COMMONWEALTH of VIRGINIA

Arne W. Owens
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
PHONE (804) 367- 4400

TO: The Honorable Glenn Youngkin
Governor of Virginia

The Honorable Mark D. Sickles
Chair, House Committee on Health and Human Services

The Honorable Ghazala F. Hashmi
Chair, Senate Committee on Education and Health

FROM: Caroline D. Juran, RPh
Executive Director, Virginia Board of Pharmacy

DATE: October 22, 2025

RE: **Report on Pharmacist Initiation of Therapeutic Interchange**

This report is submitted in compliance with SB745 passed during the 2025 General Assembly Session, which required:

> The Board of Pharmacy to convene a work group of relevant stakeholders, including representatives of the Department of Health, Boards of Medicine and Nursing, Virginia Pharmacy Association, Medical Society of Virginia, Virginia Chapter of the American Academy of Pediatrics, National Association of Chain Drug Stores, Virginia Society of Health-System Pharmacists, Virginia Hospital and Healthcare Association, Virginia Association of Health Plans, and patient advocacy groups, to (i) review and analyze the current authority of pharmacists to initiate therapeutic interchange under all health carriers and plans and health care reimbursement methods, including plans covered by the Employee Retirement Income Security Act of 1974; (ii) make recommendations to streamline the existing therapeutic interchange process in the Commonwealth; and (iii) make recommendations for the modernization of such

therapeutic interchange authority, particularly in cases of prescription drug shortages. The work group is required to report its findings and recommendations to the Governor and the Chairs of the House Committee on Health and Human Services and the Senate Committee on Education and Health by November 15, 2025.

Should you have questions about this report, please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov.

CC: The Honorable Janet Kelly, Secretary of Health and Human Resources
Arne Owens, Director, Department of Health Professions

Preface

This report is submitted in compliance with SB745 passed during the 2025 General Assembly Session, which required:

> The Board of Pharmacy to convene a work group of relevant stakeholders, including representatives of the Department of Health, Boards of Medicine and Nursing, Virginia Pharmacy Association, Medical Society of Virginia, Virginia Chapter of the American Academy of Pediatrics, National Association of Chain Drug Stores, Virginia Society of Health-System Pharmacists, Virginia Hospital and Healthcare Association, Virginia Association of Health Plans, and patient advocacy groups, to (i) review and analyze the current authority of pharmacists to initiate therapeutic interchange under all health carriers and plans and health care reimbursement methods, including plans covered by the Employee Retirement Income Security Act of 1974; (ii) make recommendations to streamline the existing therapeutic interchange process in the Commonwealth; and (iii) make recommendations for the modernization of such therapeutic interchange authority, particularly in cases of prescription drug shortages.

The bill requires the Board of Pharmacy to submit this report to the Governor and the Chairs of the House Committee on Health and Human Services and the Senate Committee on Education and Health by November 15, 2025.

Contents

I. Executive Summary

Pursuant to SB745 passed during the 2025 General Assembly Session, the Board of Pharmacy convened a workgroup which met on August 12, 2025. The workgroup considered the required topics designated in SB745, which were as follows:

1. Review and analyze the current authority of pharmacists to initiate therapeutic interchange under all health carriers and plans and health care reimbursement methods, including plans covered by the Employee Retirement Income Security Act of 1974;

2. Make recommendations to streamline the existing therapeutic interchange process in the Commonwealth; and

3. Make recommendations for the modernization of such therapeutic interchange authority, particularly in cases of prescription drug shortages.

During its review of current laws regarding therapeutic interchange in other states (Appendices 1 and 2), the workgroup appeared to reach consensus on several recommendations for possible legislation to authorize therapeutic interchange. Those recommendations are detailed below in Part IV.

Workgroup Members[1]

Erin Barrett, JD
Director of Leg. & Reg. Affairs, Virginia Department of Health Professions

Jared Calfee
Associate State Director for Advocacy and Outreach, AARP Virginia

Scott Castro
Senior Director of Health Policy, Medical Society of Virginia

Craig Connors
Vice President Payor Relations & Strategy, Virginia Hospital and Healthcare Association

Joshua Crawford, PharmD
Legislative Committee Co-Chair, Virginia Society of Health-System Pharmacists

Jennifer Deschenes, JD, MS
Deputy Executive Director, Board of Medicine

Joanne Dial, PharmD

[1] A representative from the Virginia Chapter of the American Academy of Pediatrics was unable to participate.

Pharmacy Operations Specialist III, Controls, Kaiser Permanente

Shannon Dowdy, PharmD
Vice-Chairman, Board of Pharmacy

JoeMichael Fusco, PharmD
Pharmacy Operations Manager, Department of Medical Assistance Services

Johnny Garcia, PharmD
Pharmaceutical Care Management Association (virtual participation)

Sharon Gatewood, PharmD
Past-President, Virginia Pharmacy Association

Bill Hutchens, MD
Member, Board of Medicine

Caroline Juran, RPh
Executive Director, Virginia Board of Pharmacy

Larry Kocot, JD, Chair
Board of Pharmacy

Randall Mangrum, DNP, RN
Deputy Executive Director for Advanced Practice, Board of Nursing

Laurie Mauthe, PharmD
Pharmacy Account Director, Elevance Health

Arne Owens
Director, Virginia Department of Health Professions

Jamie Smith, PharmD
Clinical Pharmacy Services Manager, Department of Corrections

Jason Spouse, PharmD
National Association of Chain Drug Stores

Stephanie Wheawill, PharmD
Director, Division of Pharmacy Services, Department of Health

Derek Webb, PharmD
Member, Board of Pharmacy

Ling Yuan, PharmD
Member, Board of Pharmacy

II. Current Authority to Perform Therapeutic Interchange

Currently Virginia Code § 54.1-3408.03 authorizes a pharmacist to dispense a "therapeutically equivalent drug product" as defined in § 54.1-3401 and § 54.1-3408.04 authorizes a pharmacist to dispense a biosimilar as defined in § 54.1-3401. Therapeutic interchange, however, generally involves the dispensing of a drug with a different chemical structure than the drug prescribed but where the drug is of the same pharmacologic or therapeutic class with a similar therapeutic effect and adverse-reaction profile when administered in a therapeutically equivalent dose. While it has been common practice for decades for health systems to use a multi-disciplinary pharmacy and therapeutic committee to establish formulary systems, therapeutic interchange is not specifically addressed in Virginia law. Furthermore, Virginia Code § 54.1-3457(16) and (17) may prohibit a pharmacist from dispensing a drug under therapeutic interchange when a prescriber has not authorized the alternate drug to be dispensed.

A review of laws in other states revealed that some states specifically authorize therapeutic interchange in various types of institutions. Other states, such as Arkansas, Idaho, Iowa, Kentucky, New Hampshire, Vermont, and Washington, authorize a broader authority which includes pharmacists practicing outside of institutions, including community pharmacists.

IV. Workgroup recommendations

While the workgroup did not vote on specific recommendations to address therapeutic interchange, the workgroup reached consensus for the following:

1. The workgroup supported the introduction of legislation to create an allowance in law for pharmacists to perform therapeutic interchange consistent with a drug formulary established by a facility's multi-disciplinary pharmacy and therapeutic committee.

   The workgroup discussed whether such a proposed law should be written broadly to be site neutral. Alternatively, the workgroup noted that a proposed law could enumerate the specific type of facilities able to perform therapeutic interchange, which should include pharmacies servicing correctional facilities. The workgroup noted that, while current law does not specifically address therapeutic interchange, a health system's electronic health record drives therapeutic interchange at the point of prescribing, thus often reducing the need for pharmacists to dispense drugs other than that which was prescribed. The workgroup also noted that pharmacy benefit managers usually rely on pharmacy and therapeutic committees to develop formularies, and that some drug formularies, such as those used in Virginia Medicaid, are based on disease or medical conditions and not drug class.

2. The workgroup supported the introduction of legislation to create an allowance in law for community pharmacists, including those practicing at the Virginia Department of Health Pharmacy Services, to benefit from the flexibility to adjust a prescription when insurance will not cover a particular drug strength or a particular drug product. This flexibility would eliminate the need for the pharmacist to contact the prescriber for authorization and eliminate subsequent patient delay in accessing the drug.

   Members of the workgroup emphasized that a proposed law on therapeutic interchange should not be mandatory and that the interchange should result in a lower cost or be cost-neutral for the patient, unless the drug was in shortage. To determine drug shortages, the workgroup recommended that a proposed law should reference both the United States Food and Drug Administration ("FDA") drug shortage list and the American Society of Health-System Pharmacists ("ASHP") drug shortage list as the ASHP list appears to be updated more frequently. The workgroup noted that Idaho's law states that the therapeutic interchange must lower the cost to the patient or occur during a drug shortage. These restrictions may address citizens' concerns with drug affordability and access. The workgroup discussed requiring pharmacy benefit managers to cover the less expensive drug or a non-formulary drug that was previously on formulary and which the patient was previously on.[2] The workgroup discussed the applicability of utilizing pharmacist therapeutic interchange authority in these cases. Those members representing health plans commented that they are required to cover the less expensive drug, and that otherwise, a process for obtaining prior authorization approval exists.

[2] *See, e.g.,* Va. Code § 38.1-3407.9:01(B)(3) (containing this allowance).

3. Any legislation introduced should require the pharmacist to notify the prescriber when the pharmacist performs a therapeutic interchange to ensure good communication between prescriber and pharmacist. The workgroup felt that "within 24 hours" constituted a reasonable window for notification.

4. Existing laws for therapeutic interchange in other states should be considered in the drafting of any potential legislation.[3]

   Idaho
   The workgroup noted that Idaho therapeutic interchange law represents a good model for Virginia.[4]

   Arkansas
   The workgroup also acknowledged Arkansas therapeutic interchange law as another good model if it was amended to specifically authorize therapeutic interchange in facilities. A workgroup member stated that a broader law such as Arkansas may result in better utilization by community pharmacists.

   Kentucky
   A few members also highlighted Kentucky therapeutic interchange law wherein the prescriber records authorization for the use of therapeutic interchange on the written prescription but stated that any proposed language using Kentucky as a model should also accommodate the recording of this information in the comments section of an electronic prescription.

   Minnesota
   A member highlighted allowances in a Minnesota provision that were in effect during the COVID-19 pandemic.[5]

5. Any legislation introduced should identify drug classifications that may not be therapeutically interchanged, such as antipsychotics, antidepressants, controlled substances, and oncolytic agents,[6] or include an ability for this limitation to be enumerated in regulation. Such restrictions, however, should not apply when a pharmacist dispenses a drug pursuant to a formulary established by a pharmacy and therapeutics committee, collaborative practice agreement, or statewide protocol.

6. Any legislation introduced should include authorization for the pharmacist to adapt or amend the prescription.

[3] A summary of states' specific therapeutic interchange law is attached as Appendix 1.
[4] Allowances under Idaho law for a pharmacist to change a prescription quantity, dosage form, or package size when the original prescription is not commercially available would be beneficial for Virginia pharmacists as well as the ability to provide a therapeutic interchange.
[5] *See* Minnesota statutory law regarding therapeutic interchanges, attached as Appendix 2.
[6] This limitation on classifications is included in Arkansas law allowing therapeutic interchanges.

The workgroup acknowledged that during therapeutic interchange the pharmacist amends the original prescription through "adaptation," a term used in other state laws, and that the pharmacist does not change the name of the prescriber on the prescription.

V. Conclusion

There appeared to be consensus for the introduction of legislation that: (i) creates an allowance in law for pharmacists to perform therapeutic interchange consistent with a drug formulary established by a facility's multi-disciplinary pharmacy and therapeutic committee; (ii) creates an allowance for community pharmacists, including those practicing at the Virginia Department of Health Pharmacy Services, to perform therapeutic interchange when insurance will not cover a particular drug strength or a particular drug product; (iii) requires the pharmacist to notify the prescriber within 24 hours of performing a therapeutic interchange; (iv) potentially mirrors existing allowances in other states such as Idaho, Arkansas, and/or Kentucky; (v) identifies drug classifications that may not be therapeutically interchanged such as antipsychotics, antidepressants, controlled substances, and oncolytic agents,[7] or includes an ability for this to be enumerated in regulation but does not prohibit the dispensing of drugs pursuant to a formulary established by a pharmacy and therapeutics committee, collaborative practice agreement, or statewide protocol; and (vi) authorizes the pharmacist to adapt or amend the prescription.

[7] This limitation would be similar to Arkansas law, as referenced in note 6.

Appendix 1

National Association of Boards of Pharmacy Summary of States with Specific Legislation Authorizing Therapeutic Interchange

State	Notes	Reference(s)
Arkansas	A pharmacist whose practice is located within this state may substitute medications for **therapeutically equivalent** medications. (a) However, a pharmacist shall not substitute a medication for a therapeutically equivalent medication if: (1) A prescription is in writing and the prescriber indicates in his or her own handwriting by name or initial that no substitution is to be made; (2) A prescription is not in writing and the prescriber expressly indicates that the prescription is to be dispensed as communicated; or (3) The Arkansas State Board of Pharmacy has determined that a therapeutically equivalent medication should not be substituted and has notified all pharmacists of that determination. Examples include but are not limited to, any antipsychotics, antidepressants, controlled substances and oncolytic agents. (b) Therapeutic equivalence may be established with clinical publications comparing dosages of drugs in a therapeutic class. (c) (1) Before dispensing, the pharmacist shall discuss verbally any suggested substitution with the patient and inform the patient that the patient has a right to refuse the substitution. This discussion shall include without limitation: (A) Notification to the patient that the therapeutically equivalent drug does not contain the identical active ingredient present in the prescribed drug; and (B) All differences in dosage and frequency between the prescribed drug and the therapeutically equivalent drug. (d) The pharmacist shall send notice of the substitution to the prescriber in writing or by electronic communication within twenty-four (24) hours after the drug is dispensed to the patient. (e) This section does not apply to specific acts of drug therapy management or disease state management delegated to a pharmacist based upon a written protocol or patient care plan approved by a physician under § 17-92-101(16)(A)(ix);	AR Rule 007.39.7-07-00-0010. **Therapeutic** Substitution

Colorado	(39) "Practice of pharmacy" means: … (c) The provision of a **therapeutic** interchange selection or a **therapeutic**ally equivalent selection to a patient if, during the patient's stay at a nursing care facility or a long-term acute care hospital licensed under part 1 of article 3 of title 25, the selection has been approved for the patient: (I) In accordance with written guidelines and procedures for making **therapeutic** interchange or **therapeutic**ally equivalent selections, as developed by a quality assessment and assurance committee that includes a pharmacist licensed under this article 280 and is formed by the nursing care facility or the long-term acute care hospital in accordance with 42 CFR 483.75; and (II) By one of the following health-care providers: (A) A physician licensed under article 240 of this title 12; (B) A physician assistant licensed under section 12-240-113; or (C) An advanced practice registered nurse prescriber licensed as a professional nurse under section 12-255-110, registered as an advanced practice registered nurse under section 12-255-111, and authorized to prescribe controlled substances or prescription drugs pursuant to section 12-255-112; (d) The dispensing of chronic maintenance drugs pursuant to section 12-280-125.5 and board rules adopted in accordance with that section; (e) Pursuant to a standing order or to a statewide drug therapy protocol developed pursuant to section 12-280-125.7, the prescribing and dispensing of post-exposure prophylaxis, as defined in section 12-280-125.7(1)(d), for nonoccupational exposure to HIV infection and preexposure prophylaxis, as defined in section 12-280-125.7(1)(e), and the ordering of lab tests in conjunction with prescribing or dispensing the drugs; (f) Providing care to patients pursuant to a collaborative pharmacy practice agreement as defined in section 12-280-601; (g) Exercising independent prescriptive authority: (I) As authorized pursuant to section 25.5-5-322, only with regard to over-the-counter medications prescribed to recipients under the "Colorado Medical Assistance Act", articles 4 to 6 of title 25.5; (II) In accordance with a collaborative pharmacy practice agreement as defined in section 12-280-601(1)(b); (III) As authorized pursuant to sections 12-30-110 and 12-280-123(3) regarding opiate antagonists; or	CO Law 12-280-103. Definitions – rules.

	(IV) For drugs that are not controlled substances, drug categories, or devices that are prescribed in accordance with the product's FDA-approved labeling and to patients who are at least twelve years of age and that are limited to conditions that: (A) Do not require a new diagnosis; (B) Are minor and generally self-limiting; or (C) Have a test that is used to guide diagnosis or clinical decision-making and is waived under the federal "Clinical Laboratory Improvement Amendments of 1988", Pub.L. 100-578, as amended; (h) Ordering and evaluating laboratory tests as related to medication therapy; (i) Performing limited physical assessments commensurate with education and training; (j) Performing other tasks delegated by a licensed physician; and (k) Providing treatment that is based on national, evidence-based, published guidance. … (51) "**Therapeutic** interchange" means the substitution of one drug for another drug with similar **therapeutic** effects.	
District of Columbia	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) **Therapeutic**ally 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 **therapeutic**ally equivalent drug product can be dispensed; or	DC Law 48-803.03 Dispensing of substitute drug products – conditions.

	(II) The **therapeutic**ally 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 **therapeutic**ally 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 **therapeutic**ally 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 **therapeutic**ally equivalent drug product for a prescription refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug but shall dispense the drug as prescribed.	
Florida	(9) A pharmacist may **therapeutic**ally substitute medicinal drugs in accordance with an institutional formulary established under s. 400.143 for the resident of a nursing home facility if the prescriber has agreed to the use of such institutional formulary for the patient. The pharmacist may not **therapeutic**ally substitute a medicinal drug pursuant to the facility's institutional formulary if the prescriber indicates on the prescription "NO **THERAPEUTIC** SUBSTITUTION" or overtly indicates that **therapeutic** substitution is prohibited as authorized under s. 400.143(5)(c).	FL Law 465.025. Substitution of drugs.
Idaho	Drug product substitutions in which a pharmacist dispenses a drug product other than that prescribed are allowed only as follows: (3-28-23) 01. Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and **therapeutic**s committee of a hospital; (3-28-23) 02. Institutional Facility. At the direction of the quality assessment and assurance committee of an institutional facility; (3-28-23) 03. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: (3-28-23) a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple book; (3-28-23) b. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. (3-28-23)	ID Rule 24.36.01.404 Filling Prescription Drug Orders: Drug Product Substitution

	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. (3-28-23) A pharmacist may adapt drugs as specified in this rule. (3-28-23) 01. Change Quantity. A pharmacist may change the quantity of medication prescribed if: (3-28-23) a. The prescribed quantity or package size is not commercially available; (3-28-23) b. The change in quantity is related to a change in dosage form, strength, or **therapeutic** interchange; (3-28-23) c. The change is intended to dispense up to the total amount authorized by the prescriber including refills; or (3-28-23) d. The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program. (3-28-23) 02. Change Dosage Form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed. (3-28-23) 03. Complete Missing Information. A pharmacist may complete missing information on a prescription if there is evidence to support the change. (3-28-23) 04. Documentation. The adaption must be documented in the patient's record. (3-28-23)	ID Rule 24.36.01.403 Filling Prescription Drug Orders: Adaptation
Indiana	Sec. 1.5. As used in this chapter, "**therapeutic** alternative" means a drug product that: (1) has a different chemical structure from; (2) is in the same pharmacological or **therapeutic** class as; and (3) usually can be expected to have similar **therapeutic** effects and adverse reaction profiles when administered to patients in **therapeutic**ally equivalent doses as another drug. Sec. 11. A pharmacist may not substitute a **therapeutic** alternative for a drug prescribed by an individual's attending physician unless the substitution is authorized by the attending physician under a valid protocol issued under this chapter.	IN Law 25-26-16-1.5 IN Law 25-26-16-11, **Therapeutic**

	Sec. 13. If a protocol developed under this chapter allows pharmacist to substitute a **therapeutic** alternative for the drug prescribed by the individual's attending physician, the attending physician's authorization of the substitution is valid only for the duration of the prescription or drug order. Sec. 2. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist: (1) changes the duration of treatment for a current drug therapy; (2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration; (3) discontinues the use of a drug; (4) adds a drug to the treatment regimen; (5) issues a new prescription for the purposes of subdivision (1), (2), or (4); or (6) makes a **therapeutic** substitution. Sec. 5. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist: (1) changes the duration of treatment for a current drug therapy; (2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration; (3) discontinues the use of a drug; (4) adds a drug to the treatment regimen; (5) issues a new prescription for the purposes of subdivision (1), (2), or (4); or (6) makes a **therapeutic** substitution.	alternative; authorization IN Law 25-26-16.5-13. Substitutions; **therapeutic** alternatives IN Law 25-26-16-2 Adjustment IN Law 25-26-16.5-5 Adjustment of Regimen
Iowa	49A. "**Therapeutic** substitution" means the replacement of a prescribed drug, biological product, or device with an alternative molecule or device with assumed equivalent **therapeutic** effect. The alternative drug, biological product, or device may be within the same class or from another class with assumed **therapeutic** equivalence.	IA Law 155A.3 Definitions IA Law 155A.32

	1. If an authorized practitioner prescribes a drug, the pharmacist may exercise professional judgment in the interest of the patient by providing a **therapeutic** substitution for dispensing and sale to the patient. 2. The pharmacist shall not provide a **therapeutic** substitution if "dispense as written" is indicated on the prescription. 3. The board shall adopt rules on proper recording and notification when a **therapeutic** substitution is made under this section.	Drug Product Selection – restrictions
Kentucky	Section 1. Dispensing. (1) A pharmacist may dispense a **therapeutic** equivalent drug product under the following conditions: (a) The ordering practitioner has indicated "formulary compliance approval" on the prescription, in one of the following ways: 1. In the practitioner's own handwriting; or 2. By checking a "formulary compliance approval" box on a preprinted form; (b) The pharmacist receives a formulary change as a consequence of the patient's third-party plan; and (c) The product designated as "preferred" by the third-party formulary is in the same **therapeutic** class as the prescribed drug. (2) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile: (a) That the pharmacist engaged in formulary compliance; and (b) The **therapeutic** equivalent drug product that was dispensed. Section 2. The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary **therapeutic** alternative.	KY Rule 201 KAR 2-280. Prescription dispensing for formulary compliance.
Maryland	C. **Therapeutic** Interchange. (1) A pharmacist may not perform a **therapeutic** interchange without the prior approval of the authorized prescriber except as provided in §C(2) of this regulation. (2) A pharmacist who provides a pharmacy service to a patient of a hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a resident of a comprehensive care or extended care facility, as defined in COMAR 10.07.02.01B, may perform a **therapeutic** interchange without the prior approval of the authorized prescriber if the governing body of the hospital, comprehensive care facility, or extended care facility has established procedures for **therapeutic** interchange.	MD Rule 10.34.10.01 Patient Safety and Welfare

	(3) This section does not permit any act not otherwise authorized by Health Occupations Article, Title 12, Annotated Code of Maryland.	
Nevada	1. The scope of services provided by a pharmacy must be consistent with the needs of the patients for medication as determined by the medical staff, managing pharmacist and other health care professionals involved in delivering or administering drugs in the hospital or correctional institution in which the pharmacy is located. 2. Pharmaceutical services may include, but are not limited to: (a) Interpreting orders for prescriptions and medication. (b) Compounding, dispensing, distributing, labeling and administering drugs and devices. (c) Monitoring drug therapy. (d) **Therapeutic** interchange. (e) Participating in evaluations of the uses of drugs and the selection of drug products. (f) Ensuring the proper and safe storage and distribution of drugs and devices, and the maintenance of proper records related thereto. (g) Providing information related to drugs, including, but not limited to, the proper dosages, hazards and the optimal use of drugs and devices. (h) Supervising pharmaceutical technicians and pharmaceutical technicians in training. (i) Conducting research. 3. As used in this section, "**therapeutic** interchange" means the dispensing of one drug in place of another pursuant to guidelines approved by an appropriate committee of the medical staff.	NV Rule 639.464 Scope of services in hospital or correctional institution
New Hampshire	(a) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug product prescribed by its trade or brand name may select a **therapeutic**ally equivalent drug product with the same established name, active ingredient, strength, quantity, and dosage form as the drug product identified in the prescription. (b) **Therapeutic**ally equivalent drugs shall include only those drug products listed in "Approved Prescription Drug Products with **Therapeutic** Equivalence Evaluations" Published by the United States Department of Health and Human Services, according to RSA 146-B:2, I, or any written notification or confirmation from the federal Food and Drug Administration (FDA) that a drug product is a **therapeutic**ally equivalent drug product. (c) The pharmacist shall not select an equivalent drug product: (1) If the prescriber handwrites "medically necessary" on the written prescription;	NH Rule Ph 703.05 Drug Product Selection

	(2) If when ordering a prescription orally, the prescriber specifies that the prescribed drug is medically necessary; or (3) If the prescription is electronically transmitted, the prescriber includes a statement on the face of the prescription indicating medically necessary. (d) The pharmacist shall not select an equivalent drug product unless its price to the purchaser or payor is less than the price of the prescribed drug product. (e) Unless the prescriber instructs otherwise, the label for every drug product dispensed shall include the product's trade or brand name, if any, or its established generic name and the name of the manufacturer, packer or distributor, using abbreviations such as the National Drug Code (NDC) number if necessary. In the interest of public health and safety, the pharmacist may, when dispensing a generic drug, include the brand name on the prescription label following the generic name. The brand name, however, shall be preceded or followed with the word "sub", indicating substituted for, or "I.C.", indicating interchanged for or “generic for”. (f) A pharmacist shall adapt drugs: (1) By changing the quantity of medication prescribed if: a. The prescribed quantity or package size is not commercially available; b. The change in quantity is related to a change in dosage form, strength, or **therapeutic** interchange; c. The change is intended to dispense up to the total amount authorized by the prescriber including refills; or d. The change extends a maintenance drug for the limited quantity necessary to coordinate a patient’s refills in a medication synchronization program; (2) By changing dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber’s directions are also modified to equate to an equivalent amount of drug dispensed as prescribed; (3) By completing missing information on a prescription if there is evidence to support the change; and (4) The adaptation is documented in the patient’s record. (g) A pharmacist may perform **therapeutic** substitutions if: (1) The pharmacist filling a prescription for a specific drug substitutes a drug in the same **therapeutic** class, the patient agrees to the substitution, and the substitution is made to replace a drug that is on back order ensures formulary compliance with the patient’s health insurance plan or in the case of an uninsured patient to the lower cost drug while maintaining safety; or	

	(2) The pharmacist is used by a long-term-care facility and the **therapeutic** interchange or a **therapeutic**ally equivalent selection for a patient, during the patient's stay at the facility, has been approved for the patient in accordance with written guidelines and procedures developed by the facility that in conjunction with the pharmacist and is current and readily available to the pharmacist at the pharmacy.	
Oregon	(55) "**Therapeutic** substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered. (1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and: (a) Is agreed to by one practitioner and one pharmacist; or (b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and **therapeutic**s committee, and one or more pharmacists. (2) A pharmacist shall engage in collaborative drug therapy management with a practitioner only under a written arrangement that includes: (a) The identification, either by name or by description, of each of the participating pharmacists; (b) The identification, by name or description, of each of the participating practitioners or group of practitioners; (c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement; (d) The types of decisions that the pharmacist is allowed to make, which may include: (A) A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case; (B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities; (C) A detailed description of the activities the pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to	OR Rule 855-006-0005. Definitions OR Rule 855-115-0315 Collaborative Drug Therapy Management

	the practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system; (D) Circumstances which will cause the pharmacist to initiate communication with the practitioner, including but not limited to the need for a new prescription order and a report of a patient's **therapeutic** response or any adverse effect. (e) Training requirement for pharmacist participation and ongoing assessment of competency, if necessary; (f) Quality assurance and periodic review by a panel of the participating pharmacists and practitioners; (g) Authorization by the practitioner for the pharmacist to participate in collaborative drug therapy; and (h) A requirement for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years. (3) The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request. (4) Nothing in this rule shall be construed to allow **therapeutic** substitution outside of the CDTM agreement.	
Rhode Island	1.5.24 **Therapeutic** Substitution A. **Therapeutic** substitutions by pharmacists are permitted in situations requiring compliance with a formulary prepared by the pharmacy and **therapeutic**s committee, and agreed to by the staff physicians of the facility: 1. In a hospital, licensed pursuant to R.I. Gen. Laws Chapter 23-17; or 2. In a nursing facility, medical institution, or hospice care facility with contracted pharmaceutical services pursuant to § 1.6.1 of this Part and licensed under R.I. Gen. Laws Chapter 23-17.	RI Rule 40-15-1.5. Pharmacies: Licensure Requirements
Vermont	… (b) A pharmacist may prescribe in the following contexts: (1) Collaborative practice agreement. A pharmacist may prescribe, for the patient or patients of a prescribing practitioner licensed pursuant to this title, within the scope of a written collaborative practice agreement with that primary prescriber.	VT Law 2023 Clinical pharmacy; prescribing

	(A) The collaborative practice agreement shall require the pharmacist and collaborating practitioner to contemporaneously notify each other of any change in the patient's pharmacotherapy or known medical status. (B) Under a collaborative practice agreement, a pharmacist may select or modify antibiotic therapy for a diagnosed condition under the direction of the collaborating practitioner. (2) State protocol. (A) A pharmacist may prescribe, order, or administer in a manner consistent with valid State protocols that are approved by the Commissioner of Health after consultation with the Director of Professional Regulation and the Board and the ability for public comment: (i) opioid antagonists; (ii) epinephrine auto-injectors; (iii) tobacco cessation products; (iv) tuberculin purified protein derivative products; (v) self-administered hormonal contraceptives, including subcutaneous depot medroxyprogesterone acetate; (vi) dietary fluoride supplements; (vii) for patients 18 years of age or older, vaccinations recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and administered consistently with the ACIP-approved immunization schedules, as may be amended from time to time; (viii) for patients five years of age or older, influenza vaccine, COVID-19 vaccine, and subsequent formulations or combination products thereof; (ix) in the event of a significant public health risk, an appropriate vaccine to mitigate the effects on public health after finding that existing channels for vaccine administration are insufficient to meet the public health need; (x) emergency prescribing of albuterol or glucagon while contemporaneously contacting emergency services; (xi) tests for COVID-19 for individuals by entities holding a Certificate of Waiver pursuant to the Clinical Laboratory Amendments of 1988 (42 U.S.C. § 263a). If a test for COVID-19, prescribed, ordered, or administered by a pharmacist in accordance with this section and the resulting State protocol incidentally detects influenza or human respiratory syncytial virus, a pharmacist shall advise the individual tested that the results indicate influenza or human respiratory syncytial virus infection and recommend to the individual to seek further care from an appropriate health care provider;	

	(xii) tests for SARS-CoV for asymptomatic individuals or related serology for individuals by entities holding a Certificate of Waiver pursuant to the Clinical Laboratory Amendments of 1988 (42 U.S.C. § 263a); and (xiii) emergency contraception. (B)(i) State protocols shall be valid if signed by the Commissioner of Health and the Director of Professional Regulation, and the Board of Pharmacy shall feature the active protocol conspicuously on its website. (ii) The Commissioner of Health may invalidate a protocol if the Commissioner finds that the protocol's continued operation would pose an undue risk to the public health, safety, or welfare and signs a declaration to that effect. Upon such a declaration, the Director shall remove the invalidated protocol from the Board website and shall cause electronic notice of the protocol's discontinuation to be transmitted to all Vermont drug outlets. (3) Accessory devices. A pharmacist may prescribe accessory-type devices, such as spacers, needles, and diabetic testing supplies, where clinically indicated in the judgment of the pharmacist. (4) Prescriber-authorized substitution. A prescribing practitioner licensed pursuant to this title may authorize a pharmacist to substitute a drug with another drug in the same **therapeutic** class that would, in the opinion of the pharmacist, have substantially equivalent **therapeutic** effect even though the substitute drug is not a **therapeutic** equivalent drug, provided: (A) the prescriber has clearly indicated that drug product substitution is permissible by indicating "**therapeutic** substitution allowed" or similar designation; (B) the drug product substitution is intended to ensure formulary compliance with the patient's health insurance plan or otherwise to minimize cost to the patient; (C) the patient's voluntary, informed consent is obtained in writing; and (D) the pharmacist or designee notifies the prescriber which drug was dispensed as a substitute within five days of dispensing. …	
Washington	(77) "**Therapeutic** substitution" means the act of dispensing an alternative drug that is believed to be **therapeutic**ally similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.	WA Rule 246-945-001 Definitions

	(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 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, or other drug prescribed to the patient to treat a serious mental illness, 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 24 weeks but no more than 48 weeks, in which case the pharmacist shall dispense the prescribed nonpreferred drug. (b) When a substitution is made under (a) of this subsection, the dispensing pharmacist shall notify the prescribing practitioner of the specific drug and dose dispensed. (2)(a) A state purchased health care program may impose limited restrictions on an endorsing practitioner's authority to write a prescription to dispense as written only under the following circumstances: (i) There is statistical or clear data demonstrating the endorsing practitioner's frequency of prescribing dispensed as written for nonpreferred drugs varies significantly from the prescribing patterns of his or her peers; (ii) The medical director of a state purchased health program has: (A) Presented the endorsing practitioner with data that indicates the endorsing practitioner's prescribing patterns vary significantly from his or her peers, (B) provided the endorsing practitioner an opportunity to explain the variation in his or her prescribing patterns to those of his or her peers, and (C) if the variation in prescribing patterns cannot be explained, provided the endorsing practitioner sufficient time to change his or her prescribing patterns to align with those of his or her peers; and (iii) The restrictions imposed under (a) of this subsection (2) must be limited to the extent possible to reduce variation in prescribing patterns and shall remain in effect only until such time as the endorsing practitioner can demonstrate a reduction in variation in line with his or her peers. (b) A state purchased health care program may immediately designate an available, less expensive, equally effective generic product in a previously reviewed drug class as a preferred drug, without first submitting the product to review by the pharmacy and **therapeutic**s committee established pursuant to RCW 70.14.050. (c) For a patient's first course of treatment within a **therapeutic** class of drugs, a state purchased health care program may impose limited restrictions on endorsing practitioners' authority to write a prescription to dispense as written, only under the following circumstances:	WA Law 69.41.190 Preferred drug substitution – Exceptions- Notice – Limited Restrictions

	(i) There is a less expensive, equally effective **therapeutic** alternative generic product available to treat the condition; (ii) The drug use review board established under WAC 388-530-4000 reviews and provides recommendations as to the appropriateness of the limitation; (iii) Notwithstanding the limitation set forth in (c)(ii) of this subsection (2), the endorsing practitioner shall have an opportunity to request as medically necessary, that the brand name drug be prescribed as the first course of treatment; (iv) The state purchased health care program may provide, where available, prescription, emergency room, diagnosis, and hospitalization history with the endorsing practitioner; and (v) Specifically for antipsychotic restrictions, the state purchased health care program shall effectively guide good practice without interfering with the timeliness of clinical decision making. Health care authority prior authorization programs must provide for responses within 24 hours and at least a 72 hour emergency supply of the requested drug. (d) If, within a **therapeutic** class, there is an equally effective **therapeutic** alternative over-the-counter drug available, a state purchased health care program may designate the over-the-counter drug as the preferred drug. (e) A state purchased health care program may impose limited restrictions on endorsing practitioners' authority to prescribe pharmaceuticals to be dispensed as written for a purpose outside the scope of their approved labels only under the following circumstances: (i) There is a less expensive, equally effective on-label product available to treat the condition; (ii) The drug use review board established under WAC 388-530-4000 reviews and provides recommendations as to the appropriateness of the limitation; and (iii) Notwithstanding the limitation set forth in (e)(ii) of this subsection (2), the endorsing practitioner shall have an opportunity to request as medically necessary, that the drug be prescribed for a covered off-label purpose. (f) The provisions of this subsection related to the definition of medically necessary, prior authorization procedures and patient appeal rights shall be implemented in a manner consistent with applicable federal and state law. (3) Notwithstanding the limitations in subsection (2) of this section, for refills for an antipsychotic, antidepressant, antiepileptic, or other drug prescribed to the patient to treat a serious mental illness, chemotherapy, antiretroviral, or immunosuppressive drug, or for the refill of an immunomodulator antiviral treatment for hepatitis C for which an established, fixed duration of therapy is prescribed for	

	at least 24 weeks by no more than 48 weeks, the pharmacist shall dispense the prescribed nonpreferred drug. (4) For the purposes of this section, “serious mental illness” means a mental disorder, as defined in the most recent edition of the diagnostic and statistical manual of mental disorders published by the American psychiatric association, that results in serious functional impairment that substantially interferes with or limits one or more major life activities.	

Appendix 2

MN Statute SF13-Art.2-Sec33 Therapeutic Interchange

Version Effective 5/28/2020 to 8/30/2021

Subdivision 1. Applicability during a peacetime emergency. This section applies during a peacetime emergency declared by the governor under Minnesota Statutes, section 12.31, subdivision 2, for an outbreak of COVID-19.
Subd. 2. Therapeutic interchange. Notwithstanding Minnesota Statutes, section 151.21, subdivision 7a, paragraph (a), a pharmacist may dispense a therapeutically equivalent and interchangeable prescribed drug or biological product, without having a protocol in place, provided:

(1) the drug prescribed is in short supply and the pharmacist is unable to obtain it from the manufacturer, drug wholesalers, or other local pharmacies;

(2) the pharmacist is unable to contact the prescriber within a reasonable period of time to get authorization to dispense a drug that is available;

(3) the pharmacist determines a therapeutically equivalent drug to the one prescribed is available and is in the same American Hospital Formulary Service pharmacologic-therapeutic classification;

(4) the pharmacist informs the patient as required in Minnesota Statutes, section 151.21, subdivision 7a, paragraph (b), and provides counseling to the patient, as required by the Board of Pharmacy rules, about the substituted drug;

(5) the pharmacist informs the prescriber as soon as possible that the therapeutic interchange has been made; and

(6) the therapeutic interchange pursuant to this section is allowed only until the expiration date under subdivision 3.

Subd. 3. Expiration. This section expires 60 days after the peacetime emergency specified in subdivision 1 is terminated or rescinded by proper authority.