COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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Tentative Agenda of Therapeutic Interchange Work Group Meeting

August 12, 2025

1:00PM

TOPIC **PAGES**

Call to Order of Work Group Meeting: Larry Kocot, JD, Chairman

- Welcome & Introductions
- Approval of Agenda

Call for Public Comment: The work group will receive public comment at this time. The work group will not receive comments on any regulation process for which a public comment period has closed or any pending disciplinary matters before a Board.

- Review Information included in Agenda Packet
  - SB745 3
  - Select Code sections regarding therapeutic equivalence, etc. 4-9
  - ASHP Guidelines on Pharmacy and Therapeutics Committee and Formulary System 10-21
  - National Association of Boards of Pharmacy Summary of States with Therapeutic Interchange 22-37
  - Excerpt of NABP Model Act 38-49
- Discussion
- Identify Next Steps

Adjourn

Therapeutic Interchange Work Group Participants

Chairman: Larry Kocot, JD, Board of Pharmacy

- Shannon Dowdy, PharmD, Vice-Chairman, Board of Pharmacy
- Ling Yuan, PharmD, Member, Board of Pharmacy
- Derek Webb, PharmD, Member, Board of Pharmacy
- Bill Hutchens, MD, Member, Board of Medicine
- Randall Mangrum, DNP, RN, Deputy Executive Director for Advanced Practice, Board of Nursing
- Sharon Gatewood, PharmD, Past-President, Virginia Pharmacy Association
- Joshua Crawford, PharmD, Legislative Committee Co-Chair, Virginia Society of Health-System Pharmacists
- Jason Spouse, PharmD, National Association of Chain Drug Stores
- Joanne Dial, PharmD, Pharmacy Operations Specialist III, Controls, Kaiser Permanente
- Clark Barrineau, Vice President of Government Affairs and Public Policy, Medical Society of Virginia
- Craig Conners, Vice President Payor Relations & Strategy, Virginia Hospital and Healthcare Association
- Doug Gray, Executive Director, Virginia Association of Health Plans
- Johnny Garcia, PharmD, Pharmaceutical Care Management Association
- Jared Calfee, Associate State Director for Advocacy and Outreach, American Association of Retired Persons
- Jamie Smith, PharmD, Clinical Pharmacy Services Manager, Department of Corrections
- JoeMichael Fusco, PharmD, Pharmacy Operations Manager, Department of Medical Assistance Services
- Stephanie Wheawill, PharmD, Director, Division of Pharmacy Services, Department of Health
- Erin Barrett, JD, Director of Legislative and Regulatory Affairs, Department of Health Professions
- Arne Owens, MS, Director, Department of Health Professions
- Jennifer Deschenes, JD, MS, Deputy Executive Director, Board of Medicine
- Caroline Juran, RPh, Executive Director, Board of Pharmacy
- Sorayah Haden, Executive Assistant, Board of Pharmacy

CHAPTER 502

An Act to direct the Board of Pharmacy to convene a work group to review and make recommendations related to the current authority of pharmacists to initiate therapeutic interchange; report.

[S 745]

Approved March 24, 2025

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Board of Pharmacy shall 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 shall 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.*

Select Sections of Code of Virginia referencing “therapeutically equivalent”, “pharmacy and therapeutic committee”, or something akin

§ 54.1-3401
"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

§ 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.

In the case of an oral prescription, the prescriber's oral dispensing instructions regarding substitution shall be followed.

B. Prescribers using prescription blanks printed in compliance with Virginia law in effect on June 30, 2003, having two check boxes and referencing the Virginia Voluntary Formulary, may indicate, until July 1, 2006, that substitution is not authorized by checking the "Dispense as Written" box. If the "Voluntary Formulary Permitted" box is checked on such prescription blanks or if neither box is checked, a pharmacist may dispense a therapeutically equivalent drug product pursuant to such prescriptions.

C. If the pharmacist dispenses a drug product other than the brand name prescribed, he shall so inform the purchaser and shall indicate, unless otherwise directed by the prescriber, on both his permanent record and the prescription label, the brand name or, in the case of a therapeutically equivalent drug product, the name of the manufacturer or the distributor. Whenever a pharmacist dispenses a therapeutically equivalent drug product pursuant to a prescription written for a brand-name product, the pharmacist shall label the drug with the name of the therapeutically equivalent drug product followed by the words "generic for" and the brand name of the drug for which the prescription was written.

D. When a pharmacist dispenses a drug product other than the drug product prescribed, the dispensed drug product shall be at a lower retail price than that of the drug product prescribed. Such retail price shall not exceed the usual and customary retail price charged by the pharmacist for the dispensed therapeutically equivalent drug product.

2003, c. 639.

§ 65.2-603.1. Use of therapeutically equivalent drug products required.
A. As used in this section, "therapeutically equivalent drug products" means drug products that (i) contain the same active ingredients, (ii) are identical in strength or concentration, dosage form,

and route of administration, and (iii) are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of Approved Drug Products with Therapeutic Equivalence Evaluations, known as the Orange Book.

B. Notwithstanding the provisions of § 54.1-3408.03, and except as provided in subsection C, any pharmacist filling a prescription for medication for a workers' compensation claimant shall dispense a therapeutically equivalent drug product for the prescribed name-brand drug product. If a therapeutically equivalent drug product does not exist or the usual and customary retail price charged by the pharmacist for the therapeutically equivalent drug product is higher than that of the prescribed name-brand drug product, the pharmacist shall dispense the prescribed name-brand drug product.

C. A prescriber may specify on the prescription "brand medically necessary" if there is a medical reason why the claimant should not have the prescription filled with a therapeutically equivalent drug product. A request by the claimant that a name-brand drug product be prescribed shall not constitute a sufficient reason under this section for the prescriber to specify "brand medically necessary" on the prescription. If the prescriber specifies on the prescription "brand medically necessary," the pharmacist shall fill the prescription with the name-brand drug product prescribed. If the prescriber calls the prescription in to the pharmacy by telephone and verbally tells the pharmacist "brand medically necessary," the pharmacist shall note on the prescription that the prescriber stated "brand medically necessary" and then fill the prescription with the name-brand drug product prescribed. The cost of any medication prescribed by any authorized treating physician and covered pursuant to this section to treat injuries or diseases that result from a compensable claim shall not be the responsibility of the claimant unless the claimant obtained the prescription through fraud.

D. An act in compliance with the provisions of this section shall not be deemed to be a prohibited act under § 54.1-3457.

2009, cc. 333, 559.

§ 38.2-3407.9:01. Prescription drug formularies.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs on an outpatient basis may apply a formulary to the prescription drug benefits provided by the insurer, corporation, or health maintenance organization if the formulary is developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics committee, a majority of whose members are actively practicing licensed pharmacists, physicians and other licensed health care providers.

B. If an insurer, corporation, or health maintenance organization maintains one or more closed drug formularies, each insurer, corporation, or health maintenance organization shall:

1. Make available to participating providers and pharmacists and to any nonpreferred or nonparticipating pharmacists as described in §§ 38.2-3407.7 and 38.2-4312.1, the complete, current drug formulary or formularies, or any updates thereto, maintained by the insurer, corporation, or health maintenance organization, including a list of the prescription drugs on the formulary by major therapeutic category that specifies whether a particular prescription drug is preferred over other drugs;
2. Establish a process to allow an enrollee to obtain, without additional cost-sharing beyond that provided for formulary prescription drugs in the enrollee's covered benefits, a specific, medically necessary nonformulary prescription drug if the formulary drug is determined by the insurer, corporation, or health maintenance organization, after reasonable investigation and consultation with the prescribing physician, to be an inappropriate therapy for the medical condition of the enrollee. The insurer, corporation or health maintenance organization shall act on such requests within one business day of receipt of the request; and

3. Establish a process to allow an enrollee to obtain, without additional cost-sharing beyond that provided for formulary prescription drugs in the enrollee's covered benefits, a specific, medically necessary nonformulary prescription drug when the enrollee has been receiving the specific nonformulary prescription drug for at least six months previous to the development or revision of the formulary and the prescribing physician has determined that the formulary drug is an inappropriate therapy for the specific patient or that changing drug therapy presents a significant health risk to the specific patient. After reasonable investigation and consultation with the prescribing physician, the insurer, corporation or health maintenance organization shall act on such requests within one business day of receipt of the request. For purposes of this subsection, substituting the generic equivalent drug, which has been approved by the U.S. Food and Drug Administration, for a branded version of such drug shall not constitute a change in drug therapy.

C. Each insurer, corporation, or health maintenance organization that applies a formulary to the prescription drug benefits provided as set forth in subsection A shall provide to each affected group health benefit plan policyholder or contract holder or each affected individual health benefit plan policyholder or contract holder not less than 30 days' prior written notice of a modification to a formulary that results in the movement of a prescription drug to a tier with higher cost-sharing requirements. This section does not apply to modifications that occur at the time of coverage renewal.

1999, cc. 643, 649; 2000, c. 873; 2014, cc. 272, 297.

§ 54.1-3442.02. Prescription drug price transparency.
A. As used in this section:

"Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under 42 U.S.C. § 262(k)(3).

"Brand-name drug" means a prescription drug approved under 21 U.S.C. § 355(b) or 42 U.S.C. § 262.

"Generic drug" means a prescription drug approved under 21 U.S.C. § 355(j) or 42 U.S.C. 262(k).

"New prescription drug" means a drug or biological product receiving initial approval under an original new drug application pursuant to 21 U.S.C. § 355(b) or under a biologics license application under 42 U.S.C. § 262.

"Nonprofit data services organization" has the same meaning as set forth in § 32.1-23.4.
"Pharmacy benefits manager" has the same meaning as set forth in § 38.2-3407.15:4.
"Wholesale acquisition cost" has the same meaning as set forth in 42 U.S.C. § 1395w-3a(c)(6)(B).

B. Every manufacturer shall report annually by April 1 to the nonprofit organization with which the Department of Health has entered into a contract or agreement pursuant to § 32.1-23.4, for each (i) brand-name drug and biologic other than a biosimilar with a wholesale acquisition cost of $100 or more for a 30-day supply or a single course of treatment and any increase of 15 percent or more in the wholesale acquisition cost of such brand-name drug or biologic over the preceding calendar year; (ii) biosimilar with an initial wholesale acquisition cost that is not at least 15 percent less than the wholesale acquisition cost of the referenced brand biologic at the time the biosimilar is launched; and (iii) generic drug with a price increase that results in an increase in the wholesale

acquisition cost of such generic drug that is equal to 200 percent or more during the preceding 12-month period, when the wholesale acquisition cost of such generic drug is equal to or greater than $100, annually adjusted by the Consumer Price Index for All Urban Consumers, for a 30-day supply, with such increase defined as the difference between the wholesale acquisition cost of the generic drug after such increase and the average wholesale acquisition cost of such generic drug during the previous 12 months, the following information:
1. The name of the prescription drug;

2. Whether the drug is a brand name or generic;

3. The effective date of the change in wholesale acquisition cost;

4. Aggregate, company-level research and development costs for the most recent year for which final audit data is available;

5. The name of each of the manufacturer's new prescription drugs approved by the U.S. Food and Drug Administration within the previous three calendar years;

6. The name of each of the manufacturer's prescription drugs that, within the previous three calendar years, became subject to generic competition and for which there is a therapeutically equivalent generic version; and

7. A concise statement regarding the factor or factors that caused the increase in wholesale acquisition cost.

C. A manufacturer's obligations pursuant to this section shall be fully satisfied by the submission to the nonprofit data services organization with which the Department of Health has entered into a contract pursuant to § 32.1-23.4 of information and data that a manufacturer includes in the manufacturer's annual consolidation report on Securities and Exchange Commission Form 10-K or any other public disclosure.
2021, Sp. Sess. I, c. 304.

§ 54.1-3457. Prohibited acts.
The following acts shall be prohibited:

1. The manufacture, sale, delivery, holding, or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded.

2. The adulteration or misbranding of any drug, device, or cosmetic.

3. The receipt in commerce of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

4. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of § 54.1-3421.
5. The dissemination of any false advertisement.

6. The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record.

7. The giving of a false guaranty or undertaking.

8. The removal or disposal of a detained article in violation of § 54.1-3459.
9. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.

10. The forging, counterfeiting, simulating, or falsely representing, or without proper authority using of any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this chapter or of the federal act.

11. The using by any person to his own advantage, or revealing, other than to the Board or its authorized representative or to the courts when relevant in any judicial proceeding under this chapter of any information acquired under authority of this chapter concerning any method or process which as a trade secret is entitled to protection.

12. The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under § 54.1-3421, or that such drug complies with the provisions of such section.
13. In the case of a drug distributed or offered for sale in this Commonwealth, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. This subdivision shall not be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

14. Placing or causing to be placed upon any drug or device or container, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by this section or making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

15. The doing of any act that causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

16. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the permission of the person ordering or prescribing, except as provided in § 54.1-3408.03 relating to dispensing of therapeutically equivalent drugs.
17. Dispensing or causing to be dispensed a biosimilar in place of a prescribed biological product or brand of biological product, except as provided in § 54.1-3408.04 related to dispensing of interchangeable biosimilars.
1970, c. 650, § 54-524.85; 1988, c. 765; 2003, c. 639; 2013, cc. 412, 544.

ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System

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Keywords: formulary, formulary system, pharmacy and therapeutics committee, medication-use evaluation, quality improvement, pharmacoeconomics

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Purpose

These guidelines outline important considerations and recommend processes for formulary system management within the context of a hospital or health system. Pharmacist responsibilities and roles in managing the formulary system in partnership with other healthcare professionals are embedded throughout. These guidelines also provide assistance to pharmacists in the organization and operation of the pharmacy and therapeutics (P&T) committee or equivalent body, evaluation of medications for formularies and consideration of rational use of medications, and development and implementation of strategies to optimize medication use through the formulary system. A glossary of terms is provided in the Appendix A.

Formulary and formulary system

A *formulary* is a continually updated list of available medications and related information, representing the clinical judgment, resulting from a review of the clinical evidence, of physicians, pharmacists, and other clinicians in the diagnosis, prophylaxis, or treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. A *formulary system* is the ongoing process through which a healthcare organization establishes policies regarding the use of drugs, therapies, and drug-related products, including medication delivery devices, and identifies those that are most medically appropriate, safe, and cost-effective to best serve the health interests of a given patient population.[1] Formulary systems are used in many different settings, including hospitals, acute care facilities, home care settings, and long-term care facilities, as well as by payers such as Medicare, Medicaid, insurance companies, and managed care organizations. Many organizations have policy statements on the use of formularies.[2-8] These guidelines focus on the use of formulary systems in hospitals and health systems, in both inpatient and outpatient settings.

Evolution of formularies

Formulary systems have evolved over time. Early formularies began as rudimentary drug lists developed by the military as early as the Revolutionary War and came into more widespread use during the 1950s.[9] Pharmacists, in conjunction with their organizations, developed policies to dispense generic equivalent drugs when a specific brand-name drug was prescribed. In the late 1950s, the ASHP minimum standard for pharmacies in hospitals called for the implementation of a formulary system.[10]

During the 1960s, the concept of a hospital formulary continued to grow. Hospitals developed policies that authorized pharmacists to make generic interchanges in an institutional formulary system based on prior consent from physicians.[11] ASHP and the American Hospital Association (AHA) issued joint statements on the legality of formularies.[12,13] The American Medical Association (AMA) and the American Pharmaceutical (later Pharmacists) Association (APhA) subsequently joined with ASHP and AHA to revise the statements.[14] In 1965, two significant events occurred: (1) Medicare listed formularies as a reimbursement eligibility requirement[15] and (2) the Joint Commission on Accreditation of Hospitals (now known as the Joint Commission) included an active P&T committee in its accreditation requirements.[16] Even with these actions, formularies were typically no more than lists of drugs stocked by the pharmacy.

By the 1980s, literature describing the clinical and economic value of well-designed formularies emerged. Evidence from the hospital setting was published first, soon followed by

evidence from the ambulatory care environment.[11] This literature led to more widespread acceptance of formularies by providers, payers, and industry.[5,17]

Today, formulary systems are considered an essential tool for healthcare organizations to foster interprofessional efforts to promote the rational use of medications. Formularies have grown from simple drug lists to comprehensive systems of medication-use policies intended to ensure safe, appropriate, and cost-effective use of pharmaceuticals in patient care.[18]

P&T committee

The P&T committee is generally the medical staff committee responsible for managing the formulary system. The P&T committee provides an evaluative, educational, and advisory service to the medical staff and organizational administration in all matters pertaining to the use of available medications. The P&T committee should be responsible for overseeing policies and procedures related to all aspects of medication use within an institution.

The P&T committee's organization and authority should be outlined in the organization's medical staff bylaws, medical staff rules and regulations, and other organizational policies, as appropriate. The description of organization and authority becomes even more important as healthcare facilities merge into larger health systems.

Typically, P&T committee member appointments and voting rights are made based on guidance from the medical staff and other affected stakeholders. Voting members may include facility medical staff, other prescribers, pharmacists, nurses, and administrators, and are a representative sample of the organization. If the scope of the P&T committee includes a health system, site representation needs to be addressed to ensure equitable input and voting authority from each facility. Additional supporting P&T committee members may include quality improvement managers, medication safety leaders, informaticists, other healthcare professionals and staff who participate in the medication-use process, and patient and family engagement advisors.

The P&T committee should have the following administrative components in place to maximize meeting effectiveness:

- Charter
- Role of the P&T secretary and/or formulary manager
- Committee and subcommittee(s) responsibility and scope
- Process to track attendance
- Definition of quorum
- Process to allow (or disallow) delegation of vote
- Process to appeal committee decisions
- Defined term limits for members
- Process for identifying, disclosing, addressing, and reporting conflicts of interest (COIs)
- Policy and procedures
- Approach to voting, including roll call votes to ensure transparency
- Scope of committee responsibility (eg, specific site or entire system; inpatient or outpatient sites; drugs, devices, and biologics)
- Process for managing minutes, agendas, record keeping, and communication of decisions made

Other responsibilities of the P&T committee include medication-use evaluation (MUE), adverse drug event monitoring and reporting, medication error prevention, medication safety, and development of clinical care plans and medication management initiatives (eg, delegation and practice protocols, restrictions, guidelines and clinical pathways). Information about these activities is available in ASHP guidelines on the topics.[19-22]

Oversight of a formulary system and the capacity to make appropriate formulary decisions requires consideration of patient care factors and a thorough, unbiased review of the biomedical literature. Voting members should be required to provide COI statements to avoid actual or perceived interference with evidence-based decisions.[23] Some healthcare organizations exclude healthcare professionals with COIs from P&T committee membership, whereas others allow participation in committee discussions but prohibit voting on particular items. Practitioners requesting additions or changes to the formulary should also be required to disclose financial relationships with pharmaceutical companies, payers and insurance companies, and other potential COIs to the P&T committee. Management of COI should be specified in organizational policies and procedures.

Managing the formulary system

Health systems should develop, maintain, and implement a formulary management process. This evidence-based process should not be based solely on economic factors. The formulary system should have aspects of financial stewardship incorporated and be standardized within integrated health systems when standardization leads to improved patient outcomes, safety, and cost-effectiveness. Decisions on the management of a formulary system should be founded on the evidence-based clinical, ethical, legal, social, logistical, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care.[24-26] The process must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals, as well representatives with expertise in finance, law, and informatics.

Management of a formulary system is a significant component of a healthcare organization's ongoing medication-use policy development process. A comprehensive, well-maintained formulary is tailored to the organization's patient care needs, policy framework, and medication-use systems while ensuring alignment with medication management standards of accrediting organizations.[27]

A well-managed formulary system ensures a close relationship among the organization's medication-use policies, the therapies offered by the organization, and the medications routinely stocked in the pharmacy. A formulary also identifies those medications that are most medically appropriate and cost-effective to best serve the health interests of the health system's patient population. The P&T committee should review all medications (see Appendix A) used in the health system. These may include alternative remedies (herbals and supplements), nonprescription drugs, blood derivatives, contrast media, and other diagnostic and treatment agents.[27] Institutional policies may need to be created for P&T committee evaluation of agents not approved by the Food and Drug Administration (FDA) (eg, herbal supplements).

The formulary system should review and approve all policies related to the medication-use process; all medication-use policies, regardless of their origination, should flow through the P&T committee. The organization's medical staff leadership (ie, the body to which the P&T committee reports) should complete the final policy approval. Policy review and revision should occur as new information becomes available and at regularly established intervals (eg, annually). The organization should have medication-use policies that address the following:

- How medications are requested for addition to or deletion from the formulary
- How medications are reviewed for addition to or deletion from the formulary, including who performs the reviews
- How and when drug class reviews are conducted
- The process for developing, implementing, and monitoring medication-use guidelines
- Methods and policies for ensuring the safe procurement, prescribing, distribution, administration, and monitoring of medications
- Methods for selection of suitable manufacturers for specific medications (ie, the pharmacy department is responsible for specifications for the quality, quantity, and source of supply of all medications, chemicals, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients)[28]
- The process for using nonformulary agents within the hospital and health system
- The process for managing radiopharmaceuticals
- The process for managing drug product shortages
- The process for developing an organization or health system–specific MUE plan
- Policies regarding specific medication-use processes (eg, procurement, prescribing, distribution, administration, monitoring, automation, and technology)
- The process for disseminating medication-use policies and how users will be educated regarding the process
- Process for accountability over medication delivery devices (eg, infusion pumps, dose error reduction software, intranasal atomizers)
- Consideration of medication access through prior authorization processes and patient assistance programs
- Implementation of P&T committee decisions into the electronic health record (EHR)

A formal process to review medication-use policies should be in place. This process may include the use of expert panels or subcommittees of the P&T committee. Expert panels or subcommittees should serve in an advisory role to the P&T committee, and their membership should include recognized experts in their areas of practice. The P&T committee may also find subcommittees that address specific therapeutic areas to be beneficial (eg, pediatrics, antimicrobial, oncology therapy, cardiovascular, adverse drug reaction, pharmacogenomics, or biotechnology subcommittees). Panels and subcommittees are helpful in applying clinical study results to specific patient populations and developing recommended strategies for the safe and effective use of medications. Subcommittee and panel members can help educate groups of clinicians, who ultimately drive prescribing behaviors, about significant formulary changes. User groups, representing those primarily affected by the policy, may also be helpful.

The P&T committee should have formal interactions (ie, communication lines) with other committees whose functions may affect the medication-use process. These committees would include those responsible for developing tools to facilitate medication use (eg, forms or order set review committee, computerized provider order entry committee), those concerned with safety or performance improvement (eg, quality improvement or patient safety committees), those involved in developing patient care policies (eg, medical and nursing committees), those involved with investigational medications (eg, investigational review boards), and other committees whose actions may affect medication use (eg, nutrition, equipment and supply, and finance committees or patient and family engagement advisors). Recommendations from other committees, subcommittees of the P&T committee, expert panels, and others should be submitted to the P&T committee for review. P&T committee decisions on recommendations should be communicated to the recommending group in a timely fashion.

Finally, the role of pharmaceutical company representatives and medical science liaisons in a healthcare organization should be carefully considered. Organizational guidelines should define appropriate relationships and interactions with such individuals. At a minimum, these guidelines should address the provision of pharmaceutical samples, indirect or direct funding support, and educational programming regarding formulary and nonformulary

medications. Applications for formulary additions should be initiated and completed independently by the requesting healthcare provider and not by an industry representative or vendor. Refer to ASHP's Guidelines on Pharmacists' Relationships with Industry for more information on appropriate interactions with industry.[29]

Evaluating medications for inclusion in the formulary

The P&T committee should use a structured, evidence-based process in the evaluation of medications for formulary consideration. The P&T committee should be provided with information that reflects a thorough, accurate, and unbiased review and analysis of the evidence available in the scientific literature. The evaluation process should encourage objective consideration of clinical and care delivery information, facilitate communication, foster positive patient outcomes, and support safe and effective medication ordering, dispensing, administration, and monitoring. Decisions made by the P&T committee should support improved patient care outcomes across the continuum of care, including considerations regarding patient access to medications upon discharge.

Evidence-based evaluation. Evidence-based medicine is a systematic approach to the evaluation of biomedical literature and application to clinical practice and should be applied to formulary decision-making for medication product selection.[25] Evidence-based decision-making standardizes and improves the quality of patient care and promotes cost-effective prescribing.[25,26] To practice evidence-based medicine, practitioners must be proficient in retrieving, evaluating, and applying the biomedical literature to clinical practice. Inclusion of a medication on a health system's formulary or the adoption of a medication-use guideline should reflect an evidence-based evaluation.

Evidence-based decision-making incorporates the systematic approach to reviewing, evaluating, and applying the biomedical literature to guide formulary decisions. Various types and strengths of evidence (eg, randomized clinical trials, meta-analyses, case reports, association consensus statements) may be useful in the decision-making process. Although different types of evidence are available for application, those with stronger evidence should be used to drive formulary decisions (eg, meta-analyses, randomized controlled trials). Other types of evidence have a role in the decision-making process, however, and may be appropriate when stronger evidence is not available. Observational studies (ie, case-control and cohort studies), case reports, and consensus opinions may be valuable even when stronger evidence is available. Some organizations find it useful to grade evidence when evaluating formulary requests; several tools are available for this purpose.[30-34]

Published evidence and expert opinion are not the only resources available to aid in the formulary decision-making process. Internal data and prescribing and outcomes information may be helpful in formulary decision-making. When published data are not available, it may be appropriate to incorporate expert opinion into the review process. Experts in practice areas sometimes have access to unpublished data or reports that may offer insight into difficult formulary decisions.

The formulary decision-making process should be guided by an independent review of evidence published in the biomedical literature, application of expert opinion, and use of internal data and benchmarking programs (see Appendix B for a description of the 4 major types of reviews used in such evaluations). If a P&T committee uses medication dossiers prepared by a pharmaceutical manufacturer, it should do so with the utmost caution, since the objectivity of these documents may be challenged.

Information used in the formulary decision-making process should be provided to the P&T committee in a written document with a standard format (eg, a drug monograph, drug review, drug-evaluation document).[35] All information provided in the drug-evaluation document should be referenced to the evidence or identified as a conclusion supported by evidence. Any areas of consensus recommendations or opinion should be clearly identified.

Formulary status recommendations (eg, from drug information services or expert groups) may be included in the drug-evaluation document. Recommendations should consider the formulary status (addition or rejection) of a medication, as well as the need for restrictions, educational efforts, or policies and procedures to ensure safe and appropriate use within the health system.

Pharmacoeconomic assessments. Rigorous pharmacoeconomic evaluations can and should be conducted in some cases when reviewing new medications. These evaluations should explicitly state the perspective of the analysis (eg, patient, healthcare provider, payer) and should include consideration of all costs and consequences relevant to that perspective. When new medications being considered are found to be therapeutically equivalent to existing alternatives (ie, having equivalent efficacy and safety), then the cost-minimization approach is appropriate. In these circumstances, it is important to consider costs associated with the medication and non–medication-related costs (eg, costs of administration, monitoring, prolonged hospital stay, operational costs, and laboratory test monitoring; costs to patients and providers).

While cost-effectiveness analysis (evaluating the incremental difference in investment necessary to produce an incremental difference in clinical outcome) is another potentially useful analytic approach, it is not often used for formulary decision-making because of its complexity and need for strong evidence or data. The academic value of this approach lies in its ability to show how little (or how much) must be spent to achieve a particular margin of clinical advantage when comparing an alternative that is more expensive but safer or more efficacious. No

standards currently exist to determine what cost is reasonable for a given improvement in outcome; however, it is unreasonable to recommend alternatives of lower quality simply to achieve cost savings. This approach can be used to demonstrate how a decrease in clinical outcomes associated with the use of a less expensive agent can be offset by investing the savings achieved in other interventions that produce even greater total benefits. When evaluating cost-effectiveness, it is important to consider the site of care for administration of the drug.

Cost-utility evaluations (evaluating the incremental difference in investment necessary to produce an incremental difference in quality-of-life-adjusted clinical outcome [eg, incremental cost per quality-adjusted life-years gained for one medication vs another]) may also be beneficial by serving to reflect patient preference in formulary decision-making. However, the same concerns related to the use of cost-effectiveness evaluations apply to this approach.[36-38]

Decision analysis models incorporating local data can be employed when published pharmacoeconomic data are limited or unavailable. Probabilities for each outcome can be extracted from the published literature or drawn from local data sources, which would provide a more relevant local perspective on outcomes. Costs associated with medications and outcomes should reflect those of the healthcare system.

Pharmacoeconomic analyses published in the medical literature or provided in the manufacturer's formulary dossier should be analyzed carefully before being included as part of the review process. Particular attention should be paid to the assumptions made in these studies. In many situations, assumptions made to simplify economic studies are not valid in particular institutions. Institution-specific costs are often different from the costs used in published studies, and local data should be used when incorporating their results into medication reviews.[39,40]

Even if a formal pharmacoeconomic evaluation is not included in a drug review document, a financial evaluation must be conducted, including consideration of site of care, non–medication-related costs, and financial consequences to the pharmacy and to the organization as a whole.

Formulary exceptions. Exclusion of a medication from a formulary may affect coverage of and access to the medication. In a closed formulary system, for example, only medications listed on the formulary are covered under the patient's drug benefit. Regardless of health-system setting, the formulary system should include an exception process that provides prescribers and patients with timely access to medications that are not on the formulary but are medically necessary for the care of the patient. The underlying principle for such a process is that unique patient needs may not be satisfied by use of the formulary medications. The formulary exception process should generate information on nonformulary medication use that will enable the P&T committee to evaluate trends in such use. Criteria for approval of nonformulary medications should be developed (eg, allergy to or therapeutic failure of formulary alternative, condition not treatable by formulary medications) and guidelines for use should be considered for nonformulary medications if they carry patient safety risks, have a Risk Evaluation and Mitigation Strategy (REMS), are expensive, and require complicated preparation.

Subformularies. Depending on state regulations, subformularies may be developed and maintained, using the same evidence-based process, to provide lists of appropriate and approved medications for furnishing by nonphysician providers or to specific patient subsets, such as Medicare patients. Health systems must follow specific rules and regulations provided under the Medicare Modernization Act of 2003 in their evaluation and inclusion of medications in a Medicare formulary for those medications to be covered.[41]

Strategies for managing medication use

Common strategies for managing medication use via the formulary include use of generic drugs, biosimilars, and specialty medications; therapeutic interchange; guided-use policies, clinical practice guidelines; and MUE.

Generic drugs. Optimizing the number of medication entities and products available from the pharmacy can produce substantial patient care and financial benefits. These benefits are greatly increased through the use of generic equivalents (drugs considered bioequivalent by FDA [ie, AB-rated drug products[42]]). The use of generic equivalents is encouraged in order to provide the best possible care at an affordable cost. Use of generic drugs that have been deemed bioequivalent by FDA does not require review or approval by the P&T committee, although a review of all new generic medications for key safety issues (eg, look-alike, sound-alike concerns) should be conducted to prevent medication errors when possible. For some drug categories, such as those with a narrow therapeutic range, a more thorough evaluation of the bioequivalency data and approval of experts or the P&T committee should be considered before implementing a generic substitution.

The P&T committee should establish policies and procedures governing the dispensing of generic equivalents when branded products are ordered. These policies and procedures should include the following points:

- The pharmacist is responsible for selecting from available generic equivalents those drugs to be dispensed pursuant to a prescriber's order for a particular medication.
- The prescriber has the option, at the time of prescribing, to specify the brand or supplier of the drug to be dispensed for that particular medication order if considered clinically justified.
- The prescriber's decision should be based on pharmacologic or therapeutic considerations (or both) relative to that patient.

Biosimilars. A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.[43] Several entities have been approved as biosimilars by FDA, and inclusion of these products on formulary should be considered as a strategy for management of the medication-use system. Biosimilars are not generically equivalent to the reference product, so the P&T committee should be involved in the decision to include these products on formulary. The implications for patients must also be considered, including legal and regulatory restrictions, coverage and reimbursement models of payers, differences in clinical indications or activity between the reference product and the biosimilar, and contractual obligations.

There are several considerations when evaluating biosimilars. When there are multiple biosimilars available for the same reference product, a close review of indications for each of the biosimilars should occur, as the indications that each biosimilar has may differ compared to each other and the reference product. FDA can deem a biosimilar as interchangeable, however, even if a product does not have this status noted in its labelling. Available switching data should be reviewed closely to determine whether patients currently receiving treatment with the reference product can be switched to the biosimilar. In instances in which FDA has determined a biosimilar product to be interchangeable, state regulations should be reviewed to determine actions required by the pharmacist when dispensing a biosimilar with an interchangeable status. In instances in which an institution may elect to have both a reference product and a biosimilar on formulary, careful attention should be paid to how these are built in the EHR to ensure the appropriate product is utilized.

Therapeutic interchange. Therapeutic interchange is the authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines, policies, or protocols within a formulary system.[1,44] Drugs appropriate for therapeutic interchange are drug products with different chemical structures that are expected to have similar therapeutic effects and safety profiles when administered to patients in therapeutically equivalent doses. Therapeutic interchange provides pharmacists with the authorization to use a formulary therapeutic alternative in place of a nonformulary medication or a nonpreferred formulary medication without having to contact the prescriber. Ideally, therapeutic interchanges are built into the EHR to allow for seamless substitution of formulary products. A process should be established for when the prescriber wishes to opt out of the interchange. Adequate educational initiatives should be undertaken to ensure that everyone affected (prescribers, patients, pharmacists, nurses, and other healthcare professionals) is notified of the therapeutic interchange.

Guided-use strategies. Medications may be added to the formulary with additional processes in place to guide the use of the medications to improve therapeutic outcomes, prevent adverse events, or reduce costs. All guidelines for use for both on- and off-label indications should be developed using evidence-based decisions, based on the current medical literature.[45] Examples of strategies to help guide the use of medications may include the following.

Established-use criteria. Patients must meet the established criteria before the medication is dispensed. A process should be developed to cover situations in which the patient does not meet the established criteria but the medication is nevertheless determined to be medically necessary. This strategy may also be useful when medications are in short supply.

Restricting drug use by specialty service. A specific service must approve the use of the drug before dispensing. This strategy can be used when inappropriate use or severe adverse effects may occur, and it can also be employed for antimicrobial agents when inappropriate use or overuse can result in resistant organisms and pose a danger to the general patient population or the public. Alternatively, ordering of a specific medication may be limited to a specific group of prescribers (eg, restricting use of chemotherapy agents to oncologists).

Designating medications for use in specific areas. Such policies can be helpful when administration of a medication requires special equipment or staff with particular skills to use the medication safely (eg, limiting neuromuscular blockers to operating rooms and critical care areas).

Approval of medical director (or designee) before drug use. This strategy is particularly appropriate when the P&T committee has reviewed a high-cost medication and determined that the drug has little or no role in the care of patients at that organization but a prescriber would like to use the medication on a nonformulary basis. This strategy may also be used as an approval pathway for medications requested for use outside of established criteria outlined in the formulary.

Clinical practice guidelines. Clinical practice guidelines are developed and disseminated by national and international organizations, but they can also be developed locally. Whether the medication formulary is a reflection of existing clinical practice guidelines in a particular organization or vice versa, it is critical that the guidelines and formulary are consistent. If a specific medication is recommended by a clinical practice guideline, it should in the majority of cases be on the formulary. As formulary changes are made, agents may need to be removed from or replaced in existing guidelines. Guidelines should avoid recommending use of nonformulary medications, and they can be useful in discouraging nonformulary medication use and guiding the appropriate use of formulary products when necessary.

Guidelines are frequently developed to address complex or particularly expensive medication therapies. However, complicated specialty therapies that will affect the care of very

few patients may not justify the time and resources necessary to develop and maintain a guideline. Guidelines may be medication specific or disease oriented and may overlap in their scope of coverage.

The development of a clinical practice guideline should begin with the synthesis of all available biomedical evidence addressing the guideline topic. In many cases, guidelines from other organizations, both national and local, can be used as a starting point for development. The subsequent consensus process, eliciting feedback and input from local stakeholders, is critical. Data from the organization should be used to make informed decisions during the consensus process. After the consensus process is completed, the guideline should be reviewed and approved by the P&T committee.

The dissemination and implementation of guidelines in the practice environment must also be carefully executed. Communication about the availability of guidelines is necessary. Guidelines should be readily available through existing health-system platforms. If feasible, it is recommended to build the guidelines into the computerized provider order entry system (eg, through order set creation) to facilitate the appropriate care of the patient. Every guideline should include a time frame for future review and revision.

If utilization of a medication is being requested outside established health-system guidelines for appropriate use, scientific evidence to support safety and efficacy should be provided and reviewed to substantiate the request.

Specialty medications. P&T committees should be involved in the organization's approach to managing specialty medications to ensure the pharmacy has the ability to provide medications in a timely manner, to support patient access to medications, and provide continuity of care. ASHP has resources to aid in specialty pharmacy management, including the ASHP Specialty Pharmacy Resource Guide.[46] This guide provides guidance on dispensing the medication directly to the site of care for patient administration (white bagging) or to the patient, who then carries it to the site of care for administration (brown bagging). Another strategy to consider in management of specialty pharmaceuticals is clear bagging. Clear bagging is the delivery of a patient-specific specialty pharmaceutical directly from a health system's specialty pharmacy directly to the health-system site of service, where it is then administered.[47]

MUE process. MUE is a quality improvement activity, but it can also be considered a formulary system management technique. MUEs have traditionally involved evaluating evidence-based criteria to determine the health system's compliance with established standards. Interventions could then be used to improve any aspect of the medication-use process based on MUE data analyses.

MUE can be simply informative (collecting data to guide decision-making) or used to measure the effect of interventions, such as the addition of a new agent to the formulary or the implementation of a new medication-use policy. While MUE often focuses on problem-prone, high-risk, or high-cost medications, MUE can be used to examine any aspect of medication use that is problematic to the institution conducting the evaluation. Medications recently added to the formulary should be evaluated, especially if there is the potential for inappropriate use or adverse effects. This review should occur 6 to 12 months after their addition to the formulary. High-cost, high-use, or problem-prone medications and outcomes of specific disease states are also good candidates for evaluation.

A systematic plan to monitor, evaluate, and improve medication use should be established within the organization.[19] Such a plan is an accreditation requirement for many organizations (eg, Joint Commission[27]). The P&T committee, or its equivalent, should be involved in the MUE process. Refer to ASHP's Guidelines on Medication Use Evaluation for more detailed information conducting an MUE.[19]

Incorporating patient safety issues in the decision-making process

The P&T committee should systematically address medication and patient safety issues as part of its deliberations. The P&T committee should ensure that medication-use policies adequately address potential risk and safety issues. Hospital or health-system medication-event data, including near misses, should consistently be reviewed by the P&T committee, along with recommendations to prevent future events. The P&T committee should also review available information on medication or patient safety events reported by other organizations to identify ways to prevent medication events and disseminate the information to healthcare providers and, when appropriate, patients.

When evaluating a medication for inclusion on the formulary, the P&T committee and its supporting subcommittees or panels should consider adverse effects, preparation issues, sound-alike or look-alike potential, practitioner safety, and dosing or administration issues. If a product has a REMS program, the requirements of this program should be carefully reviewed to ensure the institution can meet the requirements. When implementing formulary decisions for medications that have REMS, there should be processes in place to ensure compliance both during implementation and on an ongoing basis. Proactive assessments should be conducted to identify potential safety concerns posed by use of the medication, and proposed strategies to mitigate those risks should be implemented by the P&T committee. In addition, quality improvement projects to improve the safety of specific medications or to evaluate the processes involved should be conducted and reviewed by the P&T committee. The P&T committee should champion evidence-based fail-safe techniques (eg, bar coding) to prevent medication events.

Resources that provide information on medication or patient safety events include the Institute for Safe Medication Practices (www.ismp.org)

and Medwatch. The Joint Commission, Institute for Healthcare Improvement, and National Center on Patient Safety provide information about conducting and examples of failure mode and effects analysis (FMEA) projects on their websites (www.jointcommission.org/, www.ihi.org/, and www.patientsafety.va.gov).

Implementation of formulary decisions into the EHR

Use of the EHR to implement, guide, and evaluate decisions made by the P&T committee is essential. EHR technology functionality should be maximized to support drug policy and formulary management decisions. The EHR should provide guidance on dosing, monitoring, and restrictions/limitations at the point of prescription and verification. A standard process, including established expectations for timeliness, should be developed to consistently and efficiently implement these decisions into the EHR. Multihospital systems and integrated delivery networks that share the same EHR platform and formulary review process should centralize the coordination of implementation.[48] EHR implementation efforts should be coordinated with operational changes and education requirements identified in the decision-making process. Finally, resources and personnel available to support implementation into the EHR should interface with the P&T committee to ensure understanding and shared expectations of the EHR technology functionality. In addition, key content experts charged with evaluating and proposing drug policy and formulary management decisions should collaborate with informatics personnel on the design and validation of EHR content.

Drug product shortages

Health systems frequently need to address drug product shortages. Drug product shortages disrupt patient care and impact all aspects of the medication-use system, including purchasing, storage, automation systems, the EHR, preparation, administration, monitoring, and education.

During a drug product shortage, the P&T committee plays an important role. The P&T committee needs to develop strategies to address shortages in a timely manner, including designating appropriate therapeutic alternatives, identifying strategies for mitigating use of available drug product, and establishing use restrictions. All of these strategies should be developed based on available literature and best practices. Therapeutic interchange can be useful in dealing with critical drug product shortages. The P&T committee should work collaboratively with other committees and departments, such as specific medical departments, nursing, and risk management (when necessary) to develop effective management plans for addressing shortages. Given the dynamic nature of drug shortages, it is not always possible to obtain approval from P&T committee members prior to implementation of strategies if there is a need for urgent changes. To make sure the P&T committee is aware of all changes related to drug shortages, organizations should include a drug shortage update as a regular agenda item for the P&T committee. Communication with patients and staff is crucial to effectively manage shortages.

Effective integration of these strategies into the EHR is key for successful implementation of a drug shortage plan. Various strategies exist for communication in the EHR, including placing electronic alerts on medications, blocking the ordering of medications on shortage, and facilitating the build of new medication records or order sets to guide use of alternative agents during the time of the shortage.

More information about managing drug product shortages can be found in the ASHP Guidelines on Managing Drug Product Shortages.[49]

Implementing medication-use policies

Various tools can be used to implement medication-use policies. The policy should be integrated directly into the therapeutic decision-making processes that guide the use of a medication during order entry or incorporated into a diagnosis-specific electronic treatment plan. Other specific ways of communicating information about a medication-use policy may include the use of

- Inservice education,
- Facility-approved social media,
- Grand rounds,
- Communication between pharmacists and prescribers
- Staff meetings,
- E-mail,
- Electronic newsletters,
- Prescriber detailing, and
- Pharmacy or institutional websites.

Outcome-driven projects may be beneficial in illustrating the value of a new medication-use policy and support further expansion.

Reimbursement strategies and considerations

New payment models require that P&T committee members are astute in their understanding of the hospital and health system's payment policies and reimbursement strategies related to medications. A balanced approach to managing a hybrid reimbursement structure between traditional fee-for-service models and emerging value-based contracts will be required. Financing and reimbursement for medications is complex; hospitals and health systems can no longer exclusively focus on manufacturing contracts, wholesaler agreements, and inpatient reimbursement. Large health systems and integrated systems must consider implications of medication reimbursement by Medicare, Medicaid, commercial, and private payers. If applicable, 340B Drug Pricing Program policies must also be considered. Prior to approval of high-cost drugs, in collaboration with the finance department, there should be a benefits investigation conducted, factoring in local payer mix, plans for financial

monitoring, and payer negotiations. The organization should have a defined process and responsible department for validating reimbursement of therapy and financial outcomes over time. Factors include site of care decisions in determining where a medication will be administered. Each organization should have policies on the use of medications not directly procured by the hospital pharmacy. For example, some specialty medication payer agreements circumvent traditional buy-and-bill dispensing channels and instead use white or brown bagging strategies.[47] Furthermore, patient access to medications upon discharge or during transitions of care between care settings needs to be evaluated, and systems need to be in place to ensure continuity of medication use and to decrease the potential to prolong length of stay due to medications initiated during an inpatient stay that may be restricted elsewhere.

Conclusion

A formulary system is the multidisciplinary, evidence-based process employed by an organization to select and use medications that offer the best therapeutic outcomes while minimizing potential risks and costs for patients. Organizations should employ the MUE process to continually improve how medications are used within the organization at all steps in the medication-use process. Medication use is an inherently complex process that requires constant evaluation. Organizations need to implement all necessary tools and processes to meet the goals of safe and effective medication use. Professionals involved in the medication-use process need to know and understand how the organization's medication-use policies and processes can be incorporated into their daily work to ensure medications are used appropriately and safely. Technology offers many opportunities to make those processes more effective and efficient. Communicating the actions related to medication use is a constant challenge that organizations need to address.

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Additional information

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Appendix A—Glossary of terms

Cost-Effectiveness Analysis. A method for assessing the gains in health relative to the costs of different health interventions.[50]

Cost Utility Analysis. A comparison of the costs of different procedures with their outcomes measured in "utility based" units—that is, units that relate to a person's level of well-being and are most often expressed as quality adjusted life year(s).[51]

Electronic Health Record. A digital version of a patient's medical history that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that persons care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports.[52]

Formulary. A continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health.

Formulary System: An ongoing process whereby a healthcare organization, through its physicians, pharmacist, and other healthcare professionals, establishes policies on the use of drug products and therapies and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.[1]

Generic Substitution. The substitution of drug products that contain the same active ingredient or ingredients and are chemically identical in strength, concentration, dosage form, and route of administration to the drug product prescribed.[1]

Medication. Any prescription medications, sample medications, herbal remedies, vitamins, nutraceuticals, vaccines, or over-the-counter drugs; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, and intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the Food and Drug Administration (FDA) as a drug. This definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases.[27]

Medication-Use Evaluation. A systematic and interdisciplinary performance improvement method with an overarching goal of optimizing patient outcomes via ongoing evaluation and improvement of medication utilization.[19]

Pharmacy and Therapeutics (P&T) Committee. An advisory committee that is responsible for developing, managing, updating, and administering a formulary system. Institutions may refer to this committee by a different name.[1]

Therapeutic Alternatives. Drug products with different chemical structures but of the same pharmacologic or therapeutic class and usually have similar therapeutic effects and adverse-reaction profiles when administered to patients in therapeutically equivalent doses.[1]

Therapeutic Interchange. Authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines or protocols within a formulary system.[1,44]

Therapeutic Substitution. The act of dispensing a therapeutic alternative for the drug product prescribed without prior authorization of the prescriber. This is an illegal act because only the prescriber may authorize an exchange of therapeutic alternatives.[1]

Appendix B—Drug evaluation process

There are 4 major types of drug reviews: new drug monographs, reevaluations of previous formulary decisions, therapeutic class reviews, and expedited reviews of newly approved medications. Because of the expertise and training of pharmacists (drug information specialists in particular), pharmacists should play an integral part in the preparation and presentation of the drug review document to the pharmacy and therapeutics (P&T) committee.

New drug monographs. When the Food and Drug Administration (FDA) approves a new drug for marketing that is relevant to the health system, a drug monograph should be prepared for formulary consideration by the P&T committee. New chemical entities warrant a thorough evaluation and a written drug monograph. A short (eg, one-page) summary could be provided along with the full monograph.[35] Some organizations use an executive summary format. A new drug that is significantly similar to other available therapeutic alternatives may be presented in a more abbreviated manner (eg, an abbreviated monograph) provided that the P&T committee or experts agree that the drug is therapeutically equivalent to agents already available on the formulary.

Addenda to original monographs used to reevaluate previous formulary decisions. Formulary decisions may need to be reassessed based on relevant new information or in light of newly marketed drugs or dosage forms. New data on safety, efficacy, stability, methods of administration, cost, or pharmacoeconomics may warrant a reevaluation of the drug or dosage strengths or formulations stocked by the health system. An addendum to the original monograph summarizing the new information should be developed for evaluation by the P&T committee. The P&T committee may want to establish reassessment dates at the time of formulary review so that the committee can reassess the effect of a formulary decision on quality or cost of care.

Therapeutic class reviews. Review of an entire therapeutic class of drugs should be performed at regular intervals, which may be determined by the P&T committee or influenced by regulatory agencies. A therapeutic class review should include all formulary and nonformulary medications within the class and may include institutional utilization or outcomes data and newly published information. Therapeutic class

reviews may lead to formulary removal of therapeutically equivalent drugs or a change in restriction or guideline status for a drug.

Expedited reviews. A process should be available for the P&T committee to conduct an expedited review of a new drug, new indication for a drug, or reevaluation of a previous formulary decision. Criteria should be in place to describe when an expedited review is warranted. For example, approval of a new chemical entity for a disease with no therapeutic alternative may warrant an expedited review to ensure availability of the drug for patients who need it. Likewise, a significant new safety concern may warrant an expedited review for addition of restrictions or removal from the formulary.

NABP 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.	

Model State Pharmacy Act
and Model Rules of the
National Association of Boards of Pharmacy

August 2024

Section 103. Statement of Purpose.

It is the purpose of this Act to promote, preserve, and protect the public health, safety, and welfare through the effective control and regulation of, as well as through access to, health care providers who engage in the practice of pharmacy; the licensure of pharmacists; the licensure of certified pharmacy technicians and certified pharmacy technician candidates; the licensure, control, and regulation of all sites or persons, in or out of this state, that distribute, manufacture, or sell drugs (or devices used in the dispensing and administration of drugs), within this state, and the regulation and control of such other materials as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual.[2]

Section 104. Definitions for the Practice of Pharmacy and Related Terms.

The "practice of pharmacy" means, but is not limited to:

(1) interpreting, evaluating, compounding, dispensing, and/or administering medical orders;
(2) providing patient counseling;
(3) assessing the patient for the purposes of prescribing drugs and devices;
(4) initiating and/or providing pharmacist care services;
(5) using continuous quality improvement programs, emerging technologies, and competency-based education to improve patient safety and the quality of services provided;
(6) engaging in collaborative pharmacy practice.[3]

"Pharmacist care services"[4] mean services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination or reduction of symptoms, and promotion of health and wellness. Pharmacist care services include but are not limited to:

(1) drug utilization review;
(2) medication adherence monitoring service;
(3) emergency use prescribing and dispensing;[5]
(4) medication therapy management;

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[2] The Statement of Purpose is designed to define the general scope of the Pharmacy Act. It provides for the control and regulation of the practice of pharmacy and the licensure of facilities engaged in the distribution of drugs and related devices. A board will have full knowledge of the whereabouts of drugs in the legitimate stream of intrastate and interstate commerce, providing it with the ability to better prevent diversion, effectuate recalls, ensure the quality of drugs dispensed or administered to patients, and effectively protect the public.

[3] The definition of the "practice of pharmacy" is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the board of pharmacy in the adoption of implementing rules. Inclusion of or authorization for specific activities, such as the administration of drugs, is purposely not delineated in the definition in order to be empowering and not proscriptive. To assist states in the interpretation of the revised definition of the "practice of pharmacy," the *Model Act* includes the definition of "pharmacist care services" and Model Rules for the Provision of Pharmacist Care Services for those states that need to include specific lists of activities or authorizations due to legislative and/or administrative policies and procedures.

The definition also acknowledges that pharmacy is a dynamic profession, and a broad definition of the practice will permit the board to make necessary changes from time to time to meet the changing practice. Such changes may be affected by new or amended rules, which would be promulgated pursuant to the requirements of the state Administrative Procedures Act, affording all interested parties an opportunity to review and comment on any proposed rules.

[4] Objectives of pharmacist care services include cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or prevention of a disease or symptomatology. Pharmacist care services should be provided by all pharmacists within the standard of care to the extent of their abilities regardless of the practice setting.

[5] Pharmacists may prescribe drugs for emergency use pursuant to specific statewide protocols or standing orders.

(5) reviewing, selecting, and developing formularies and/or practice guidelines;
(6) performing drug product selection, substitution, therapeutic interchange,[6] prescription adaptation or continuation of therapy;
(7) ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived[7] lab tests.

"Collaborative pharmacy practice" means that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol and in collaboration with practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes.

"Medication therapy management" includes the following:
(1) patient health status assessment and evaluation;
(2) medication reconciliation;
(3) formulating medication treatment plan;
(4) selecting, prescribing, modifying, discontinuing, or administering drugs, devices, vaccines, or biologicals;
(5) monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
(6) performing a comprehensive drug utilization review to identify, resolve, and prevent medication-related problems, including adverse drug events;
(7) documenting the care delivered and communicating essential information to the patient's prescribing practitioner(s) and primary care providers;
(8) providing education, support services, and resources designed to enhance patient adherence with therapeutic regimens, such as medication synchronization;
(9) coordinating and integrating services within the broader health care management services being provided to the patient; and
(10) such other patient care services as may be allowed by law.

Section 105. Definitions.

(1) "Active ingredients" means chemicals, substances, or other components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.
(2) "Added substances" mean the ingredients necessary to prepare the drug product but are not intended or expected to cause a human pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded drug product or alter the composition and effectiveness of the compounded drug product. The term "added substances" is used synonymously with the terms "inactive ingredients," "excipients," "flavoring agents," and "pharmaceutic ingredients."
(3) "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.
(4) "Adulterated": A Drug or Device shall be deemed to be adulterated
(a) if:

[6] Providing it is within the same FDA drug class and not prohibited by the prescriber.

[7] Most recent version.

(101) "State of emergency" means a governmental declaration, usually issued as a result of a public health emergency, that may suspend certain normal functions of government, alert citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.

(102) "Sterile drug" means any dosage form of a drug, including but not limited to parenteral (eg, injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.

(103) "Summary suspension" means the suspension of a license, which requires the licensee to cease the practice of pharmacy immediately pending the results of a timely hearing.[39]

(104) "Suspect product" means a product for which there is reason to believe that such product:
- (a) is potentially counterfeit, diverted, or stolen;
- (b) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- (c) is potentially the subject of a fraudulent transaction; or
- (d) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(105) "Suspension" means the withdrawal of the license to practice pharmacy in the state for a specified period of time.

(106) "Therapeutic interchange" means substitution by the pharmacist of one drug for another drug with a similar therapeutic effect, at the time of dispensing.

(107) "Third-party logistics provider" means an entity that:
- (a) provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition; and
- (b) is licensed as a third-party logistics provider.

(108) "USP Standards" means standards published in the current official United States Pharmacopeia (USP) or National Formulary.

(109) "Valid patient-practitioner relationship"[40] means the relationship that is established between a patient and a practitioner which was based upon the following:

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[39] If the board believes it necessary to protect the public health and safety, it may summarily suspend a license and order a prompt hearing on the matters in question.

[40] A valid patient-practitioner relationship includes a relationship with a consulting practitioner or a practitioner to which a patient has been referred, or a covering practitioner, or an appropriate practitioner-board-approved telemedicine practitioner providing that a physical examination had been previously performed by the patient's practitioner.

To best protect the public, the issue of a valid patient-practitioner relationship should be addressed in each jurisdiction's Medical Practice Act and the Consumer Fraud Protection Act or their equivalent.

A face-to-face physical examination is not required to establish a valid patient-practitioner relationship if:

- (a) the prescribing practitioner is issuing a prescription or dispensing a non-controlled substance legend drug in accordance with the expedited partner therapy in the management of sexually transmitted diseases guidance document issued by the US Centers for Disease Control and Prevention;
- (b) the prescription, administration, or dispensing is through a public health clinic or other distribution mechanism approved by the state health authority in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of a biological, chemical, or radiological agent;
- (c) the prescribing practitioner is issuing a prescription through a telemedicine practice approved by the appropriate state agency that provides health care delivery, diagnosis, consultation, or treatment by means of audio, video, or data communications. Standard telephone, facsimile transmission, or both, in the absence of other integrated information or data, do not constitute telemedicine practice; or
- (d) the state allows third-party prescribing of opioid reversal agents, such as naloxone, or other drugs as allowed by state law to a person other than the patient.

limited to, the prescription drug order requirements and records of dispensing as indicated in Section 4 of this Rule; and

(ii) The storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV are subject to federal regulations.

(b) Security

To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented, including the identification of the pharmacist responsible for the alteration.

(c) System Backup (Auxiliary Records Maintenance)

(i) In the event of an unscheduled system interruption, sufficient patient data and prescription drug order data should be available to permit reconstruction of such data as soon as possible for the pharmacist to dispense drugs with sound professional judgment.

(ii) An auxiliary system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason and to ensure that all refills are authorized by the original prescription drug order and that the maximum number of refills is not exceeded.

(iii) The auxiliary system shall be in place to provide for the maintenance of all necessary patient drug information (as outlined in this rule) until the automated system becomes operational. However, nothing in this Section shall preclude the pharmacist from using professional judgment for the benefit of a patient's health and safety.

(iv) When the automated system is restored to operation, the information regarding prescription drug orders dispensed and refilled during the inoperative period shall be entered into the automated system as soon as possible.

(v) Routine backup systems and procedures (hard copy, copy, disk, etc) shall be in place and operational to ensure against loss of patient data.

(vi) In the event that permanent dispensing information is lost due to unscheduled system interruption, the board of pharmacy shall be notified as soon as possible.

Section 6. Pharmacist Care Services.

(1) Pharmacist care services are services intended to achieve patient outcomes related to the treatment or prevention of disease, elimination or reduction of symptoms, and promotion of health and wellness. Pharmacist care services include, but are not limited to:

(a) drug utilization review;

(b) emergency use prescribing and dispensing;[121]

(c) medication therapy management;

[121] Pharmacist may prescribe drugs for emergency use pursuant to specific statewide protocols or standing orders.

(d) reviewing, selecting, and developing formularies and/or practice guidelines;
(e) performing drug product selection, substitution, therapeutic interchange[122] prescription adaptation or continuation of therapy;
(f) performing drug product selection, substitution, therapeutic interchange[123] prescription adaptation or continuation of therapy; and
(g) ordering, interpreting laboratory tests, and performing Clinical Laboratory Improvement Amendments-waived[124] lab tests.

(2) Drug Utilization Review (DUR)[125]
A pharmacist shall obtain and review the patient records and medical history for each prescription drug order for:
(a) known allergies;
(b) rational therapy contraindications;
(c) reasonable dose, duration of use, and route of administration, considering age, gender, and other patient factors;
(d) reasonable directions for use;
(e) potential or actual adverse drug reactions;
(f) drug-drug interactions;
(g) drug-food interactions;
(h) drug-disease contraindications;
(i) therapeutic duplication;
(j) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(k) abuse/misuse.
Upon recognizing any of the above, which may also include information obtained from reviewing data found in the prescription monitoring program, the pharmacist shall take appropriate steps to avoid or resolve the problem which, if necessary, includes consultation with the practitioner.

(3) Patient Counseling[126]
(a) Upon receipt of a prescription drug order and following a review of the patient's record, a pharmacist shall engage in discussion of matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone or other audio/visual means of communication and shall include appropriate elements of patient counseling. Such elements may include the following:
(i) the name and description of the drug;
(ii) the dosage form, dose, route of administration, and duration of drug therapy;
(iii) intended use of the drug and expected action;

[122] Provided it is within the same FDA Drug class and not prohibited by the prescriber.

[123] Provided it is within the same FDA Drug class and not prohibited by the prescriber.

[124] Most recent version.

[125] Pharmacists should be permitted to use computer software, if available, to accomplish this review.

[126] The intent of this Section is to require that the pharmacist personally initiate patient counseling for all new prescription drug orders and exercise their professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

(a) Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of patients, and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other sources.

(b) All emergency kit drugs shall be provided and sealed by a pharmacist or their designee in accordance with applicable security and inventory control policies and procedures.

(c) The supplying pharmacist and the medical staff of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits.

(d) Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs within them.

(e) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall contain a listing of the drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying pharmacy.

(f) Drugs shall be removed from emergency kits only pursuant to a valid chart order.

(g) Whenever an emergency kit is opened, the supplying pharmacy shall be notified, and the pharmacy shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.[172]

(h) The expiration date of an emergency kit shall be the earliest date of expiration of any drug supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacy shall replace the expired drug.

(i) The pharmacy that supplies controlled substances for emergency kits must comply with applicable state and federal requirements.

Section 4. Drug Distribution and Pharmacist Care Services.

(1) The pharmacist-in-charge shall establish written procedures for the safe and efficient acquisition, handling, storage, and dispensing of drugs, including investigational drugs, patient-supplied drugs, and for the provision of pharmacist care services. An annual updated copy of such procedures shall be available for inspection by the board of pharmacy.

(2) A pharmacist may engage in therapeutic interchange or formulary substitution as authorized by the facility's interdisciplinary committee[173] of health care providers, at a minimum to include a practitioner and a pharmacist.

(3) To ensure continuous patient care, the facility's director of nursing or their documented licensed health care designee may transmit the chart order to a pharmacy.[174]

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[172] When the pharmacist restocks and reseals the emergency kit drugs, it is recommended that a lock or other similar device be used to assure that unauthorized access to the kit is minimized.

[173] This is often referred to as the pharmacy and therapeutics committee or the quality assessment and assurance committee.

[174] Federal law may restrict who can transmit a chart order for a controlled substance.

(4) The pharmacist shall assess each patient's medication regimen based on a review of the health record, either remotely or on site, in a timely manner that promotes improving patient clinical outcomes, medication safety and education, and appropriate care management.

(5) If the institutional pharmacy is not located within an institutional facility, the pharmacist-in-charge may designate a licensed nurse to restock an automated pharmacy system using verification technology such as bar code scanning, electronic, or other technology in accordance with established policies and procedures.

(6) Institutional pharmacies either located within or not within institutional facilities may dispense drugs to patients upon discharge in order to ensure a transition of care between settings until a new prescription drug order is issued.

Section 5. Shared Pharmacy Services Utilization for Immediate Need.[175]

(1) In accordance with the Section addressing shared pharmacy services in the *Model Rules for the Practice of Pharmacy*, an institutional pharmacy may outsource services to another pharmacy for the limited purpose of ensuring that drugs or devices are available to meet the immediate needs of patients of the institutional facility or when the institutional pharmacy cannot provide services on an ongoing basis, provided that the institutional pharmacy:
   (a) has obtained approval from the institutional facility to outsource shared pharmacy services for its inpatients; and
   (b) shares a valid chart order with the pharmacy it has contracted with for the shared pharmacy services without the need to transfer the order.

Section 6. Relabeling of Previously Dispensed Outpatient Drugs for Institutional Use.

(1) At a patient's or patient's caregiver's request, an institutional pharmacy may relabel for institutional use a drug previously dispensed by an outpatient pharmacy to the patient.

(2) The institutional pharmacy providing relabeling services shall have established policies and procedures to:
   (a) assess whether the drug may be adulterated or misbranded; and
   (b) package and label the drug in compliance with state and federal requirements and USP standards.

(3) An institutional pharmacy that relabels a previously dispensed outpatient drug shall retain all original prescription information in accordance with state record-keeping requirements.

[175] Although institutional pharmacies primarily outsource services to another pharmacy for the purposes of meeting the immediate needs of patients and residents when the institutional pharmacy is closed, it is also recognized that other services may be outsourced that the institutional pharmacy is not able to provide on an ongoing basis.