substitution and the patient consents.**	
South Dakota (SD)	36-11-46.1 (Current as of 2024)[43] Section 36-11-46.1 - Dispensing equivalent drug products **A pharmacist** dispensing a prescription drug order for a drug product prescribed by its brand name **may select** any equivalent drug product, if the manufacturer or distributor of the equivalent drug product holds, if applicable, either an approved new drug application or an approved abbreviated new drug application, unless other approval by law or from the Federal Food and Drug Administration is required.	Permitted
Tennessee (TN)	53-10-205 (Current as of 2023)[44] § 53-10-205. Least expensive generic equivalent if authorized by prescriber. (a) When a pharmacist receives a written, verbal, electronic or facsimile prescription order, and the prescriber has not noted medical necessity of the brand name prescribed, as required in § 53-10-204, the **pharmacist shall dispense the least expensive generic equivalent** in stock, or a generic equivalent covered under the patient's drug plan, except as provided in subsections (c) and (d). (b) A pharmacist shall make a reasonable attempt to notify a prescriber if a generic equivalent has become available since the last dispensing of a prescription, and, if authorized by the prescriber, the pharmacist shall dispense the least expensive generic equivalent in stock, or a generic equivalent covered under the patient's drug plan. (c) If a pharmacist has reason to believe that the brand name drug or drug product is less expensive to the patient or patient's drug plan than the generic equivalent, the pharmacist shall fill the prescription with the brand name drug or drug product.	Mandated

	(d) Nothing in this section shall be construed as prohibiting a pharmacist from complying with the request of a patient with a valid prescription order to obtain a brand name drug or drug product, if: (1) The patient has prescription drug coverage under a prescription benefit plan and agrees to pay the additional cost, if any, of purchasing the brand name drug or drug product, as that cost is determined according to the benefits provided by the patient's prescription benefit plan and when cost sharing that would be required to cover the additional cost is permissible under the patient's prescription benefit plan guidelines and all applicable laws and regulations; or (2) The patient does not have a prescription benefit plan or the patient's prescription benefit plan does not provide coverage for the brand name drug or drug product, and the patient agrees to pay the entire cost at the pharmacy of the brand name drug or drug product.	
Texas (TX)	22 Tex. Admin. Code § 309.3 (Current as of 2024)[45] Section 309.3 - Substitution Requirements (a) General requirements. In accordance with Chapter 562 of the Act, **a pharmacist may dispense a generically equivalent drug** or interchangeable biological product if: (1) the generic drug or interchangeable biological product costs the patient less than the prescribed drug product; (2) the patient does not refuse the substitution; and (3) the practitioner does not certify on the prescription form that a specific prescribed brand is medically necessary as specified in a dispensing directive described in subsection (c) of this section.	Permitted
Utah (UT)	58-17b-605. Drug product equivalents (Current as of 2024)[46] (2) **A pharmacist** or pharmacy intern dispensing a prescription order for a specific drug by brand or proprietary name **may substitute:** (a) a drug product equivalent for the prescribed drug if: (i) the purchaser specifically requests or consents to the substitution of a drug product equivalent; (ii) the drug product equivalent is of the same generic type and is designated the therapeutic equivalent in the approved drug products with therapeutic equivalence evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration; (iii) the drug product equivalent is permitted to move in interstate commerce; (iv) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the prescribed drug, whether a substitute or not; (v) the substitution is not otherwise prohibited by law; and	Permitted

	(vi) the prescribing practitioner has not indicated that a drug product equivalent may not be substituted for the drug, as provided in Subsection (6)	
Vermont (VT)	18 V.S.A. § 4605 (Current as of 2024)[47] 4605. Alternative drug or biological product selection (a)(1) When a pharmacist receives a prescription for a drug that is listed either by generic name or brand name in the most recent edition of or supplement to the U.S. Department of Health and Human Services' publication Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book) of approved drug products, the **pharmacist shall select the lowest priced drug from the list which is equivalent as defined by the Orange Book**, unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher-priced drug.	Mandated
Virginia (VA)	54.1-3408.03. (Current as of 2024)[48] 54.1-3408.03. Dispensing of therapeutically equivalent drug product permitted. A. **A pharmacist may dispense** a therapeutically equivalent drug product for a prescription that is written for a brand-name drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on the dispensing of the brand-name drug product.	Permitted
Washington (WA)	RCW 69.41.190 (Current as of 2024)[49] Preferred drug substitution—Exceptions—Notice—Limited restrictions. (1)(a) Except as provided in subsection (2) of this section, **any pharmacist filling a prescription** under a state purchased health care program as defined in *RCW 41.05.011(2) **shall substitute**, where identified, a preferred drug for any nonpreferred drug in a given therapeutic class, unless the endorsing practitioner has indicated on the prescription that the nonpreferred drug must be dispensed as written, or the prescription is for a refill of an antipsychotic, antidepressant, antiepileptic, chemotherapy, antiretroviral, or immunosuppressive drug, or for the refill of a immunomodulator/antiviral treatment for hepatitis C for which an established, fixed duration of therapy is prescribed for at least twenty-four weeks but no more than forty-eight weeks, in which case the pharmacist shall dispense the prescribed nonpreferred drug.	Mandated (but with lots of specifications)
Washington, D.C. (DC)	§ 48–803.02. Dispensing of generically equivalent drug product or interchangeable biological product. (Current as of 2024)[50] (a)(1) When a pharmacist receives a prescription for a brand name drug, the **pharmacist may dispense a generically equivalent drug product** or interchangeable biological product that is	Permitted (But with restriction such as requested by patients;

	listed in the Orange Book; **provided, that the pharmacist shall dispense** a generically equivalent drug product or interchangeable biological product **if requested by the purchaser**, except as provided in § 48-803.03. § 48–803.03. Dispensing of substitute drug products — conditions.[51] A pharmacist shall not dispense a: (1) Substitute drug product if the person purchasing the drug product or the patient for whom it is intended indicates a preference for the drug product actually prescribed; (2) Generically equivalent drug product or interchangeable biological product pursuant to § 48-803.02 if: (A) The prescriber writes on a prescription order, signed by the prescriber, in the prescriber's own handwriting "dispense as written" or "D.A.W." or a similar notation; provided, that checking or initialing a box preprinted or stamped on a prescription form shall not constitute an acceptable notation; or (B) The prescriber, by telephone, expressly indicates that the prescription is to be dispensed as communicated and this indication is noted in the pharmacist's own handwriting in the manner provided in subparagraph (A) of this paragraph; (3)(A) Therapeutically equivalent drug product unless: (i)(I) The pharmacist or pharmacist's agent obtains prior approval from the prescriber or the prescriber's agent before the therapeutically equivalent drug product can be dispensed; or (II) The therapeutically equivalent drug product is included on the therapeutic interchange list and the endorsing prescriber has given consent to the Boards of Pharmacy and Medicine to permit therapeutic interchange without prior approval; (ii) The person purchasing the drug product provides consent to the therapeutic interchange; (iii) The therapeutically equivalent drug product does not have a higher cost to the purchaser than the originally prescribed drug product; provided, that the pharmacist may dispense a more expensive therapeutically equivalent drug product if consent is provided by the purchaser; and (iv) The dispensing pharmacist, or pharmacist's agent, has notified the prescriber or prescriber's agent of the specific drug and dose dispensed. (B) A pharmacist shall not dispense a therapeutically equivalent drug product for a prescription refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug but shall dispense the drug as prescribed.	more exceptions listed under 48-803.03)

West Virginia (WV)	§30-5-12b. Definitions; selection of generic drug products; exceptions; records; labels; manufacturing standards; rules; notice of substitution; complaints; notice and hearing; immunity. (Current as of 2024)[52] (6) "Equivalent" means drugs or drug products which are the same amounts of identical active ingredients and same dosage form and which will provide the same therapeutic efficacy and toxicity when administered to an individual and is approved by the United States Food and Drug Administration. (b) **A pharmacist** who receives a prescription for a brand name drug or drug product **shall substitute a less expensive equivalent generic name drug** or drug product unless, in the exercise of his or her professional judgment, the pharmacist believes that the less expensive drug is not suitable for the particular patient: Provided, That a substitution may not be made by the pharmacist where the prescribing practitioner indicates that, in his or her professional judgment, a specific brand name drug is medically necessary for a particular patient.	Mandated
Wisconsin (WI)	WI Stat § 450.13 (Current as of 2024)[53] 450.13 Using drug product equivalent in dispensing prescriptions. (1e) Definition. In this section, “drug product equivalent" means a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration as set forth in the latest edition of or supplement to the federal food and drug administration's Approved Drug Products with Therapeutic Equivalence Evaluations. (1s) Drug product or equivalent to be used. Except as provided in sub. (2), **a pharmacist shall dispense every prescription using either the drug product prescribed or its drug product equivalent**, if its drug product equivalent is lower in price to the consumer than the drug product prescribed, and shall inform the consumer of the options available in dispensing the prescription. (2) Exception. A prescribing practitioner may indicate, by writing on the face of the prescription order or, with respect to a prescription order transmitted electronically, by designating in electronic format the phrase “No substitutions" or words of similar meaning or the initials “N.S.", that no substitution of the drug product prescribed may be made under sub. (1s). If such indication is made, the pharmacist shall dispense the prescription with the specific drug product prescribed. No preprinted statement regarding drug product substitution may appear on the face of the prescription order.	Mandated
Wyoming (WY)	WY Stat § 33-24-149 (Current as of 2023)[54] 33-24-149. Drug substitution procedures.	Permitted

	(a) **A pharmacist** who receives a prescription for a brand name prescription drug **may dispense** any interchangeable biological product or generically equivalent drug of the brand name prescription drug prescribed, unless the prescribing practitioner has clearly indicated substitution is not permitted.	

Table 2: List of FDA General Guidances that Relate to Drug-Device Combination Products[55]

Name of Guidance	Published	Topics Covered
Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA: Draft Guidance for Industry[56]	January 2017 (Draft Guidance)	Recommendations about how to assess device user interface between proposed generic and RLD product (comparative analyses and comparative use human factors studies).
Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development[57]	February 2016 (Draft Guidance)	Underlying principles of human factors (HF) studies during the development of combination products as defined under 21 CFR Part 3.
Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products--Quality Considerations[58]	April 2018 (Draft Guidance)	MDI and DPI product development, MDI and DPI product characterization studies, and approaches to evaluating delivered dose uniformity (DDU)
Nasal Spray and Inhalation Solution, Suspension, and Drug Products--Chemistry, Manufacturing, and Controls Documentation[59]	July 2002 (Final Guidance)	CMC information related to drug products, drug product characterization studies, labeling considerations.
Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products[60]	June 2013 (Final Guidance)	Technical and scientific information that FDA expects in a marketing application for a pen, jet, or related injector device intended for use with a drug or biological product.
Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for	April 2013 (Draft Guidance)	Technical information that Applicants should submit for a glass syringe product and connectivity issues between the glass syringe and connecting device(s). The recommendations in this guidance are applicable

Standardization (ISO) Standard 11040-4[61]		to drugs or biologicals delivered with glass syringe products.
Principles of Premarket Pathways for Combination Products[62]	January 2022 (Final Guidance)	Describes regulations and premarket submissions for: (1) Drug-Led combination products (NDA, ANDA), (2) Device-Led combination products (PMA, De Novo, 510k), and (3) Biologic-led combination products (BLA under section 351(a), BLA under section 351(k)).
Classification of Products as Drugs and Devices and Additional Product Classification Issues[63]	September 2017 (Final Guidance)	Classification of products as devices or drugs, and information about how to obtain classification determinations from FDA for medical products.
Requesting FDA Feedback on Combination Products[64]	December 2020 (Final Guidance)	Ways that Applicants can obtain feedback from FDA on scientific and regulatory questions, best practices when discussing development of combination products, and regulatory considerations for combination products.

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