ASHP POLICY POSITIONS 1982-2026

Introduction

ASHP Policy Positions 1982–2026 is a catalog of professional policy positions adopted by the ASHP House of Delegates, organized from the most current year, 2026, back to those adopted in 1982. The foundations for ASHP's policy positions are its Mission Statement and its purposes as stated in the ASHP Charter. ASHP is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients. In addition, ASHP is the accrediting body for pharmacy residency and technician training programs and provides comprehensive resources to support pharmacy professionals through every stage of their careers. For more information, visit ashp.org and ASHP's consumer website, SafeMedication.com. ASHP is the only national organization of hospital and health-system pharmacists and has a long history of improving medication use and enhancing patient safety. ASHP has extensive publishing and educational programs designed to help members improve their delivery of pharmaceutical care, and it is the national accrediting organization for pharmacy residency and pharmacy technician training programs.

ASHP believes that the mission of pharmacists is to help people achieve optimal health outcomes. ASHP helps its members achieve this mission by advocating and supporting the professional practice of pharmacists in hospitals, health systems, ambulatory clinics, and other settings spanning the full spectrum of medication use. ASHP serves its members as their collective voice on issues related to medication use and public health. The purposes of ASHP, as stated in the ASHP Charter, are as follows:

1. To advance public health by promoting the professional interests of pharmacists practicing in hospitals and other organized health-care settings through:
    a. Fostering pharmaceutical services aimed at drug-use control and rational drug therapy.
    b. Developing professional standards for pharmaceutical services.
    c. Fostering an adequate supply of well-trained, competent pharmacists and associated personnel.
    d. Developing and conducting programs for maintaining and improving the competence of pharmacists and associated personnel.
    e. Disseminating information about pharmaceutical services and rational drug use.
    f. Improving communication among pharmacists, other members of the health-care industry, and the public.

    g. Promoting research in the health and pharmaceutical sciences and in pharmaceutical services.
    h. Promoting the economic welfare of pharmacists and associated personnel.
2. To foster rational drug use in society such as through advocating appropriate public policies toward that end.
3. To pursue any other lawful activity that may be authorized by ASHP's Board of Directors.

Each policy position in this catalog is identified by a four-digit number: the first two digits show the year that the policy was approved by the House of Delegates, and the third and fourth digits are sequencing numbers. The source for each policy position indicates how the policy position was introduced to the House of Delegates, e.g., in a report of a council, through the Chair of the Board, or as a resolution. The rationale for policy positions approved since 2009 are provided following the text of the policy. This information is intended to support the ASHP policies approved by ASHP's councils, Board, and House of Delegates, but it is not ASHP policy and should not be interpreted or construed as such.

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Practice-Related Positions Listed by Topic

Automation and Information Technology

2610 - Advancing Technology Innovation and Vendor Accountability in Health-System Pharmacy
2520 - Safe Technology Implementation and Expansion of Pharmacist Services
2413 - Role of Artificial Intelligence in Pharmacy Practice
2303 - Interoperability of Patient-Care Technologies
2304 - Patient Medication Delivery Systems
2332 - Barcoding of Lot Number and Expiration Date
2204 - Mobile Health Tools, Clinical Apps, and Associated Devices
2246 - Autoverification of Medication Orders
2255 - Therapeutic Indication for Prescribed Medications
2147 - Pharmacist's Role in Healthcare Information Systems
2015 - Network Connectivity and Interoperability for Continuity of Care
1529 - Online Pharmacy and Internet Prescribing
1212 - Clinical Decision Support Systems
0712 - Electronic Health and Business Technology and Services
0105 - Computerized Provider Order Entry
9813 - Regulation of Automated Drug Distribution Systems

Drug Distribution and Control

2511 - Safe and Secure Transfer of Controlled Substances
2222 - Pharmacist's Role in Medication Procurement, Distribution, Surveillance, and Control
2145 - Reduction Of Unused Prescription Drug Products
2042 - Controlled Substances Diversion Prevention

Preparation and Handling

2616 - Safe and Effective Compounding
2412 - Prehospital Management of Medications
2415 - Enhancing the Safety of Hazardous Drug Product Handling
2024 - Safety and Efficacy of Compounded Topical Formulations
1903 - Verifying Compounded Sterile Preparations
1813 - Use of Closed-System Transfer Devices to Reduce Drug Waste
0903 - Pharmaceutical Waste
0614 - Safe Disposal of Patients' Home Medications

Distribution

2416 - Independent Double Checks for Single Practitioners
2335 - Pharmaceutical Distribution Systems
2022 - Dispensing by Nonpharmacists and Nonprescribers
0310 - Technician-Checking-Technician Programs

Education and Training

2608 - Optimizing Career Fulfillment in Pharmacy
2609 - Quality of Pharmacy Education
2601 - Responsible Integration of Artificial Intelligence in Pharmacy Education and Training
2501 - Professional Development as a Retention Tool
2504 - Cultural Competency and Trauma Informed Care
2420 - Opposition to Pharmacy Jurisprudence Examination Requirement
2424 - Additional Education Requirements for Pharmacy Technicians in Advanced Roles
2301 - Education and Training in Digital Health
2329 - Well-Being and Resilience of the Pharmacy Workforce
2201 - State-Specific Requirements for Pharmacist and Pharmacy Technician Continuing Education
2203 - Preceptor Skills and Abilities
2216 - Career Counseling
2105 - Interprofessional Education and Training
2106 - Pharmacy Education and Training Models
2107 - Pharmacy Internships
2027 - Residency Training for Pharmacists Who Provide Direct Patient Care
1911 - Pharmacy Expertise in Sterile Compounding
1912 - Pharmacy Technician Training and Certification
1917 - Pharmacy Technician Student Drug Testing
1918 - Minimum Educational Qualification Standards for Pharmacists
1826 - Student Pharmacist Drug Testing
1827 - Collaboration on Experiential Education
1706 - ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process
1317 - Education and Training in Health Care Informatics
1109 - Residency Equivalency
1112 - Innovative Residency Models
1008 - Employment Classification and Duty Hours of Pharmacy Residents
0913 - Pharmacy Student Experiences in Medically Underserved Areas
0916 - Continuing Professional Development
0704 - Residency Programs
0510 - Health Literacy and Communication Among Health-System Pharmacy Practitioners, Patients, and Other Health Care Providers
0325 - Public Funding for Pharmacy Residency Training

Ethics

2615 - Pharmacy Workforce Right of Conscience and the Patient's Right of Access to Therapy
2508 - Patient's Right to Choose
2414 - Pharmacist's Role on Ethics Committees to Medications
1704 - Medical Aid In Dying
1531 - Pharmacist Role in Capital Punishment

1116 - Ethical Use of Placebos in Clinical Practice
2509 - Recovery and Assistance Programs for Healthcare Workers with Substance Use Disorder

Formulary Management (Medication-Use Policy Development)

2510 - Cellular and Gene Therapies
2308 - Pharmacogenomics
2016 - Medication Formulary System Management
1820 - Medical Devices

Government, Law, and Regulation

2602 - Safe Use of Controlled Substances Through Regulatory Reform
2604 - Integrity of Pharmacist Provided Health Information
2605 - Deregulation of Prescription Drugs
2607 - Direct-to-Consumer Clinical Genetic Tests
2611 - Standard of Care Regulatory Model
2612 - Promoting Environmental Sustainability in Healthcare
2614 - Pharmacy Workforce Leadership in Improving Vaccine Access
2618 - FDA's Public Health Role
2505 - Funding, Expertise, and Oversight of State Boards of Pharmacy
2506 - Payment Parity for Pharmacists' Services
2518 - Quality Consumer Medication Information
2619 - Protecting the Pharmacy Workforce Against Unauthorized Synthetic Media
2405 - Pharmacist Access to Provider Networks
2507 - Interstate Pharmacist Licensure
2417 - State Prescription Drug Monitoring Programs
2425 - Liability Protection
2306 - Support for FDA Expanded Access (Compassionate Use) Program
2307 - Biosimilar Medications
2317 - Emergency Medical Kits
2322 - Availability and Use of Fentanyl Test Strips
2323 - DEA Scheduling of Controlled Substances
2325 - Nonprescription Availability of Self-Administered Influenza Antivirals
2326 - Over-the-Counter Availability of Hormonal Contraceptives
2330 - Pharmacist Prescribing Authority for Antiretroviral Therapy for the Prevention of HIV/AIDS
2239 - Drug Pricing Proposals
2111 - Pharmacist Involvement in the Strategic National Stockpile
2112 - Medication Price-Gouging Laws
2114 - FDA Requirement for Dose-Response Information
2115 - Medical Cannabis
2118 - Supply Chain Resilience During Disasters and Public Health Emergencies
2142 - Pharmacy Services in a State of Emergency
2144 - Agricultural Use of Hormone and Prohormone Therapy
2004 - Evaluation of Abuse-Deterrent Drug Mechanisms

2007 - Use of Surrogate Endpoints for FDA Approval of Drug Uses
2012 - Importation of Drug Products
2013 - Public Quality Standards for Biologic Products
2019 - Access to Affordable Healthcare
2023 - New Categories of Licensed Pharmacy Personnel
2025 - Postmarketing Studies
2026 - Gabapentin as a Controlled Substance
2040 - Premarketing Comparative Clinical Studies
2043 - Drug Product Supply Chain Integrity
1904 - Notification of Drug Product Price Increases
1905 - Mitigating Drug Product Shortages
1908 - 340B Drug Pricing Program Sustainability
1909 - Pharmacist Authority to Provide Medication-Assisted Treatment and Medications for Opioid Use Disorder
1922 - Antimicrobial Use in Agriculture
1803 - Confidence in the U.S. Drug Approval and Regulatory Process
1815 - Impact of Drug Litigation Ads on Patient Care
1818 - Federal Quality Rating Program for Pharmaceutical Manufacturers
1819 - Intravenous Fluid Manufacturing Facilities as Critical Public Health Infrastructure
1713 - Partial Filling of Schedule II Prescriptions
1715 - Collaborative Practice
1716 - Greater Competition Among Generic and Biosimilar Manufacturers
1501 - Pharmacist Participation in Health Policy Development
1405 - Automatic Stop Orders
1406 - Federal and State Regulation of Compounding
1411 - Expedited Pathways for FDA Drug Approval
1412 - FDA Oversight of Laboratory-Developed Tests
1310 - Regulation of Telepharmacy Services
1311 - Regulation of Centralized Order Fulfillment
1216 - Pharmacy Technicians
1219 - Stable Funding for HRSA Office of Pharmacy Affairs
1223 - Globalization of Clinical Trials
1121 - Poison Control Center Funding
1002 - Risk Evaluation and Mitigation Strategies
1003 - FDA Authority on Recalls
1007 - Regulation of Home Medical Equipment Medication Products and Devices
0909 - Regulation of Interstate Pharmacy Practice
0811 - Regulation of Dietary Supplements
0813 - Medicare Prescription Drug Benefit
0719 - FDA Authority to Prohibit Reuse of Brand Names
0516 - Mandatory Registration of Clinical Trials

Medication Safety

2617 - Role of the Pharmacy Workforce to Combat Public Health Disinformation and Misinformation
2318 - Raising Awareness of the Risks Associated with the Misuse of Medications
2241 - Human Use of Veterinary Pharmaceuticals
2132 - Standardizing and Minimizing the Use of Abbreviations
2044 - Drug Names, Labeling, and Packaging Associated with Medication Errors
1505 - Statutory Protection for Medication-Error Reporting
1524 - Support for Second Victims
1530 - Standardization of Small-Bore Connectors to Avoid Wrong-Route Errors
1115 - Just Culture
1021 - Just Culture and Reporting Medication Errors

Medication Therapy and Patient Care

Organization and Delivery of Service

2623 - Evidence-Based Medicine
2513 - Pharmacy Services to Optimize Patient Throughput
2514 - Accurate and Timely Height and Weight Measurements
2515 - Clinical and Safety Considerations of Naming Drug Moieties and Complexes
2516 - Clinical, Operational, and Safe Use of Manipulated Drug Products and Alternate Administration Routes
2521 - Health Care Quality Standards and Pharmacy Services
2403 - Medication Stewardship Programs
2408 - Supporting High Reliability in Pharmacy Practice
2418 - Testing for Pregnancy Status
2421 - Documentation of Patient-Care Services in the Permanent Health Record
2423 - Independent Prescribing Authority
2320 - Pharmacoequity
2302 - Digital Therapeutics Products
2309 - Payer-Directed Drug Distribution Models
2310 - Use of Social Determinants of Health Data in Pharmacy Practice
2313 - Reducing Healthcare Sector Carbon Emissions to Promote Public Health
2315 - Responsible Medication-Related Clinical Testing and Monitoring
2319 - Standardization of Medication Concentrations, Dosing Units, Labeled Units, and Package Sizes
2321 - Medication Administration by the Pharmacy Workforce
2205 - Transitions of Care
2206 - Continuous Performance Improvement
2208 - Pharmacist's Role in Team-Based Care
2214 - Medication Adherence
2235 - Use of Inclusive Verbal and Written Language
2238 - Patient Disability Accommodations
2252 - Standard Drug Administration Schedules

2108 - Patient Experience
2109 - Pharmacy Services for Uninsured and Underinsured Patients
2110 - Patient Access to Pharmacy Services in Small And Rural Hospitals
2121 - Universal Influenza Vaccination
2124 - Preventing Exposure to Allergens
2126 - Use of Race Correction in Clinical Algorithms
2128 - Use of Unapproved Gene Therapy Products, Drugs, Biologics, and Medical Devices (Biohacking)
2137 - Documentation of Pharmacist Patient Care
2008 - Health-System Facility Design
2033 - Health-System Use of Administration Devices Supplied Directly to Patients
2039 - Complementary, Alternative, and Integrative Medicine Products
1809 - Health Insurance Policy Design
1811 - Use of International System of Units for Patient- and Medication-related Measurements
1822 - Rational Use of Medications
1824 - Use of Biomarkers in Clinical Practice
1523 - Pharmacist's Role in Population Health Management
1525 - Standardization of Doses
1313 - Drug-Containing Devices
1107 - Patient-Reported Outcomes Tools
1114 - Pharmacist Accountability for Patient Outcomes
1005 - Medication Therapy Management
1023 - Consistent and Timely Access to Pharmacist Medication Order Verification
0525 - Mandatory Tablet Splitting for Cost Containment

Specific Practice Areas

2613 - Body Size Inclusivity
2620 - Tobacco and Nicotine Cessation and Control
2621 - Safe and Effective Use of Long-Acting Injectable Antipsychotics
2517 - Expedited Partner Therapy
2401 - Role of the Pharmacy Workforce in Improving Mental Health
2402 - Suicide Awareness, Prevention, and Response
2410 - 5-HT_2 Agonist, Entactogen, and Empathogen (Psychedelic) Assisted Therapy
2419 - Nonprescription Status of Rescue and Reversal Medications
2426 - Access to Reproductive Health Services
2333 - End-of-Life Treatment and Care
2305 - Education About Performance-Enhancing Substances
2324 - Point-of-Care Testing and Treatment by Pharmacists
2328 - Removal of Injectable Promethazine from Hospital Formularies
2211 - Naloxone Availability
2212 - Safe and Effective Therapeutic Use of Invertebrates
2213 - Criteria for Medication Use in Geriatric Patients
2220 - Promoting Telehealth Pharmacy Services
2224 - Drug Desensitization

2240 - Post-Intensive Care Syndrome
2245 - Substance Use Disorder
2254 - Pain Management
2102 - Use of Antimicrobials in Surgical Wounds and Procedures
2127 - Testing and Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship
2135 - Role of the Pharmacy Workforce in Pandemic Preparedness and Response
2136 - Role of the Pharmacy Workforce in Supporting Patient Access to Medical Supplies
2001 - Safety and Effectiveness of Ethanol for Prevention or Treatment of Alcohol Withdrawal Syndrome
2003 - Anticancer Treatment Parity
2009 - Role of the Pharmacy Workforce in Identifying and Caring for Victims of Human Trafficking
2017 - Role of the Pharmacy Workforce in Preventing Accidental and Intentional Firearm Injury and Death
2018 - Safe Use of Transdermal System Patches
2029 - Preserving Patient Access to Pharmacy Services for Medically Underserved Populations
2035 - Role of the Pharmacy Workforce in Violence Prevention
1910 - Therapeutic Use of Cannabidiol
1725 - Drug Dosing in Extracorporeal Therapies
1603 - Stewardship of Drugs with Potential for Abuse
1604 - Appropriate Use of Antipsychotic Drug Therapies
1605 - Safety of Epidural Steroid Injections
1607 - Use of Methadone to Treat Pain
1527 - Pharmacist's Role in Urgent and Emergency Situations
1402 - Safe Use of Radiopharmaceuticals
1214 - Pharmacist's Role in Accountable Care Organizations
0908 - Pharmacist Role in the Health Care (Medical) Home
0912 - Safe and Effective Use of Heparin in Neonatal Patients

Pharmaceutical Industry

Drug Products, Labeling, and Packaging

2622 - Dosing of Combination Antibiotics
2407 - Unit Dose Packaging Availability
2221 - Tamper-Evident Packaging on Multidose Products
2244 - Pediatric Dosage Forms
2146 - Expiration Dating of Pharmaceutical Products
2002 - Excipients in Drug Products
1812 - Availability and Use of Appropriate Vial Sizes
1821 - Ensuring Effectiveness, Safety, and Access to Orphan Drug Products
1711 - Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use
0920 - Standardized Clinical Drug Nomenclature
0720 - Standardizing Prefixes and Suffixes in Drug Product Names

0002 - Drug Shortages
9608 - Use of Color to Identify Drug Products

Marketing

2210 - Drug Samples
1806 - Manufacturer-sponsored Patient Assistance Programs
1714 - Restricted Drug Distribution
1620 - Manufacturer Promotion of Off-Label Uses
1624 - Ban on Direct-to-Consumer Advertising for Prescription Drugs and Medication-Containing Devices
1521 - Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs

Pharmacy Management

2603 - Pharmacy Leadership of Infusion Services
2422 - Safe Medication Sourcing, Storage, Preparation, and Administration in All Sites of Care
2334 - Pharmacist Leadership of Pharmacy Practice
2311 - Pharmacy Accreditations, Certifications, and Licenses
2218 - Pharmacy Executive Oversight of Areas Outside Pharmacy
2228 - Role of the Pharmacist in Service-Line Development and Management
2028 - Pharmacist's Role in Health Insurance Benefit Design
1915 - Pharmacy Department Business Partnerships
1522 - Disposition of Illicit Substances
1417 - Integration of Pharmacy Services in Multifacility Health Systems
0901 - Workload Monitoring and Reporting
0504 - Pharmacy Staff Fatigue and Medication Errors

Compensation and Reimbursement

2502 - Pharmacy Access to Payer Networks
2331 - Sustainable Billing, Reimbursement, and Payment Models
2232 - Revenue Cycle Management and Reimbursement and Pharmacist Compensation for Drug Product Dispensing
2233 - Value-Based Purchasing
1814 - Direct and Indirect Remuneration Fees
1301 - Payer Processes for Payment Authorization and Coverage Verification
0206 - Reimbursement for Unlabeled Uses of FDA-Approved Drug Products

Human Resources

2503 - Support of Global Health Organizations
2509 - Recovery and Assistance Programs for Healthcare Workers with Substance Use Disorder
2512 - Addressing and Preventing Moral Distress and Moral Injury in the Healthcare Workforce

2519 - Support for Caregiving Responsibilities in the Pharmacy Workforce
2404 - Flexible Workforce Models
2336 - Promotion of the Pharmacy Profession
2209 - Drug Testing as Part of Diversion Prevention Programs
2234 - Financial Management Skills
2237 - Universal Vaccination for Vaccine-Preventable Diseases in the Healthcare Workforce
2129 - Professional Identity Formation
2130 - Career Opportunities for Pharmacy Technicians
2131 - Zero Tolerance Of Harassment, Discrimination, and Malicious Behaviors
2133 - Optimal Pharmacy Staffing
2011 - Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice
1916 - Intimidating or Disruptive Behavior
1415 - Credentialing, Privileging, and Competency Assessment
1225 - Board Certification for Pharmacists
0810 - Education, Prevention, and Enforcement Concerning Workplace Violence
0812 - Appropriate Staffing Levels
0218 - Pharmacist Recruitment and Retention

Practice Settings

2219 - Hospital-at-Home Care
2427 - Use of Two Patient Identifiers in the Provision of Patient Care
1623 - Home Intravenous Therapy

Research

2606 - Drug Dosing in Conditions that Modify Pharmacokinetics or Pharmacodynamics
2207 - Institutional Review Boards and Investigational Use of Drugs
2243 - Enrollment of Underrepresented Populations in Clinical Trials

ASHP Statements, Endorsements, and Governance Positions

Approval of ASHP Statements

2522 - ASHP Statement on the Pharmacist's Role in Substance Use Disorder Prevention, Treatment, and Recovery
2428 - ASHP Statement on Artificial Intelligence in Pharmacy
2409 - ASHP Statement on the Community Pharmacist's Role in the Care Continuum
2312 - ASHP Statement on Leadership as a Professional Obligation
2316 - ASHP Statement on Precepting as a Professional Obligation
2202 - ASHP Statement on Professionalism
2215 - ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics
2223 - ASHP Statement on the Role of the Pharmacy Workforce in Emergency Preparedness
2225 - ASHP Statement on Pharmacist Prescribing of Statins
2226 - ASHP Statement on the Role of Pharmacists in Primary Care
2227 - ASHP Statement on Telehealth Pharmacy Practice

2119 - ASHP Statement on the Pharmacist's Role in Public Health
2120 - ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics
2143 - ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive
1919 - ASHP Statement on the Role of the Medication Safety Leader
1830 - ASHP Statement on Advocacy as a Professional Obligation
1534 - ASHP Statement on the Pharmacist's Role in Clinical Informatics
1537 - ASHP Statement on the Roles of Pharmacy Technicians
1227 - ASHP Statement on the Pharmacist's Role in Medication Reconciliation
1228 - ASHP Statement on the Use of Social Media by Pharmacy Professionals
1025 - ASHP Statement on Bar-Code Verification During Inventory, Preparation, and Dispensing of Medications
0922 - ASHP Statement on Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control
0923 - ASHP Statement on the Health-System Pharmacist's Role in National Health Care Quality Initiatives
0818 - ASHP Statement on Bar-Code-Enabled Medication Administration
0820 - ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems
0821 - ASHP Statement on Pharmacy Services to the Emergency Department
0822 - ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System
0823 - ASHP Statement on the Confidentiality of Patient Health Care Information
0724 - ASHP Statement on the Role of Health-System Pharmacists in Public Health
0415 - ASHP Statement on the Use of Dietary Supplements
0234 - ASHP Statement on the Pharmacist's Role in Hospice and Palliative Care
0235 - ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness
9916 - ASHP Statement on the Pharmacist Decision-Making on Assisted Suicide
9821 - ASHP Statement on the Pharmacist's Role in Clinical Pharmacokinetic Monitoring
9504 - ASHP Statement on the Pharmacist's Responsibility for Distribution and Control of Drug Products
9505 - ASHP Statement on the Role of the Pharmacist in Patient-Focused Care
9304 - ASHP Statement on Pharmaceutical Care
9306 - ASHP Statement on the Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices
9208 - ASHP Statement on Use of Medications for Unlabeled Uses
9111 - ASHP Statement on Pharmaceutical Research in Organized Health-Care Settings
8907 - ASHP Statement on Unit Dose Drug Distribution
8504 - ASHP Statement on Third-Party Compensation for Clinical Services by Pharmacists

ASHP Endorsements

9607 - Code of Ethics

ASHP Governance

0118 - State Affiliate Membership and ASHP Appointments

2026 Policy Positions

2601
RESPONSIBLE INTEGRATION OF ARTIFICIAL INTELLIGENCE IN PHARMACY EDUCATION AND TRAINING
Source: Council on Education and Workforce Development

To advocate for the responsible integration of artificial intelligence (AI) into pharmacy education and training programs to support learner development and practice readiness; further,

To advocate for development of competencies for discerning AI-generated content, including strategies to validate the accuracy, credibility, and applicability of information produced by AI systems; further,

To collaborate on the development of standards for AI use in pharmacy education and training.

Rationale
AI has the potential to evolve education and the learning environment by delivering personalized experiences, simulating clinical decision-making, and expanding access to knowledge resources. Conversely, AI also introduces unique challenges related to academic integrity, validation of information, learner overreliance, and responsible application, such as generative AI, which uses AI to create original content.

Emerging platforms which leverage AI to analyze, synthesize, and present clinical literature demonstrate both the potential value and the risks of integrating AI into the education and training of future healthcare professionals. In a recent JAMA article, Building the AI-Enabled Medical School of the Future, the authors highlight that academic institutions must move quickly to embed AI literacy, validation skills, and ethical awareness into curricula to ensure learners are equipped for practice in AI-enabled health systems.

This pharmacy education and training-focused policy will emphasize the need to equip learners with skills to critically evaluate and responsibly apply AI outputs, prepare future practitioners with competencies to navigate AI-enabled health systems, support faculty and preceptors in integrating AI appropriately into teaching, learner assessment and professional development activities, and establish safeguards to ensure integrity and alignment with professional values.

2602
SAFE USE OF CONTROLLED SUBSTANCES THROUGH REGULATORY REFORM
Source: Council on Pharmacy Management

To advocate for the reform of the Controlled Substances Act (CSA) to align with contemporary healthcare practice standards, with input from pharmacists and other stakeholders; further,

To urge the Drug Enforcement Administration (DEA) to issue transparent and practical guidance when interpreting and applying laws and regulations related to the CSA and other drug laws that affect patient care; further,

To encourage the DEA and other regulatory agencies to balance regulatory requirements with patient access to medically necessary controlled substances when developing regulations and interpreting and enforcing laws and regulations; further,

To promote collaboration among the DEA, professional associations, and regulatory agencies to identify and reduce: 1) barriers to patient care; 2) burdens on healthcare workers; and 3) cost of healthcare delivery in the establishment and enforcement of controlled substance laws and regulations.

Rationale

The Drug Enforcement Administration (DEA) and Department of Justice (DOJ) routinely update regulations and measures to counter substance abuse in the US. Two major implications of these changes include: (1) increasing regulatory burden on pharmacy operations and (2) a lack of standardized education and resources to support pharmacies in adequately responding to DEA inspections.

The mission of the DEA is to enforce U.S. controlled substance laws and regulations. The DEA has the authority to enter the controlled premises of a registered location and conduct administrative inspections both routinely and as circumstances warrant (21 U.S.C. 880 and 21 CFR 1316.03). The primary purpose of an inspection is to ensure compliance with the Controlled Substances Act (CSA) of 1970 regarding record-keeping, inventory, security, access controls, training records, and reports. Inspections can be conducted with voluntary consent of the DEA registrant or by an administrative inspection warrant by any judge of the United States or of a state court of record (21 U.S.C 880). Upon notice of CSA violations, pharmacies may face criminal investigations, civil and administrative actions, letters of admonishment, or even revocation of registration, which can be detrimental to both the organization and individual pharmacists. To mitigate or prevent avoidable CSA violations, transparency and uniformity in DEA interpretation and application of laws and regulations is essential. DEA should provide transparent and practical guidance that clearly communicates expectations, explains enforcement rationale, and maintains publicly accessible, up-to-date information about how it interprets and enforces laws and regulations under the CSA and related drug policies.

Since the original authorship of the CSA in 1970, health-system pharmacy practice has evolved significantly, yet the laws governing controlled substances have remained largely unchanged. Dissonance between practice and law presents ongoing challenges for compliance and vulnerabilities within health systems. Pharmacists and pharmacy technicians responsible for overseeing and monitoring controlled substances often face challenging situations, including how to respond to specific patient care scenarios (e.g., the handling and disposition of controlled substances brought into hospitals by patients) that conflict with the CSA or involve product-specific nuances that are not addressed by the CSA. Modernization of the CSA would provide an opportunity for the DEA to collaborate with key stakeholders, including health-system pharmacists, to achieve greater alignment with practice, improve regulatory

compliance, and reduce the overall regulatory burden. Some examples to consider for the modernization of the CSA include expansion and formalization of telemedicine authority for CS prescribing; creation of a national telemedicine registration that would eliminate the need for a state-by-state DEA registration requirement; establishment of risk-based flexibility for patients with chronic conditions who need to maintain continuity of therapy during emergencies; and shifting from weight-based production quotas to dosage-form based quotas to mitigate drug shortages for clinically appropriate care.

2603

PHARMACY LEADERSHIP OF INFUSION SERVICES

Source: Council on Pharmacy Management

To encourage healthcare organizations to engage pharmacists and pharmacy leaders in the development and management of infusion service lines; further,

To advocate for payment commensurate with the level and complexity of care and services provided to support sustainable infusion business models; further,

To advocate for the elimination of site of care restrictions to ensure patient preference and continuity of care in infusion services; further,

To encourage use of technology that integrates with patient medical records to enhance medication safety and streamline authorization and adjudication processes.

Rationale

Members of the pharmacy workforce practicing within the infusion business are required to be experts throughout multiple stages of the patient's treatment including knowledge of the disease states, the management of complex medication regimens, patient education, regulatory requirements, and determination of the appropriate site of care for patients based on clinical needs, policies, and payer requirements. The number of patients receiving home and specialty infusion services has grown rapidly and is projected to continue to grow given the aging population, rates of chronic disease, shift to outpatient services, and increased development of injection-based medications.

Complex payer policies and proposed reimbursement models further complicate infusion therapy. Many patients receiving infusions are shifted to lower cost sites of care, mandated by their health insurers, which may lead to lapses in care, missed infusions, and disconnect from the primary care team. Site neutral payments, prior authorizations, payer denials, and bagging practices all present unique challenges for hospital and health-system pharmacy. Given the high cost, safety considerations, and operational complexity associated with most infusion therapies, health systems have increasingly focused on the oversight and execution of these services. Support is needed to establish sustainable reimbursement models that allow for high-quality, patient-centered infusion services.

The pharmacy workforce has unique knowledge and expertise to navigate most challenges in infusion care, which should be leveraged to provide leadership and oversight for infusion care. This includes the full scope of services encompassing preparation, administration,

authorization, and adjudication of care. For example, shifting infusion care to the home setting offers potential cost-savings for health systems and payers, while providing a more convenient option for patients. This shift to home-based care requires care coordination, assessment of home care viability for specific patients, considerations for safety, adherence to regulatory requirements, and around-the-clock access to care. In support of this, pharmacy leaders must identify treatments available for safe and effective administration in the home setting and determine resources required for home-based treatments.

Successful execution of infusion services requires up-to-date technology that fully integrates with health-system electronic medical records. These systems should manage the full breadth of services, from ordering and processing to authorization and adjudication of medication claims. This ensures medications are safely prepared, authorized, and administered in an efficient manner.

2604

INTEGRITY OF PHARMACIST PROVIDED HEALTH INFORMATION

Source: Council on Public Policy

To oppose any governmental restriction on pharmacists' ability to provide evidence-based health information to patients; further

To urge policymakers to protect pharmacists' professional autonomy in educating patients on medications, public health issues, and emerging scientific developments; further

To oppose the elimination, suppression, manipulation, or politicization of evidence-based public health data and drug safety information by any entity; further

To advocate for legislation that protects scientific integrity and ensures transparency in the dissemination of public health information; further

To affirm that pharmacists are trusted and reliable medication experts and have the professional responsibility to disseminate evidence-based, health information to patients and communities.

Rationale

Pharmacists play a vital role in public health, serving as reliable, accessible, and trusted sources of evidence-based medical information for patients and communities. As experts in medication therapy, pharmacists ensure individuals have the knowledge and information they need to make informed decisions about their care.

However, in recent years, pharmacists’ ability to share accurate, science-based health information has been threatened by political interference, unjustified restrictions, and the deliberate distortion or suppression of public health data. These threats not only undermine pharmacists’ professional autonomy but also endanger the communities they serve.

Pharmacists must be free to practice in accordance with scientific evidence and professional ethics, without being curtailed by political agendas. Any effort to restrict their

ability to educate the public, speak truthfully about medications, or respond to emerging health threats must be met with firm opposition.

Because misinformation can spread rapidly, it is more important than ever to uphold integrity and transparency. Silencing or censoring pharmacists risks irreparable harm. It compromises patient safety, erodes public trust, and weakens the very foundations of our healthcare system. Policymakers must ensure that pharmacists remain empowered to educate patients on medications, emerging scientific advancements, and critical public health concerns.

2605

DEREGULATION OF PRESCRIPTION DRUGS

Source: Council on Therapeutics

To oppose legislation or regulations that permit reclassification of prescription medications to over-the-counter (OTC) status outside of the established Food and Drug Administration (FDA) review and approval process.

Rationale

The FDA requires manufacturers seeking to market a prescription drug product as nonprescription (Rx-to-OTC switch) to demonstrate that the medication is safe and effective for self-care. Regulation requires OTC drug labeling that is easily understood without the guidance of a healthcare professional, and that OTC drugs should treat conditions suitable for self-diagnosis, such as allergies or headache. Approval decisions are predicated on robust evidence from clinical trials, consumer behavioral studies, and post-marketing surveillance data. Manufacturers may also switch a prescription drug to OTC by including an Additional Condition for Nonprescription Use (such as a required questionnaire or pharmacist consultation before purchase) to address safety concerns and ensure patients have the information needed to choose the right medication for their condition.

State-level efforts to deregulate prescription drugs outside of this established framework (e.g., state laws authorizing OTC sale of ivermectin) bypass FDA safety standards and may pose significant risks to patients. While ASHP strongly supports initiatives (such as expansion of pharmacist prescribing authority) that increase patient access to clinically appropriate, evidence-based healthcare services and drug therapies, deregulation of prescription drugs outside the FDA process eliminates essential safeguards. Many prescription medications have important contraindications, toxicities, drug-drug interactions, or monitoring needs that require evaluation by a pharmacist or prescriber or are used to treat conditions requiring a medical diagnosis. Removing the opportunity for patient education and clinical assessment undermines safe medication use, increases the risk of harm, and weakens public trust in the medication-use process.

Drug deregulation also carries significant legal, regulatory, and liability concerns to pharmacists. Although some state laws include provisions for civil or criminal immunity or prohibit license revocation for pharmacists who dispense drugs under such statutes, selling medications without FDA-approved nonprescription labeling may constitute misbranding under the Food, Drug, and Cosmetic Act. This conflict between federal and state law has not yet been adjudicated, creating substantial legal uncertainty. Pharmacies may elect not to offer

deregulated drugs under these conditions, further confusing patients and limiting access while failing to achieve the intended goal of expanding medication availability.

2606
DRUG DOSING IN CONDITIONS THAT ALTER PHARMACOKINETICS AND PHARMACODYNAMICS
Source: Council on Therapeutics

To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic conditions; further,

To encourage drug product manufacturers and other stakeholders to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, geriatric, and patients at the extremes of weight to facilitate safe and effective dosing of drugs in these patient populations; further,

To advocate healthcare provider education and training that facilitate optimal patient-specific dosing in populations of patients with altered pharmacokinetics and pharmacodynamics; further,

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and electronic health record documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic conditions.

This policy supersedes ASHP policy 1804.

Rationale
The pharmacokinetic and pharmacodynamic properties of drugs found in drug information monographs are based on the drug's absorption, distribution, metabolism, and excretion in healthy, adult patients during Phase I of a drug's clinical trials. Many patients receiving drug therapy do not fit this profile, and many have compromised organ function. The medical community has long recognized the need for a standardized approach to evaluating organ system dysfunction. Although there are methods to determine organ function (e.g., the Cockcroft-Gault equation for renal function or the Child-Turcotte-Pugh Classification for Severity of Cirrhosis), there is debate as to whether these methods are true indicators of organ function, as the components that comprise these equations may fluctuate based on severity and patient status. Traditional laboratory values used to evaluate organ dysfunction can be bidirectional and conflicting as well.

With the exception of adjustments for renal dysfunction, there is not much information regarding dosage adjustment for specific drugs. Many organ systems are involved in a drug's absorption, distribution, metabolism, and excretion. Hepatic effects, for example, are a risk area, as those effects are slower to be seen and have not been the subject of much research, and the number of drugs affected are smaller in number than renally excreted drugs. Both acute and chronic aspects of patient conditions may require monitoring and adjustment, including sepsis, encephalopathies, pregnancy, heart failure exacerbations, and cystic fibrosis. Certain protocols, such as therapeutic hypothermia, can also have clinically significant impact on a

drug's pharmacokinetic and pharmacodynamic behavior. There is also need to promote research and utilization of biomarkers into practice, as these may reflect organ function and may provide pharmacists with a more complete clinical picture.

Pharmacists are also seeing an increase in the number of patients at both extremes of weight, and there is a lack of information regarding dosing medications for these populations. ASHP advocates that the Food and Drug Administration develop guidance for voluntary drug dosing studies in these populations, as the need for this guidance is supported by the complexity of drug dosing that can vary based on drug and patient characteristics. Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies, and to publicly report the results, especially for drugs for which significant weight extremes may have a clinical impact.

2607

DIRECT-TO-CONSUMER CLINICAL GENETIC TESTS

Source: Council on Therapeutics

To support research to validate and standardize genetic markers used in direct-to-consumer clinical genetic tests and guide the application of test results to clinical practice; further,

To encourage the Food and Drug Administration (FDA) to continue to regulate direct-to-consumer clinical genetic tests as medical devices and work with the National Institutes of Health to evaluate and approve direct-to-consumer clinical genetic tests; further,

To advocate that direct-to-consumer clinical genetic tests be provided to consumers through the services of appropriate healthcare professionals who order tests from laboratories certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA); further,

To support FDA policies and procedures regarding advertising of direct-to-consumer clinical genetic tests, including the following requirements: (1) the relationship between the genetic marker and the disease or condition being assessed is clearly presented, (2) the benefits and risks of testing are discussed, (3) such advertising is provided in an understandable format, at a level of health literacy that allows the intended audience to make informed decisions, and includes a description of the established patient-healthcare provider relationship as a critical source for information about the test and interpretation of test results; and (4) how patient information is collected, protected, shared, and used; further,

To encourage health systems to create policies and procedures addressing direct-to-consumer genetic testing results as it relates to confirmatory testing, integration of genomic information into the healthcare record, genetic counseling, and clinical decision-making; further,

To encourage pharmacists to educate consumers and clinicians on the potential risks and benefits of direct-to-consumer clinical genetic tests for disease diagnosis and decisions involving drug therapy management.

This policy supersedes ASHP policy 2101.

Rationale

Since 2018, the FDA has implemented multiple processes, procedures, and guidance documents surrounding in vitro diagnostics (IVDs), also referred to as direct-to-consumer (DTC) testing. The FDA now reviews DTC tests for moderate- to high-risk medical purposes, to determine the validity of the test claims. The FDA review consists of assessing for analytical validity, clinical validity, and claims made by the company marketing the test about how well it works. Additionally, the FDA reviews descriptive information about the test for accuracy and for an appropriate level of health literacy.

The FDA now regulates DTC tests as medical devices. The specific regulatory requirements depend on the risk classification of the individual IVD. The FDA has been proactive about streamlining the regulation of DTC tests, as well as determining appropriate for use by a consumer without the involvement of a healthcare provider.

In October 2018 and April 2019, the FDA issued a safety communication to alert the public to concerns regarding pharmacogenetic tests with unapproved claims to predict an individual's response to a specific therapeutic drug, where these claims may not be supported by clinical evidence. Warning letters were sent by the FDA to select companies. Patients and providers were advised the FDA has not evaluated genetic tests, which make claims regarding the effects of a specific medication. Pharmacists should continue to educate patients about the potential limitations and variability of DTC genetic tests.

As consumer use of DTC testing continues to be prevalent, it is critical healthcare systems develop policies and best practices related to the utilization of data patients may present to their healthcare teams. Providers should be aware that for most medications the relationship between genetic variations and a medication's effects has not been established. If a patient provides a test report from a genetic DTC test claiming to predict a person's response to a specific medication, the healthcare team should seek information in the FDA-approved drug label regarding whether genetic information should be used for determining therapeutic treatment. Confirmatory testing should be considered by the healthcare team from a CLIA-certified laboratory.

Finally, DTC genomic testing is done outside of a healthcare system where they are considered assets of the company, which does not provide the same protections. In 2023, the genetic testing company, 23andMe, with over 12 million customers, suffered a cyber-attack that had compromised data for nearly 7 million users – exposing sensitive personal and genetic data, including names, photos, birth years, ethnicity, and information from family trees. 23andMe filed for bankruptcy in 2025 and placed its assets up for sale. In the wake of this, there have been multiple concerns regarding the sale of customer data (DNA, health, ancestry, etc.). and it is unknown what new owners might do with that data. Customers are also concerned that deleting their account or deleting the DNA sample is complicated or slow, and they’re not confident the data is actually removed after confirmation. Currently, there is no federal genetic privacy law and few states have some consumer protections regarding data privacy which complicates this further.

2608

OPTIMIZING CAREER FULFILLMENT IN PHARMACY

Source: Council on Education and Workforce Development

To recognize that fostering career fulfillment strengthens patient care and advances the profession by promoting a resilient, engaged, and purpose-driven workforce; further,

To advocate for dedicated organizational priorities focused on career fulfillment that integrate recognition strategies, structured development guidance, and individualized support and mentoring across the care continuum; further,

To encourage the pharmacy workforce to align their professional development plans with their personal definitions of career fulfillment and core values to help support sustainable engagement and well-being throughout their careers.

Rationale

Career fulfillment represents a holistic and evolving concept that extends beyond workforce retention and professional development. While professional development equips individuals with skills, career fulfillment addresses the alignment of those skills and roles with personal values, well-being, and long-term satisfaction. The pharmacy workforce increasingly seeks meaningful work environments where structured development guidance, recognition strategies, and individualized pathways reflect both organizational needs and individual aspirations.

Current organizational structures often require pharmacy leaders to juggle the dual responsibilities of overseeing daily operations and providing individualized career guidance and fulfillment-focused support. Establishing dedicated roles or frameworks to share these responsibilities can enhance workforce engagement, growth, and well-being ultimately advancing organizational performance and strategic goals.

Supporting career fulfillment requires organizations to create dedicated roles and structures that provide education, training, and tailored guidance. These efforts are particularly important during transitional moments, such as entry into practice, advancement to new responsibilities, or shifts into leadership or nontraditional roles. Frameworks that incorporate coaching and mentorship can help individuals navigate these transitions effectively and maintain engagement throughout their careers.

Equally important is empowering the pharmacy workforce to take ownership of their professional journeys by aligning personal values with professional development plans. By recognizing fulfillment as a key component of workforce well-being, organizations can create sustainable career pathways that not only enhance satisfaction and promote resilience but also elevate the profession and strengthen the quality of patient care delivered across all practice settings.

2609

QUALITY OF PHARMACY EDUCATION

Source: Council on Education and Workforce Development

To support the Accreditation Council for Pharmacy Education's continuing role of promulgating accreditation standards and guidelines and engaging in sound accreditation processes to ensure quality in the education provided by colleges of pharmacy; further,

To advocate that pharmacy education should proactively incorporate established and emerging practice advancements, practice standards, and innovative technology; further,

To acknowledge that, in addition to a robust curriculum, access to quality experiential educational sites and the availability of qualified faculty (including preceptors) are essential determinants of the ability to provide a quality pharmacy education.

This policy supersedes ASHP policy 1108.

Rationale

The Council supports the Accreditation Council for Pharmacy Education's role in ensuring the quality of education provided by colleges of pharmacy. Multiple factors contribute to ongoing fluctuations in the supply and demand of the pharmacy workforce. It remains important that workforce projections are thoughtfully considered when decisions are made regarding program development and expansion. Colleges of pharmacy continue to face nationwide challenges related to enrollment trends, operational costs, and constrained higher education funding. Given our professional responsibility to prepare the next generation of pharmacists for the workforce, colleges of pharmacy and other partners should work innovatively to find solutions that support pipeline development, didactic and experiential education, workforce recruitment and retention, and sustainability across both academic and practice enterprises. Further, we support the ongoing research about the pharmacy workforce through reports such as data from the Bureau of Labor Statistics, the National Pharmacist Workforce Study, and other similar state-level projections.

Incorporating pharmacy practice advancements and innovative technology into pharmacy education is essential to prepare future-ready pharmacists who can thrive in evolving healthcare environments. As pharmacists take on expanded roles in clinical decision-making, public health, and digital health, education must align with these changes by integrating tools such as telepharmacy, and AI-assisted care.

Bridging the gap between academic training and real-world practice ensures graduates are competent, collaborative, and adaptable. Additionally, leveraging technologies such as virtual simulations and personalized learning platforms enhances student engagement and skill development. These innovations also support equitable healthcare delivery by training students to serve diverse and underserved populations through modern, accessible care models.

2610

ADVANCING TECHNOLOGY INNOVATION AND VENDOR ACCOUNTABILITY IN HEALTH-SYSTEM PHARMACY

Source: Council on Pharmacy Management

To urge hospitals and health systems to actively engage pharmacy departments in prospective assessment, governance, competitive procurement, ongoing performance monitoring, and evaluation of technologies impacting patient care, inclusive of pharmacy informatics leadership; further,

To encourage pharmacy leaders to take ownership of pharmacy's role in implementing, maintaining, and optimizing medication-related technologies, including associated processes and governance; further,

To support collaboration between pharmacy leaders and technology vendors in the design, implementation, maintenance, and ongoing optimization of technologies that improve patient-care outcomes and the user experience, consistent with appropriate procurement and contracting requirements; further,

To encourage technology vendors to provide transparent estimates of the resources required for implementation, integration, training, maintenance, and long-term support; further,

To advocate for federal laws and regulations that establish appropriate oversight mechanisms and define technology vendors' responsibilities for safety, performance transparency, and timely remediation of identified risks.

This policy supersedes ASHP Policy 2406.

Rationale

The adoption of medication-related technology [e.g., health information technology (HIT)] in hospitals has been steadily increasing. The 2024 ASHP National Survey of Pharmacy Practice in Hospital Settings reports basic analytics (e.g., data from smart pumps, clinical decision support, compounding technology) are used in nearly 80% of hospitals and advanced analytics (e.g., artificial intelligence, machine learning, predictive analytics) are used in about 7% of hospitals, an increase from 4% in 2021 and 2.6% in 2020. Investing in technology and properly integrating it within healthcare can prevent errors, improve quality, and prevent waste. Emerging or novel technologies offer opportunities to transform the medication use process. These technologies offer significant opportunities to increase direct patient care time, close care gaps, reduce administrative burden, and minimize repetitive tasks. However, without a coordinated approach, adoption can be fragmented, underused, or misaligned with hospital goals.

Before selecting or upgrading medication-related technology, organizations must determine their needs and goals. For instance, the Office of the National Coordinator for HIT maintains the Health IT Playbook to help clinicians, administrators, and clinician-practice staff. The Health IT Playbook provides tools to help healthcare organizations choose and implement

the right HIT systems for their needs. As hospitals and providers implement HIT within their institutions and practices, however, they often encounter new types of errors and problems. The medical literature is replete with many reports of the unintended consequences of HIT, so continuous monitoring of these systems is required. It has become increasingly important to properly assess the interface between HIT and users to identify whether any new risk has been introduced to the system and implement HIT appropriately, considering medication-use processes and human factors. Critical questions hospitals and health systems face include (1) when do HIT advances exceed the capacity for integration into workflow, (2) when does HIT begin to introduce risk into the medication-use process rather than improve patient safety, and (3) what are the accountabilities of HIT providers, regulators, and providers to ensure the necessary product development and assessments are made before implementation of new HIT.

ASHP advocates that the pharmacy department be part of the implementation team for any medication-related technology within an institution. Pharmacy technology solutions are capital investments with major budget implications costing millions of dollars annually. Given the rising cost of healthcare and internal competition for finite capital dollars, it is important to identify solutions that will improve quality and safety while being fiscally responsible. Pharmacy leaders must assume responsibility for guiding the design, selection, assessment, and implementation of new and existing medication-related technologies within the department of pharmacy, including their governance and continuous evaluation. Technology assessment tools should be applied by the pharmacy workforce to proactively determine gaps in function prior to implementation, during upgrades, and as part of the continuous evaluation of technology performance. Assessments should include but are not limited to, risk, cybersecurity, clinical and operational. The use of failure modes effects analysis (FMEA) and other resources should be considered. Organizations selecting or upgrading medication-related technology should work closely with implementation partners or vendors to ensure the following: (1) products are suited to the organization's needs; (2) Technology will be usable by clinicians and staff; and (3) accurate estimates of resources needed are identified to implement and support new or upgraded technology. It is imperative that technology vendors provide comprehensive estimates that clearly specify all required human, technical, financial, and operational resources and time commitments necessary for the implementation, integration, training, and long-term support of new or upgraded technology solutions. These processes also provide opportunities to examine and optimize care delivery processes. Tailoring both technology and processes around care pathways takes advantage of the technology's potential to support safer care, inclusive of patient goals, while reducing burdens on healthcare professionals. Risk assessment should also be considered when implementing any new technology to ensure that unintended consequences are minimized. Regulatory and accreditation organizations include components of risk assessment and quality improvement within their criteria, but hospitals need to incorporate these into their overall plans. Such risk assessments may lead to reduced scrutiny of certain medication-related technology implementations as purchasers are often not required to research each product's capabilities and limitations. Finally, federal law should recognize vendors' accountability for the safety of their products as implemented.

Pharmacy workforce involvement in the development of technologies is critical. ASHP supports collaboration between pharmacy leaders and technology vendors to share pharmacy input for the development or enhancement of innovative technologies that improve patient

outcomes and optimize usability. The medication-use process is inherently a multi-disciplinary process requiring involvement from numerous health-system departments. Pharmacy leadership is necessary and core principles of system-wide strategic alignment, collaboration, and change management are also fundamental. ASHP encourages members of the pharmacy workforce to actively pursue and engage in opportunities to influence technology construction.

2611
STANDARD OF CARE REGULATORY MODEL
Source: Council on Pharmacy Management

To promote the adoption of a standard of care regulatory model for pharmacy practice.

Rationale

Standard of care regulatory models for pharmacy practice (e.g., pharmacist-provided clinical care, patient safety, automation, compounding standards) allow pharmacists to operate with greater autonomy and use their professional judgment and expertise within a defined scope of practice. States with existing standard of care regulatory models include: Idaho (implemented in 2018), Alaska (transitioned to through rulemaking in 2023), Montana (passed a bill in 2023), and Iowa (adopted via legislative reform in 2024). The federal pharmacy services (e.g., Veterans Affairs, Department of Defense, Public Health Service) operate under a standard of care framework and credential and privilege pharmacists using a defined scope of practice.

As regulation of pharmacy practice has become more complex, there is a growing interest in adopting a standard of care regulatory model, which has the potential to remove a significant volume of detailed rules. Today, many states have complex rules dictating exactly which test, therapy, or disease state intervention pharmacists can provide. Each new statutory allowance introduced into pharmacy practice often necessitates the development of corresponding competencies or implementation of training courses. Much like physicians, nurses, and other healthcare professionals, pharmacists should instead be held to the standard of care rather than relying on 'brightline' rules or standards, which leave little room for interpretation. The standard of care model allows practice to align with the highest level of education and training for that individual.

Like physicians, privileging and credentialing will help to determine the appropriate education and training associated with the scope of practice required for the setting. ASHP encourages health systems to incorporate pharmacists into established privileging programs that align with education, training, and practice experience in their designated setting(s) (see ASHP policy 1415, Credentialing, Privileging, and Competency Assessment). Within many health-systems, pharmacists have been integrated into their privileging processes but adoption of standard of care regulatory models will require revised privileging procedures and pharmacists' inclusion in healthcare insurance credentialing procedures to support reimbursement. ASHP advocates for the inclusion of pharmacists in health insurance credentialing processes consistent with their authorized scope of practice (see ASHP policies 2011, Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice; and 2405, Pharmacist Access to Provider Networks).

2612

PROMOTING ENVIRONMENTAL SUSTAINABILITY IN HEALTHCARE

Source: Council on Pharmacy Practice

To acknowledge the importance of environmental sustainability in promoting and preserving public health; further,

To encourage implementation of environmentally conscious practices that reduce waste within the healthcare system; further,

To advocate for legislation and regulation that enables waste-minimization efforts in medication-use practices across all points of the pharmacy supply chain; further,

To advocate for environmentally sustainable drug manufacturing processes that minimize the environmental impact across the full medication and supply life cycle; further,

To encourage members of the pharmacy workforce to seek out opportunities that promote environmental sustainability and health.

Rationale

In healthcare, sustainability refers to the implementation of cost-efficient, environmentally responsible practices that support healthy and resilient communities over time. Environmental health, a key component of public health, focuses on how natural and built environments affect human health and disease.

As part of the built environment, healthcare facilities are increasingly expected to enhance environmental stewardship in support of patient and public health. Healthcare activities generate substantial amounts of waste, which, if improperly managed, can have serious environmental and public health consequences. According to the World Health Organization (WHO), approximately 85% of healthcare waste is non-hazardous general waste, while the remaining 15% consists of hazardous materials, including infectious, chemical, and radioactive waste. Improper disposal of both hazardous and non-hazardous healthcare waste can contribute to environmental pollution, the spread of infectious diseases, and occupational risks for healthcare workers.

In the United States, healthcare facilities produce more than six million tons of solid waste annually, with plastics accounting for 20% to 25% of that total. Approximately 91% of plastics, including those used in healthcare, are not recycled, contributing to landfill accumulation and environmental degradation. A single hospital bed is estimated to generate nearly 30 pounds of waste per day, highlighting the scale of the issue in high-volume facilities.

2613

BODY SIZE INCLUSIVITY

Source: Council on Pharmacy Practice

To recognize that body size bias influences health outcomes, social interactions, and decisions across workplaces and healthcare settings; further,

To promote the use of body size inclusivity in practice to ensure a comprehensive, patient-centered approach to care; further,

To encourage adoption of best practices that minimize body size bias across professional and healthcare settings.

Rationale

Body size inclusivity is defined as "accepting and respecting a wide range of body types and ensuring that all individuals, regardless of their body size, feel valued and included." It is the intentional acknowledgment, respect, and accommodation of people of all body sizes in personal, professional, and organizational settings. In contrast, weight stigma refers to discriminatory acts and ideologies targeted towards individuals because of their weight and size, favoring smaller body sizes and perpetuating stigma, bias, and discrimination. Research demonstrates that weight-based stigma is a social determinant of health, associated with increased psychological stress, anxiety, depression, and lower self-esteem, contributing to both mental and physical health burdens for affected individuals.

Several healthcare organizations have developed policies and initiatives to promote body size inclusivity, aiming to reduce psychological harm and stigma associated with weight bias. For example, the World Obesity Foundation has advocates for system-level change to eliminate weight bias in healthcare and other sectors. The Massachusetts Medical Society emphasizes that with increased risk of weight bias comes increased incidence and prevalence of depression, social rejection, anxiety, and suicidality across all ages. Guidelines from the American Diabetes Association and other groups recommend comprehensive provider training, inclusive clinical environments, and respectful, person-centered communication to reduce stigma and improve obesity care. Lastly, the Health at Every Size (HAES) movement promotes body size inclusivity while focusing on overall health rather than weight. HAES emphasizes holistic well-being, self-acceptance, and the removal of weight-centered biases from health assessments and social interactions. It offers the following HAES principles and framework of care:

- Healthcare is a human right for people of all sizes, including those at both extremes of weight.
- Comprehensive care is free of anti-fat bias and considerate of all body types.
- Wellbeing, care, and healing are collective and deeply personal resources.
- Health is a sociopolitical construct that is often reflective the of society's values.

Professional policies can play a central role in promoting body size inclusivity by setting clear expectations for equitable treatment, implementing anti-discrimination protections, and providing training to staff and leadership on recognizing and counteracting weight and height bias. Organizations can also audit existing policies and practices through a body-size lens to identify areas for improvement, while maintaining the collection of body size information needed for patient care decisions. By institutionalizing these changes, organizations signal a commitment to the psychological safety and dignity of all employees, reducing stigma, and promoting an environment where health, productivity, and professional success are not contingent on body size. Pharmacists and pharmacy technicians with education and training on

the importance of body size inclusivity represents an opportunity to be a trusted and patient-centered professional.

2614
PHARMACY WORKFORCE LEADERSHIP IN IMPROVING VACCINE ACCESS
Source: Council on Pharmacy Practice

To affirm the pharmacy workforce is the leader in increasing patient access to vaccinations to improve public health; further,

To collaborate with key stakeholders to support the public health role of the pharmacy workforce in the initiation, preparation, and administration of all adult and pediatric vaccinations; further,

To advocate that state and federal health authorities establish required centralized databases for timely documentation of vaccine administrations that are interoperable and accessible to all healthcare providers; further,

To advocate for payer coverage guarantees without cost sharing of evidence-based vaccines; further,

To work with federal, state, and local governments and others to improve the vaccine development and supply system in order to ensure an adequate supply of vaccines; further,

To foster public vaccine confidence through consistent, evidence-based, and culturally sensitive engagement with individuals and communities.

This policy supersedes ASHP policy 2247.

Rationale
Increasing adult and pediatric patients' access to vaccinations is an important public health challenge. The unique training and expertise of members of the pharmacy workforce in all aspects of the medication-use system can help expand patients' access to vaccinations and promote disease prevention in all practice settings. Hospital and health-system pharmacists, student pharmacists, and pharmacy technicians provide care to a patient population that is at risk and often critically ill, and such patients are especially dependent on herd immunity. Patients in rural areas, where a pharmacy may provide the only convenient access to a healthcare professional, will benefit from increased pharmacy workforce vaccination authority.

Although all states permit pharmacist administration of some vaccines, state laws differ in the range of vaccines pharmacists and pharmacy technicians may administer and the patient populations they are permitted to vaccinate. During the COVID-19 public health emergency, new regulatory flexibility under the Public Readiness and Emergency Preparedness (PREP) Act allowed pharmacy technicians and pharmacy students, under the supervision of a licensed pharmacist, to administer COVID-19 and influenza vaccines through 2029. Permanently allowing trained and certified pharmacists, including student pharmacists, to order and

administer all adult and pediatric vaccines (e.g., by eliminating the requirement that some vaccinations be conducted within a collaborative practice agreement) would encourage standardization of pharmacy vaccination practice within and among states, as would permitting appropriately trained and supervised pharmacy technicians to prepare and administer vaccinations. ASHP also advocates for payer coverage guarantees without cost sharing of vaccines and appropriate reimbursement of the pharmacy workforce for all vaccination services.

To aid in sharing important patient vaccination information, centralized and interoperable databases of patient vaccinations should be established, and all authorized vaccination providers, including pharmacists, student pharmacists, and pharmacy technicians, should be required by law or regulation to document their vaccinations in those databases in a timely manner when they become available.

Pharmacists, student pharmacists, pharmacy technicians, and pharmacy educators should embrace their role in this important public health effort by providing education about the importance of vaccination in disease prevention, participating in community vaccination programs, and training vaccination providers.

The pharmacy workforce has an integral role in promoting disease prevention by promoting vaccine confidence. The CDC defines vaccine confidence as "the trust that patients, their families, and providers have in recommended vaccines, the providers who administer vaccines, and the processes and policies that lead to vaccine development, licensure or authorization, manufacturing, and recommendations for use." Building vaccine confidence can involve helping patients, caregivers, healthcare providers, and members of the public overcome vaccine hesitancy, which is a delay in acceptance or refusal of vaccination despite availability of vaccination services.

The pharmacy workforce, and in particular its leaders, also has an important role in working with federal, state, and local government, the pharmaceutical industry, and other stakeholders to improve the vaccine development and supply system to ensure a consistent and adequate supply of vaccines.

2615

PHARMACY WORKFORCE RIGHT OF CONSCIENCE AND THE PATIENT'S RIGHT OF ACCESS TO THERAPY

Source: Council on Pharmacy Practice

To support processes that protect patients' access to legally prescribed treatments while reasonably accommodating members of the pharmacy workforce exercising rights of conscience; further,

To affirm the value of shared decision-making that protects patient well-being and continuity of care while balancing the rights of conscience held by members of the pharmacy workforce and other healthcare professionals; further,

To recognize the right of pharmacy workforce members to decline participation in non-emergency care delivery activities they consider morally, religiously, or ethically objectionable; further,

To support the principle that a member of the pharmacy workforce exercising rights of conscience must remain respectful of, and responsive to, and serve the legitimate health care needs and preferences of the patient and shall provide appropriate referral or transfer of care without any actions to persuade, coerce, or otherwise impose personal values, beliefs, or objections on the patient.

This policy supersedes ASHP policy 0610.

Rationale

ASHP affirms members of the pharmacy workforces' right to decline to participate in therapies they consider to be morally, religiously, or ethically troubling but recognizes that a right of conscience must balance a pharmacist's or pharmacy technician's deeply held beliefs with his or her professional duty and the patient's autonomous right to access legally prescribed and medically indicated treatments. To achieve this balance, systems to protect the patient's right to timely access to therapy should be developed in advance of non-emergent clinical scenarios where a member of the pharmacy workforce might exercise the right of conscience. The right of conscience therefore creates an affirmative responsibility on the part of the pharmacist or pharmacy technician to proactively notify his or her employer about therapies of concern. In addition, a pharmacist and pharmacy technician exercising the right of conscience must respect and serve the legitimate healthcare needs and desires of the patient and must provide a referral without any actions to persuade, coerce, or otherwise impose on the patient the pharmacist's or pharmacy technician's values, beliefs, or objections. For the purposes of this policy, "referral" is defined in manner similar to that used by the American Academy of Family Physicians (Consultations, Referrals, and Transfers of Care; 2012 COD): a referral is a request from one member of the healthcare workforce to another to assume responsibility for management of one or more of a patient's specified problems, for a specified period of time, until the problem(s)' resolution, or on an ongoing basis, and represents a temporary or partial transfer of care to another member of the healthcare workforce for a particular condition. When conscience requires a pharmacist or pharmacy technician also to decline to refer the patient to a specific provider who can provide the legally prescribed and medically indicated treatment, the pharmacist or pharmacy technician should offer impartial guidance to patients about how to inform themselves regarding access to the therapy. The National Catholic Bioethics Center suggests that healthcare providers declining to refer may assist patients with accomplishing a transfer of care to another provider or institution of the patient's choosing by providing a general list of other providers or institutions based on geographic vicinity or area of specialty, so long as the list is not developed based on the criterion of whether the providers are known or believed to offer the therapy in question. Institutions should have processes in place to ensure that the transfer of care process does not interfere with the patient's right to obtain legally prescribed and medically indicated treatments. Any accommodations made on the basis of a pharmacist's or pharmacy technician's decision to exercise the right of conscience should be nonpunitive.

2616
SAFE AND EFFECTIVE COMPOUNDING
Source: Council on Pharmacy Practice

To affirm that compounding of medications, when done to meet immediate or anticipatory patient needs, is part of the practice of pharmacy and is not manufacturing; further,

To support preferential use of commercially manufactured products in ready-to-administer dosage forms where barriers do not exist; further,

To encourage the pharmacy workforce members who compound medications to use only drug substances that have been manufactured in Food and Drug Administration-registered facilities and that meet official United States Pharmacopeia (USP) compendial requirements; further,

To advocate that all compounding activities meet applicable USP standards and federal and state regulations; further,

To support the principle that the pharmacy workforce be adequately trained and have sufficient facilities, equipment, automation, and technology to ensure the quality of compounded medications; further,

To encourage USP to develop compounded preparation monographs for commonly compounded preparations; further,

To educate prescribers, other healthcare professionals, and patients about the potential risks associated with the use of compounded preparations.

This policy supersedes ASHP policy 2139.

Rationale

The practice of compounding has evolved along with the profession of pharmacy and it remains an essential component of patient care and pharmacy practice. With advances in pharmaceutical manufacturing, the need for preparation of individualized medications based on a prescription or medication order has decreased but not disappeared. Extemporaneous compounding of medications, when done to meet immediate or anticipatory patient needs, will likely always be an essential part of the practice of pharmacy, and cannot be replaced by any manufacturing model currently envisioned. Commercially and readily available drug products in the form necessary to meet patient needs should always be preferred to extemporaneously compounded alternatives, except when excipients or other components render the commercially available product clinically inappropriate for an individual patient. When extemporaneous compounding is required, it should meet strict requirements to protect patients from receiving substandard or poor-quality medications that pose a safety risk to their health and well-being. In particular, extemporaneously compounded sterile preparations must

ensure highest quality. Extemporaneous compounding should be performed only using drug substances that have been manufactured in Food and Drug Administration-registered facilities and that meet official United States Pharmacopeia (USP) compendial requirements. Such compounding should only be performed by adequately trained pharmacists and pharmacy technicians, in facilities and with equipment that meet technical and professional standards to ensure the quality and integrity of the compounded medication, and in accordance with USP standards and other applicable federal and state regulations. To facilitate such a high level of compounding, USP should develop drug monographs for commonly compounded preparations. ASHP and its members have always devoted a great deal of effort to promoting safe extemporaneous compounding, through education of pharmacists and pharmacy technicians, publication of best practices, and advocacy, recognizing the inherent risks of any such endeavor. Pharmacists and pharmacy technicians have a responsibility to safely prepare and distribute compounded medications to meet the unique and customized therapeutic needs of their patients, and ASHP and pharmacists therefore have a responsibility to educate prescribers, other healthcare professionals, and patients about the potential risks associated with the use of extemporaneously compounded preparations.

2617

ROLE OF THE PHARMACY WORKFORCE TO COMBAT PUBLIC HEALTH DISINFORMATION AND MISINFORMATION

Source: Council on Pharmacy Practice

To affirm that disinformation and misinformation undermine public health and trust in health care professionals, increasing risk of potential harm and adverse patient outcomes; further,

To educate individuals on how to recognize and counter disinformation and misinformation; further,

To oppose and actively dispel the dissemination of disinformation and misinformation by members of the pharmacy workforce; further,

To collaborate with key partners to combat disinformation and misinformation.

Rationale

Public health disinformation and misinformation pose a growing threat to patient safety, population health, and trust in healthcare professionals. Disinformation is defined as false or misleading information that is deliberately created, presented, and disseminated with the intent to deceive, mislead, or cause harm. Misinformation is defined as inaccurate or false information shared without intent to deceive, often due to misunderstanding, incomplete information, or rapidly evolving science. In the public health context, disinformation often aims to undermine evidence-based guidance, erode trust in health institutions or professionals, or influence health behaviors in ways that increase risk to individuals or communities.

A longstanding area of concern related to disinformation and misinformation is with vaccines and vaccine preventable diseases. Maintaining public trust in vaccine evidence-based recommendations is essential to protecting patient and public health, and that trust depends on transparent, rigorous processes grounded in scientific evidence. The pharmacy workforce needs to remain steadfast in their commitment to science-driven decision making related to vaccines and patient education in order to support shared clinical decision making.

Clinical decisions often require nuance, and pharmacists may reasonably differ in how they interpret evolving evidence, weigh risks and benefits, or apply guidelines to individual patients. Differences in evidence-informed professional opinions, including vaccine recommendations based on patient factors or emerging data, are not the same as misinformation. Good faith interpretation of available evidence, even when it does not fully align with a guideline, is an essential part of professional practice. Efforts to address disinformation must distinguish intentional or reckless spread of falsehoods from legitimate clinical judgment that reflects the complexity of real-world care.

ASHP, state affiliates, and its members have a professional duty to recognize and combat disinformation and misinformation with their constituencies and in their communities. It is imperative that the pharmacy workforce serve as a source of truth for scientific and evidence-based information. Many leading health professional organizations, including the American Medical Association and the American Nurses Association, have advanced policy statements that outline key elements for addressing disinformation and misinformation such as conveying clear definitions, reinforcing professional responsibility, providing trusted education and communication, creating accountability, and collaborating with other partners with similar goals and policy positions. ASHP should align and collaborate with peer pharmacy and medical organizations to reinforce shared principles and support critical public health initiatives that uphold scientific integrity and patient safety.

2618

FDA'S PUBLIC HEALTH ROLE

Source: Council on Public Policy

To affirm that the Food and Drug Administration's public health role is to ensure the safety and effectiveness of drugs, biologics, and medical devices through risk assessment, appropriate product approval and labeling, manufacturing oversight, maintaining consumer confidence in medications, and consultation with health professionals, while deferring to state regulation and professional self-regulation on matters related to the use of drugs, biologics, and medical devices; further,

To support the allocation of sufficient federal resources to allow FDA to meet its defined public health mission; further,

To support the appointment of practicing pharmacists to FDA advisory committees as one mechanism of ensuring that decisions made by the agency incorporate the unique knowledge of the profession of pharmacy for the further benefit of the patient; further,

To support an ongoing dialogue between FDA and ASHP for the purpose of exploring ways to advocate the best use of FDA-regulated products by consumers and health care professionals.

This policy supersedes ASHP policy 0012.

Rationale

ASHP recognizes the critical importance of the FDA in protecting public health by ensuring the safety of drugs, biologics, and medical devices. Strong federal oversight of drug safety is vital and requires robust federal funding to allow FDA to fulfill its mission, particularly in a rapidly evolving healthcare landscape. Public health would also benefit from the inclusion of practicing pharmacists, particularly those with hospital or health system experience, on FDA advisory committees, which would ensure that the agency has benefits from pharmacists' unique clinical and pharmacotherapeutic expertise, ultimately enhancing patient care. FDA's stakeholder engagement, including its long history of collaboration with ASHP and other pharmacy organizations, is integral to fostering shared efforts to promote medication and device safety, and must be protected from political interference.

2619

PROTECTING THE PHARMACY WORKFORCE AGAINST UNAUTHORIZED SYNTHETIC MEDIA

Source: Council on Public Policy

To advocate for federal and state laws, regulations, public education efforts, and enforcement mechanisms that protect the pharmacy workforce and healthcare organizations from liability and other harms arising from unauthorized, nonconsensual, or deceptive synthetic media generated or materially manipulated content; further,

To advocate for standardized, accessible, and timely methods and frameworks at the federal, state, and local levels addressing the hazards associated with and mitigating the dangers posed by such content.

Rationale

Advances in artificial intelligence have enabled the rapid creation and spread of highly realistic synthetic media, including "deepfake" audio, video, text, and simulated professional interactions. When used to impersonate health professionals and pharmacy organizations without authorization, these technologies pose significant risks. Pharmacists, student pharmacists, and pharmacy technicians may have their names, likenesses, or credentials misused to lend credibility to false or misleading medical information. Such content can spread medication-related misinformation, undermine trust in evidence-based care, and cause reputational harm to pharmacy personnel falsely portrayed as providing inaccurate guidance.

Current legal and regulatory frameworks do not consistently address AI-generated impersonation of healthcare professionals or provide clear protections when professional identities are misused. Federal and state policies are needed to protect the pharmacy workforce from liability and reputational harm and to ensure accountability for misuse. Standardized frameworks for reporting suspected AI deepfakes would also support timely

identification and removal of harmful content, helping protect patient safety and maintain trust in medication-related information.

2620
TOBACCO AND NICOTINE CESSATION AND CONTROL
Source: Council on Therapeutics

To support pharmacists' practice in providing nicotine-cessation counseling and comprehensive medication management, including the appropriate use of FDA-approved nicotine-replacement therapy, and to promote pharmacist prescriptive authority; further,

To discourage the use and oppose the distribution and sale of tobacco, tobacco products, and non-tobacco nicotine (NTN) delivery systems not approved as cessation therapies; further,

To support efforts to expand patient access to tobacco cessation medications, including availability of affordable tobacco cessation medication (including zero-cost options); further,

To advocate for healthcare environments to be free of tobacco and NTN.

This policy supersedes ASHP Policy 2125.

Rationale
Pharmacists, as healthcare providers, have long discouraged the use of tobacco and tobacco products as a threat to public health. Non-tobacco nicotine (NTN) is available in numerous forms, including electronic nicotine delivery systems (e.g. vaporizers, vape pens, hookah pens, and electronic cigarettes and pipes), and more recently, nicotine pouches. Contents of these highly addictive systems include nicotine, flavorings, propylene glycol, glycerin, potentially harmful aerosols, and other unknown ingredients. The long-term effects of use are still relatively unknown, and given these uncertainties, pharmacists should discourage their use. ASHP opposes the distribution or sale of tobacco, tobacco products, and other nicotine delivery systems by pharmacies or facilities that contain a pharmacy (e.g., grocery or retail stores) and advocates that hospitals and health systems be tobacco-free environments.

Through Section 907 of the Federal Food, Drug and Cosmetic Act, the Food and Drug Administration (FDA) has the authority to propose and adopt tobacco product standards including maximum N-Nitrosonornicotine (NNN) in smokeless tobacco products, nicotine yield in cigarettes, and other regulation for combusted tobacco products. The 2009 Family Smoking Prevention and Tobacco Control Act (TCA) prohibits cigarettes or any of their component parts (including the tobacco, filter, or paper) shall not contain artificial or natural flavor (other than tobacco or menthol) or an herb or spice. Flavor, an often characterizing element of tobacco products, has significantly influenced nicotine use in children and adolescents. In response to the increase in NTN products, Congress passed H.R.2471 which expanded FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine.

Pharmacists have a role in recommending and managing drug therapy to support cessation of nicotine-containing products, including tobacco and electronic nicotine delivery

systems, as described in the ASHP Therapeutic Position Statement on Cessation of Tobacco Use. Newer therapies, including varenicline, are associated with more and evolving safety risks when compared to nicotine replacement therapies. Given the complexity of drug therapy, pharmacists should play a central role in ensuring the safe and appropriate use of these therapies including patient assessment, education, prescribing, and monitoring of pharmacologic therapies. Given the public health impact of smoking, several states already have programs that provide, cover, or facilitate access to nicotine cessation programs that primarily operate through State Departments of Health (or Public Health), Medicaid Agencies, and State Quitlines, with some providing tobacco cessation medications for qualifying patients and/or have collaborative practice agreements that permit pharmacists to prescribe tobacco cessation medications.

2621

SAFE AND EFFECTIVE USE OF LONG-ACTING INJECTABLE ANTIPSYCHOTICS

Source: Council on Therapeutics

To advocate for the development and implementation of standardized, pharmacist-led processes to ensure the safe, effective, and coordinated use of long-acting injectable (LAI) antipsychotics across the continuum of care; further,

To advocate for a centralized health information exchange that collects real-time and standardized information of LAI antipsychotic administrations accessible to all healthcare providers engaged in the care of the patient; further,

To collaborate with key stakeholders on the development of best practices for the safe use and management of LAI antipsychotics, regardless of site of care.

Rationale

Long-acting injectable (LAI) antipsychotics offer improved adherence, reduced relapse and hospitalization rates, and more consistent therapeutic drug levels with clear accountability for treatment engagement. However, their use may be limited by access barriers, clinician training or experience, as well as prescribing biases that reserve LAIs for patients with documented nonadherence rather than incorporating them as a proactive treatment option. System-level challenges include limited access, difficulty obtaining reimbursement, and fragmented care pathways that disrupt continuity and follow-up. Because this class of medications often lacks standardized protocols for administration, documentation, and monitoring, patients may receive duplicated doses, missed doses, or incorrect formulations, particularly during transitions of care. Variability in prescribing practices, inadvertent switching of medications from initiation to maintenance regimens, irregular dosing intervals, and non-standardized documentation across care settings further complicates the use of these medications.

Integrating pharmacists into the administration process of LAIs has expanded access and improved safety. Patients with schizophrenia and related chronic conditions often require sustained therapy to prevent relapses and support recovery. Pharmacists are essential to optimizing care with long-acting injectable (LAI) antipsychotics. They administer injections, educate patients and providers, support medication adherence, monitor for side effects, and

coordinate care. By serving as accessible points of contact, pharmacists help address barriers such as needle anxiety and limited access. Their active involvement enhances adherence and clinical outcomes, reduces hospitalizations, and expands treatment access—particularly in community pharmacy settings and through home-based services. The implementation of a standardized state or national LAI database similar to state PDMPs, is critical as it would centralize documentation from various settings, align dosing schedules, and offer clinicians real-time access to administration histories. Adopting this approach will enhance patient safety, reduce dosing errors, and facilitate greater pharmacist involvement in interdisciplinary care, consistent with ASHP's commitment to promoting medication management continuity and data interoperability for patient care.

2622
DOSING OF COMBINATION ANTIBIOTICS
Source: Council on Therapeutics

To advocate for Food and Drug Administration-approved standardized labeling of combination antibiotics with dosing instructions that include each component in a clear and unambiguous manner; further,

To support the continuous evaluation and streamlining of combination antibiotic formulation ratios; further,

To advocate for information system vendors to incorporate discrete data fields and for drug reference resources to reflect each antibiotic component; further,

To encourage healthcare organizations to adopt strategies that ensure appropriate dosing of combination antibiotics; further,

To educate stakeholders and the public regarding the safe dosing and administration of combination antibiotics for pediatrics and adults.

Rationale
Combination antibiotics pose a unique challenge for pharmacists because each product contains two active components, each with its own strength, and variations in how doses are calculated can create confusion in dosing, dispensing, and administration. In adults, dosing and dispensing of these drugs is done with standard doses equivalent to the sum of the two antibiotic components and are provided from manufacturers in standardized formulations, often in ready to administer bags. Conversely, pediatric patients are often dosed based on the weight-based dosing of one component of the combination drug (e.g the beta-lactam or the trimethoprim component) with a few exceptions based upon the goal of treatment. While most intravenous concentrations of these medications are standardized, there are 11 dosage formulations of amoxicillin-clavulanate on the US market, including five different amoxicillin to clavulanate ratios (i.e., 2:1, 4:1,7:1, 14:1, 16:1). These multiple ratio formulations further increase the risk of prescribing, dispensing, and administration errors which can impact the effectiveness and/or the toxicity of these antibiotics. While this phenomenon is decreasing,

many manufacturers' labeling and dosing references describe doses in a variety of ways, and multiple presentations exist even within the same reference. This has also led to dosing errors with the intravenous antibacterial drugs due to confusion about the drug strength displayed on the vial and carton labels.

Furthermore, many pediatric patients are not treated at standalone children's hospitals where there is infrastructure and support, including pediatric specific order sets, pump libraries, drug information and pharmacists trained to care for pediatric patients exist. A 2024 study in Journal of Pediatric Pharmacology and Therapeutics (JPPT) surveyed pharmacists treating pediatric patients in a variety of settings cited that barriers to dosing and administration of combination drugs including: extended infusions, infusion pump interoperability challenges, CPOE (computerized physician order entry) auto-adjustments, dose rounding, drug shortages, premade adult products, non-formulary drugs, and different ordering processes for pediatric and adult patients. This study also found that order sets, guidelines, and intranet pages were the most common sources of internal antibiotic dosing recommendations, where dosing may be different than what is found in external antibiotic dosing references including Lexicomp, Micromedex, Sanford Guide and more. A 2023 study from JPPT reviewed amoxicillin-clavulanate use at standalone and children's hospitals within acute care hospitals and found that significant formulation selection variability exists across the United States with these institutions carrying on average five amoxicillin-clavulanate products.

In the outpatient setting, medication errors during order entry and dispensing include: information and knowledge gaps about medication indications or doses for pediatric patients, communication gaps between health care providers and caregivers, and product preparation vulnerabilities. An additional study that looked at pediatric medication errors, found that antibiotics emerged as the most frequently implicated drug class.

2623
EVIDENCE-BASED MEDICINE
Source: Council on Therapeutics

To define evidence-based medicine as the conscientious, explicit, and judicious appraisal and application of the best-available current data integrated with clinician expertise and patient values to inform the development and implementation of professional policies, standards, and clinical practice decisions; further,

To affirm evidence-based medicine as a foundational principle of pharmacy practice, patient care, and the development of ASHP professional policies and advocacy positions, including clinical decision-making and public health guidance**.**

Rationale

Evidence-based medicine (EBM), also known as evidence-based practice, evidence-based clinical practice, evidence-based healthcare, evidence-based method, and evidence-based approach are all encompassing terms that describe a methodical approach to clinical decision-making. EBM is a cornerstone of modern healthcare, emphasizing the use of the best available research evidence to guide clinical decision-making. The goal of EBM is to improve patient care by using the most current and reliable scientific research—such as randomized controlled trials,

systematic reviews, and meta-analyses—to guide diagnosis, treatment, and management decisions. It involves critically evaluating and integrating evidence into the clinical decision-making process, ensuring that the interventions provided are both effective and appropriate for the individual patient.

However, there is controversy surrounding the term. This arises from its ideal of objective, standardized care, which sometimes clashes with the realities of clinical practice, patient individuality, and the inherent limitations of research. In recent years, particularly with the rapidly evolving need for safe and effective treatment during the COVID-19 pandemic, adoption of artificial intelligence, and proliferation of publications, the term evidence-based medicine has evolved from an approach to patient care that uses best available evidence, clinical expertise, and patient values to one that includes these values but also a more nuanced understanding of the complexities inherent in translating research into practice, recognizing that both organizations and clinicians are subject to their own biases. Ultimately, EBM uses diligent, explicit, and sensible use of available evidence to care for individual patients that integrates individual clinical expertise that is diverse in origin. EBM is not a replacement for individual clinical expertise and does not consist only of randomized controlled trials or meta-analyses, nor considers data that is outdated or impossible to practice.

2025 Policy Positions

2501
PROFESSIONAL DEVELOPMENT AS A RETENTION TOOL
Source: Council on Education and Workforce Development

To recognize that pharmacy workforce development is an essential component of staff recruitment, retention, and well-being; further,

To recognize that pharmacy workforce development encompasses more than formal education programs and includes informal learning among colleagues, mentoring, participation in activities of professional organizations, and other types of learning; further,

To encourage healthcare executives to support pharmacy workforce development programs, including leadership succession planning, as an important benefit that aids in recruiting and retaining qualified staff; further,

To support healthcare executives with pharmacy workforce development by providing educational programs, services, and resources.

To encourage organizations to assess the effectiveness of professional development initiatives by evaluating their impact on recruitment and retention outcomes.

This policy supersedes ASHP policy 2103.

Rationale
Workforce development can take many forms, including formal education, informal mentoring, participation in certification programs, career ladder implementation, and expansion of experiences. The need for job growth and career advancement is an important motivator for job satisfaction among those entering the workforce, such as pharmacy technicians, student pharmacists, and residents. Evidence suggests that staff development programs are associated with increased pharmacist retention. There is also a growing need to provide education on topics, such as clinical management, which are not taught in education and training programs and nurture the workforce to provide continuous succession planning. Moreover, by evaluating the impact of professional development initiatives on these critical workforce metrics, healthcare organizations can better understand how such programs contribute to employee satisfaction, growth, and long-term career advancement. This data driven approach helps ensure that professional development efforts are not only enhancing skills but are also addressing workforce stability, which is essential for maintaining high-quality patient care in an ever-evolving healthcare environment.

2502
PHARMACY ACCESS TO PAYER NETWORKS
Source: Council on Pharmacy Management

To oppose pharmacy access criteria that impose discriminatory requirements or qualifications on participation in insurance payer networks that interfere with patient continuity of care or patient site-of-care options; further,

To advocate for laws and regulations that require healthcare payers to disclose to pharmacies applying to participate in payer networks the criteria and the clinical and operational outcome data reporting requirements used to include, retain, or exclude pharmacies; further,

To encourage healthcare payers to standardize network access criteria and eliminate those reporting requirements already imposed by accrediting bodies or regulatory agencies.

This policy supersedes ASHP policy 2031.

Rationale
As hospitals and health systems have become more engaged in developing ambulatory care services, pharmacies (e.g., health-system specialty pharmacy, outpatient infusion, community pharmacy) in those settings increasingly find themselves excluded from healthcare payer networks and, a related concept, drug manufacturer networks (see ASHP policy 1714, Restricted Drug Distribution). Vertical integration in healthcare has led to many discriminatory practices by pharmacy benefit managers (PBMs) to carve out care from hospitals and health systems providing patient care, which may include infusion services and specialty medications. Vertically integrated systems allow payers to steer patients toward lower cost-of-care options and carve out health-system pharmacies from joining their networks. ASHP acknowledges that healthcare payers, PBMs, and drug manufacturers may develop and use criteria to determine pharmacy access to their networks to ensure the quality of services and the financial viability of pharmacies (i.e., ensuring sufficient patient volume to profitably operate). However, when creating pharmacy networks, payers, and manufacturers should also consider the potential impacts on a patient's care and choice. Patients generally choose pharmacies that are most convenient for them. When pharmacies are locked out of a payer network, patients may face barriers (e.g., physical access) to therapy, which can delay or otherwise frustrate treatment.

Pharmacies within health systems have an advantage when it comes to electronic health record integration, proximity and relationship to providers, and, in some cases, onsite clinical pharmacy specialists. Significant research has been conducted demonstrating the positive impact of utilizing a health-system-based pharmacy. Specifically, integrated health-system-based specialty pharmacies have been shown to lead to improved patient outcomes, superior patient and provider satisfaction, and reduced overall healthcare costs. This is achieved through reduced primary and secondary non-adherence, decreased time to specialty therapy initiation, real-time patient safety initiatives, proactive patient monitoring and outreach, reduced polypharmacy, and enhanced care coordination with internal health-system providers. This clinically superior environment, coupled with health systems' ability to measure and meet

outcome-based metrics, allows them to easily compare their performance against other pharmacies. Therefore, inclusion of health-system pharmacies in payer and manufacturer networks could improve care coordination and quality-based care and reduce overall healthcare costs. Exclusion of health-system pharmacies from these networks, coupled with rising drug costs, infrastructure costs, and reduced reimbursement due to site of care challenges have had a severe impact on the financial margins of many hospitals and health systems.

Within contracting for both access to payer networks and manufacturer limited distribution drug agreements, there are sometimes terms requiring health-system pharmacies to provide substantial amounts of data in exchange for inclusion in these networks. These data reporting requirements are variable depending on the negotiating parties and are often duplicative with reporting requirements imposed by accrediting bodies or regulatory agencies. Since there is not a standardized reporting approach to payers, pharmacies are faced with having to create different reports to different payers that meet contractual obligations to ensure proper reimbursement (ASHP policy 2232, Revenue Cycle Management and Reimbursement and Pharmacy Compensation for Drug Product Dispensing). Similarly, specialty pharmacies that are accredited must demonstrate compliance with required metrics. These requirements often call into question the ownership and privacy of certain patient-related data, but compliance is often required to successfully gain access to the necessary networks to provide patient care. The lack of transparency of PBM practices throughout the entire process introduces significant barriers to health systems' ability to provide optimal, effective, and timely care to patients. Hospitals and health systems may choose to enter a dispute resolution process (e.g., arbitration) if a pharmacy is excluded from participation in a network, but this process is costly and time-consuming. Furthermore, the health systems may struggle to negotiate better deals and write more effective contracts to establish a more satisfying pharmacy-payer relationship (ASHP policies 1809, Health Insurance Policy Design and 2028, Pharmacist's Role in Health Insurance Benefit Design.) Obstacles to preserving continuity of care for patients include increasing complexity of navigating the vertically integrated pharmacy marketplace, contracting for inclusion in payer networks, and scope of data reporting requirements imposed on pharmacies to maintain access to these networks.

2503

SUPPORT OF GLOBAL HEALTH ORGANIZATIONS

Source: Council on Public Policy

To strongly support the mission and work of global health organizations in their role in public health preparedness, prevention, and control to improve the health and well-being of people globally.

This policy supersedes ASHP policy 2037.

Rationale

In an age of global travel between and among countries, efforts to prevent, control, treat, and eradicate diseases and conditions that decrease health and well-being are critical to all countries, regardless of factors such as income and education. New vectors of disease

transmission and behavioral conditions related to lifestyle and environmental conditions continue to provide challenges that need to be addressed. Domestic and international organizations that provide evidence-based warnings, guidelines, education, research, and advocacy, and that collect data to help countries prepare their public health infrastructure, are essential in providing people around the world with the tools and resources needed to address critical health issues globally.

2504

CULTURAL COMPETENCY AND TRAUMA INFORMED CARE

Source: Council on Education and Workforce Development

To foster the ongoing development of cultural humility and competency within the pharmacy workforce and promote a whole-person-health approach to care; further,

To educate the pharmacy workforce on how to interact with patients, caregivers, and other healthcare professionals in a manner that demonstrates respect for and responsiveness to all; further,

To educate healthcare providers on the importance of providing culturally congruent and trauma-informed care to achieve quality care and patient engagement.

This policy supersedes ASHP policy 2231.

Rationale

Culture influences a patient's belief and behavior toward health and illness. Healthcare workers who demonstrate cultural humility and competence can improve clinical outcomes. Cultural humility is having an awareness of how a person's culture can impact health behaviors and then using this knowledge to approach the patient's treatment. Research has shown that overlooking cultural beliefs may lead to negative health consequences. Cultural competence is a set of congruent behaviors, attitudes, and policies that come together in a system, agency or among professionals and enable that system, agency or those professions to work effectively in cross-cultural situations. According to the National Center for Cultural Competency, there are numerous examples of benefits derived from cultural competence on quality and effectiveness of care in relation to health outcomes and well-being. Further, pharmacists can contribute to providing "culturally congruent care," which can be described as "a process of effective interaction between the provider and patient," by recognizing that "[p]atients and families bring their own values, perceptions, and expectations to healthcare encounters."

Whole person health includes consideration of how biological, behavioral, environmental, and social factors impact a patient's health outcomes. When considering holistic approaches to patient care, clinicians should recognize and respond effectively to all personal and social identities. Spiritually congruent care may be expressed in prayer requests, in clinician-chaplain collaborations, and through health care organizations' religious accommodations for patients and staff. Numerous publications have outlined the role of spirituality in overall health, longevity, and quality of life, especially for patients with severe illness. The pharmacy workforce should be educated on the importance of individual patient

spirituality and its impact on health and on ways to facilitate patient access to spiritual care services.

Trauma is a widespread public health issue that can stem from various sources, including abuse, neglect, poverty, and other emotionally harmful experiences. Trauma-informed care (TIC) is an essential healthcare approach that recognizes and responds to the impact of trauma on patients' physical and mental health. Increasing evidence shows that implementing TIC can improve patient outcomes, including engagement, satisfaction, and adherence, while addressing complex patient needs. For pharmacy professionals, integrating TIC is crucial to providing tailored care. Additionally, TIC can help healthcare workers, who face higher risks of trauma post-pandemic, recognize signs and symptoms of trauma thereby reducing burnout and turnover. Training healthcare providers to understand the effects of trauma at both the clinical and organizational levels is vital for improving patient care and outcomes.

2505

FUNDING, EXPERTISE, AND OVERSIGHT OF STATE BOARDS OF PHARMACY

Source: Council on Public Policy

To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and related agencies whose mission it is to protect the public health; further,

To advocate adequate representation on state boards of pharmacy and related agencies by pharmacists and pharmacy technicians representing hospitals and health systems; further,

To advocate for the dedicated funds for the exclusive use by state boards of pharmacy and related agencies to carry out expected duties; further,

To advocate for consistent application of state board**s** of pharmacy regulations by inspectors with demonstrated competency in diverse pharmacy practice areas and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice; further,

To advocate state boards of pharmacy develop quality assurance processes for evaluating the performance of inspectors to ensure consistency.

This policy supersedes ASHP policy 2021.

Rationale

In recent years, the regulatory scope of boards of pharmacy has grown to address new and expanded scopes of practice and healthcare while fulfilling their mission of protecting the public health. In addition, coordination with federal agencies (e.g., Food and Drug Administration, Drug Enforcement Administration) and related state agencies adds to the complexity of a state board’s mission. With this expanded scope and mission comes the need for additional resources, both financial and human. Specific knowledge acquired by pharmacists

and pharmacy technicians is essential to the safe regulation of practice. Thus, inspectors need to have demonstrated competency in the applicable area of practice in order to assure the health and safety of the public. Further, inspectors should provide evidence for variance to established BOP rules to ensure that rules are applied as objectively and consistently as possible.

2506
PAYMENT PARITY FOR PHARMACISTS' SERVICES
Source: Council on Public Policy

To advocate pharmacists, as healthcare providers, receive payment that is commensurate with services provided within their scope of practice.

This policy supersedes ASHP policy 1502.

Rationale
Recognition of pharmacists as healthcare providers is emerging and is being codified in state law as well as in current federal legislative proposals (e.g., H.R. 592, S. 314). In some cases, this recognition also includes specified compensation through existing payment mechanisms (e.g., federal Medicare Part B or state Medicaid programs). With recognition, pharmacists should be sustainably compensated for their patient-care services by all public and private payers using standardized billing processes.

2507
INTERSTATE PHARMACIST LICENSURE
Source: Council on Public Policy

To advocate for improved timeliness of the pharmacist licensure application approval process; further,

To advocate for interstate pharmacist licensure; further,

To support streamlined reciprocity processes, including temporary licensure mechanisms, as progress toward interstate licensure.

This policy supersedes ASHP policy 1621.

Rationale
Pharmacists sometimes face challenges from delays in obtaining licensure by transfer or reciprocity when moving their practice from one jurisdiction to another. Such delay may be due to the need for boards to review pharmacists' licensure records in all jurisdictions in which they are licensed, administer a state pharmacy law exam, complete a criminal background check, and, in some cases, schedule an interview with the board. To address these challenges, boards of pharmacy should allow pharmacists in good standing to immediately practice in a different jurisdiction when they change employment or enter a residency program. Granting pharmacists a temporary license for a period of up to six months while the board completes its review

would help meet workforce demands while continuing to safeguard the public health. In some cases, pharmacists who are unable to obtain a license in a timely manner are unable to fully use the skills in which they have been trained. Without a license, the pharmacist may temporarily have to function as a technician or perform other tasks. For pharmacists participating in residency programs outside their jurisdiction of licensure, several months of their residency program can elapse before they receive licensure transfer or reciprocity. Upon completion of a year-long residency program, many residents move to another jurisdiction to practice and have to start the transfer or reciprocity process again.

Members in several states have reported that in recent years boards of pharmacy have been slow to issue pharmacy licenses. This delay is especially problematic for pharmacy residents from another jurisdiction who rely on boards to grant them a license prior to performing in a clinical capacity. Given that the licensing period can take several months, this delay has presented a problem for pharmacy residents who have a limited timeframe to successfully complete their duties, typically one year. In some cases, state boards are urging residents to obtain a pharmacy technician license; however, this is inappropriate given the expertise and education residents have and the level of practice they're expected to engage in. Given its national scope, NABP is well-positioned to explore a broad solution to this problem rather than the current, incremental, state-by-state approach.

2508

PATIENT'S RIGHT TO CHOOSE

Source: Council on Public Policy

To acknowledge that patients or their representative have the right to be fully informed about their medication options and to be involved in the decision-making process; further,

To support the right of patients or their representative to have their preferences considered respectfully, within the limits of clinical appropriateness, formulary considerations, safety, and legal requirements; further,

To recognize the right of the patient or their representative to refuse care and have those decisions respected.

This policy supersedes ASHP policy 0013.

Rationale

ASHP supports the right of the patient, or their representative as allowed under law to make informed decisions regarding the patient's care plan. The patient's right to choose includes being entitled to be informed of their health status, involved with care and treatment, allowed to request or refuse treatment, execute advance directives, and have healthcare practitioners adhere to those directives.

2509
RECOVERY AND ASSISTANCE PROGRAMS FOR HEALTHCARE WORKERS WITH SUBSTANCE USE DISORDER

Source: Council on Pharmacy Management

To advocate that hospitals and health systems support and promote recovery and assistance programs for healthcare personnel with substance use disorders, including those who have diverted controlled substances to support their own drug addiction; further,

To encourage state licensing boards to support structured rehabilitation programs that demonstrate a clear pathway for recovery and hospitals and health systems to support the return to practice upon successful completion of the program.

Rationale

At least one in every 100 healthcare workers (HCWs) is estimated to have diverted medication. Because most drug diversion goes undetected, the true number is likely much higher. Moreover, an estimated 10-15% of HCWs will misuse substances within their career. Due to the physical demands of the job, increasing levels of burnout, and ease of access to controlled substances (CS), occupational risk factors contribute to substance misuse in the healthcare setting. Substance use disorders (SUDs) are formally recognized by *The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, with decades of research linking these disorders to changes in brain chemistry. Historically, the stigma associated with such diagnoses and the fear of license revocation have prevented HCWs from seeking treatment. Many hospitals and health systems have begun to offer confidential faculty and staff assistance programs; however, these resources continue to be underutilized. Even after diverters have been caught, many will not admit to any wrongdoing for fear of loss of employment. These situations can lead to the diverter resigning and seeking employment elsewhere. Often, the behavior will continue, putting patients and co-workers at risk for safety events. Furthermore, the risk of suicide is high after personnel are confronted about diversion.

To prevent poorer overall health and financial instability, HCWs need to retain their healthcare insurance and access treatment on while on leave of absence or disability, with return to work after completing state board-mandated protocols. ASHP supports employer-sponsored drug programs that promote the recovery of impaired individuals (see ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance). Less punitive approaches are recommended in the ASHP Guidelines on Preventing Diversion of Controlled Substances, which state that sanctions should take into account whether the HCW is supporting his or her own substance use disorder (or that of an associate) or there has been theft of CS for sale and financial gain. The guidelines further recommend that when an HCW is diverting to support a substance use disorder, the diversion should be reported to applicable licensing boards, and the HCW should be referred to a substance abuse program. The guidelines encourage healthcare organizations to establish a process to support recovery for HCWs who are diverting CS for an active substance abuse problem (i.e., an employee assistance program process, which may include mandatory program referral, reporting to the relevant state board or professional assistance program, and a contract for the HCW's return to work). Also known as alternatives to discipline programs (APDs), APDs are non-punitive monitoring

programs that allow HCWs to return to work after receiving treatment for an SUD.

The intent of these programs is to support decriminalization of SUDs to avoid interfering with an empathetic approach to employee substance use disorders. However, this must be balanced with other priorities, including patient safety, legal and regulatory compliance, and employee protection. A 2021 ASHP survey found that 83% of surveyed healthcare organizations supported employee substance use recovery programs, and 65% had return-to-work policies for employees who wanted to re-enter the workforce following recovery. SAMHSA defines recovery as a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential. State boards of pharmacy have embraced employee substance use recovery programs and return-to-work policies. Given their essential role in enabling HCWs to return to practice, ASHP encourages all state bodies responsible for licensing HCWs to support accessible, affordable, and structured rehabilitation programs for HCWs with substance use disorders that lead to return to practice upon successful completion.

2510

CELLULAR AND GENE THERAPIES

Source: Council on Pharmacy Management

To affirm that the pharmacy workforce serve key roles in the use of cellular and gene therapies (CGTs), spanning supply chain management, operational oversight, and clinical consultation on individual patients; further,

To recognize that CGTs are managed in the medication-use process; further,

To assert that health-system decisions on the selection, use, and management of CGTs are made through the formulary system; further,

To advocate for payment models that facilitate patient access, coverage, and reimbursement for CGTs with consideration of total cost of care; further,

To advocate for manufacturer processes that decrease the burden and resources required for hospitals and health systems to use CGTs.

This policy supersedes ASHP policy 1802.

Rationale

Currently, cellular and gene therapies (CGTs) are defined as "Advanced Therapy Medicinal Products", comprising a large group of cellular types that are either alone or in combination with gene and tissue engineering technology. The U.S. Food and Drug Administration (FDA) recognizes cellular therapy products as cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications, including hematopoietic stem cells and adult and embryonic stem cells. The FDA regulates CGTs as biological products, meaning they are considered therapeutics subject to standard drug regulations. The FDA recognizes human gene therapy seeks to modify or manipulate the

expression of a gene or to alter the biological properties of living cells for therapeutic use. Together, CGTs are a rapidly growing and important area of medicine. The 2023 *AJHP* article Role of Pharmacy in Cellular-Based Therapy cites the need for pharmacists to take a leadership role in managing CGTs and delineates three major areas for pharmacy leadership: biologic drug management, multidisciplinary team coordination, and supportive care management. Additionally, the pharmacist, working collaboratively with the interdisciplinary team, should take the lead in ensuring successful use of CGTs (e.g., patient navigation, care coordination lead, proactive review, and assessment for eligibility and reimbursement, measuring and monitoring outcomes). Like other therapeutics, CGT agents should be managed as a part of the formulary system. As described in more detail in the ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System, a fundamental characteristic of the formulary system is that all decisions are made based on evidence-based clinical, ethical, legal, social, logistical, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care; include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals, as well representatives with expertise in finance, law, and informatics; and are not based solely on economic factors.

However, as reported in the ASHP/ASHP Foundation Pharmacy Forecast 2024, the ultra-high expense of these therapies, coupled with uncertain reimbursement, warrants careful financial, service-line, and external partnership analyses. Pharmacy leadership, service-line stakeholders, and the pharmacy and therapeutics committee should collaborate with health-system finance experts to gauge budget impact and measure financial risk associated with the provision of CGTs. Pharmacy should be integral in the development of procedures regarding storage, prescribing, dosing, preparation, labeling, dispensing, transport, safe and compliant administration, clinical decision support tools, and disposal when working with CGTs. To ensure the accuracy of the dose, product, and labeling, pharmacists should have the ability to verify the product when it's prepared in the pharmacy and should be involved when order sets or labeling procedures are developed. Well-known challenges are presented by the use of these agents in structuring clinical decision support tools. These agents are often measured in volumetric dosing (e.g., vector genomes per kilogram), and their documentation often requires use of exponents. Therefore, ASHP recognizes, as part of the medication-use process, the need for innovation in electronic health records and pharmacy workflow systems so that these doses can be displayed accurately while avoiding the use of free text in the electronic health record, which may lead to dosing and entry errors. Safety checks, including robust double check systems, should be in place to avoid errors due to compounding and order entry. Finally, advocacy for patient access to, full coverage of, and reimbursement for CGTs is necessary to develop new capabilities and enable pharmacy services to adapt to these new ultra-high-cost therapeutic innovations.

Public and private payers lack coverage policies and restrictions for CGTs. Many payers use traditional pricing models, such as fee-for-service or utilization management tools, to manage CGT but these models are not suitable for ultra-high-cost therapies. Some hospitals may lack economies of scale to support CGTs and may choose to opt-out of providing them to patients due to insufficient reimbursement. For instance, many hospitals consistently lose revenue on CAR T-cell therapy due to the high readmission rates within 72 hours that are then tied to the diagnostic related groups. CGTs are time intensive therapies, requiring hospitals to

take on financial risk. Hospitals should be paid at cost plus and reimbursement, which should not be dependent on readmission factors due to CGT drug-related events. Several payers plan to leverage reinsurance (e.g., annuity payments) as well as increase their use of value- and outcomes-based contracting. However, legal and regulatory barriers currently prevent or limit the use of innovative, value-based payment models. One value-based agreement under consideration ties reimbursement to value and durability, such as CGT developers reimbursing payers when therapy does not provide sufficient benefit. This approach has the potential to incentivize manufacturers to develop effective therapies, while also ensuring patients receive the best possible treatment. Reimbursement and pricing challenges faced by CGT are complex and require innovative solutions. Value-based arrangements and reinsurance are potential models that could help address these challenges.

2511

SAFE AND SECURE TRANSFER OF CONTROLLED SUBSTANCES

Source: Council on Pharmacy Practice

To advocate for the standardization of policies, procedures, and practices in the handling of controlled substance medications throughout the care process, including transfers involving emergency medical services and during interfacility transport; further,

To promote closed loop communication and chain of custody documentation processes related to controlled substance medication management during patient transfers; further,

To collaborate with emergency medical services and other stakeholders involved in pre- and post-hospital and interfacility transfers of controlled substances to improve patient safety, increase standardization, and ensure compliance.

Rationale

Compliance with Drug Enforcement Administration (DEA) regulations and applicable state laws and regulations is crucial for protecting public health and preventing misuse and diversion of controlled substances (CS). Health systems are required to provide leadership and oversight of handling and storage of CS. They are also required to comply with laws and regulations in the transfer of CS between institutions and other DEA registrants. This can be a complex process, particularly in the absence of clear federal and state policies.

There is a lack of uniformity and clarity in allowances and processes for the transfer of CS from a hospital or health system to nonhospital-based emergency medical services (EMS) (e.g., state or local government-owned agencies) and vice versa. To address this, the Protecting Patient Access to Emergency Medications Act of 2017 (PPAEMA) authorized the DEA to amend the Controlled Substances Act to clarify the receipt, movement, and storage of CS for an EMS agency.[4,5] PPAEMA states that CS can be stored in the DEA-registered EMS agency location, in EMS vehicles used by the agency, and in unregistered locations as long as the US Attorney General is notified of the location at least 30 days before the CS is initially delivered for storage. In addition, hospitals may restock CS for an EMS agency following an emergency response. However, the DEA has not finalized regulations as authorized by PPAEMA, creating challenges for states and hospitals to interpret federal regulations while implementing systems and

solutions for the safe and lawful transfer of CS to EMS. A uniform approach or standard development may assure accountability and prevent diversion while meeting patient care needs.

2512
ADDRESSING AND PREVENTING MORAL DISTRESS AND MORAL INJURY IN THE HEALTHCARE WORKFORCE
Source: Council on Pharmacy Practice

To acknowledge the acute and chronic exposure of the healthcare workforce to potentially morally injurious events across the continuum of care; further,

To recognize the risk of moral distress and moral injury when a healthcare worker is unable to provide ethical, safe, and effective care; further,

To advocate for consistent support for equitable and transparent allocation of resources across care teams and health systems to ensure that healthcare workers can provide safe and comprehensive patient care services; further,

To advocate organizations prevent and address moral distress and moral injury among healthcare workers.

Rationale
Moral injury is defined as the "perceived betrayal by a legitimate authority in a high stakes situation, which leads one, through action or inaction, to deeply transgress held moral beliefs and expectations." It is considered to be a syndrome associated with clinical symptoms such as psychological distress, increased thoughts of self-harm and various mental illnesses. Moral injury occurs when workers begin to question the moral framework of the system and their own moral framework for continuing to work within that system. It is increasingly being included in discussions with occupational burnout, as a differentiating factor for healthcare workers from other professional fields struggling with occupational burnout in their workforces and due to exposures to potentially morally injurious events that occur in healthcare environments. It provides an important insight for healthcare workers who believe that occupational burnout, a syndrome of emotional exhaustion, depersonalization, and a low sense of accomplishment, is a symptom of a larger problem, beyond individual well-being and resilience.

Moral injury has been described as a process, or continuum, in which an individual progresses through a range of experiences from moral dilemma, to moral distress, and then to moral injury. The Workforce Change Collaborative advanced a National Framework for Addressing Burnout and Moral Injury in the Health and Public Safety Workforce which overlays the continuum of moral injury and burnout and depicts environmental, relational, and operational drivers and outcomes impacting workers and learners, patients and community, organizations, and society. Left unresolved, moral injury has not only consequences for the individuals experiencing it, but also for patients who are impacted by increased risk of errors, threats to safety, and diminished quality of service. Organizations may experience significant

employee turnover and declines in quality and patient satisfaction ratings.

Moral injury was originally a military term used to describe a soldier's response to serving during times of conflict depicted as a "deep soul wound that pierces a person's identity, sense of morality, and relationship to society." In the context of healthcare, moral injury is not comparable to a soldier's actions taken during a war; however, it occurs when a healthcare worker feels unable to provide high-quality care due to ethical dilemmas experienced in their workplace. Calls for action include commitments from leadership and organizations to be proactive and corrective in addressing patterns that lead to moral distress and moral injury and ensuring equitable allocation of resources for healthcare workers to perform their jobs in an ethical, safe, and effective manner.

2513

PHARMACY SERVICES TO OPTIMIZE PATIENT THROUGHPUT

Source: Council on Pharmacy Practice

To support the integration of pharmacy services to improve safe and efficient throughput and patient flow throughout the health system; further,

To advocate for pharmacists to serve as key decision-makers in improving medication management to optimize patient flow throughout the continuum of care.

Rationale

Efficient movement of patients throughout their course of care during a hospital stay, otherwise referred to as patient throughput, is important for care outcomes and organizational productivity. Increases in patient demand for healthcare services, high-acuity patient needs, healthcare worker staffing shortages, and constraints on organizational capacity create tensions in the flow of a patient's hospital stay from admission through discharge (Health Policy. 2022;126:87-98).

Barriers to patient throughput in emergency departments (EDs) is also a hospital-wide problem as it leads to long wait times and crowding, compromises quality of care, decreases patient and healthcare worker satisfaction, and increases costs. Root causes identified as contributors to these barriers are lack of staff, lack of standards and routines, insufficient operational planning, lack of technology functions, insufficient discharge routines, insufficient facilities and layout, insufficient communication, insufficient transfer coordination, random internal disturbances, unpredictable patient problems, lack of beds, medical quality priorities, lack of ancillary services, increased demand, and lack of separate tracks (Health Policy. 2022;126:87-98).

The Institute for Healthcare Improvement white paper, "Achieving Hospital-wide Patient Flow" identifies the following principles to achieve optimal patient throughput:

- System-wide approach to patient flow,
- Hospital-wide learning system,
- Integration of various approaches,
- Utilization of advanced data analytics, and
- Focus on reducing and shaping demand.

The white paper also suggests following three rules for clinicians and staff as a means for ensuring patients receive the right care, in the right place, at the right time:

1. Right Care, Right Place: Patients are placed on the appropriate clinical unit with the clinical team that has disease- or condition-specific expertise.
2. Right Time: There are no delays greater than two hours in patient progression from one hospital unit or clinical area to another, based on medical readiness criteria.
3. Available Capacity: Ensure each unit or clinical area has some capacity at the beginning of each day.

There are numerous reports focused on improving throughput and efficiencies with processes within the pharmacy department; however, there is limited literature about pharmacy department contribution to hospital-wide patient throughput processes. One report suggests a framework for establishing pharmacy services to support a co-located long-term acute care hospital within a health system. The suggested framework includes operationalizing processes, ensuring licensure and regulations compliance, enhancing information technology, aligning staffing models, managing pharmacy operations and distribution services, implementing clinical services, and demonstrating quality. Pharmacy service interventions included medication clarification, therapy optimization, discharge process support, antimicrobial stewardship, discontinuation of unnecessary or inappropriate medications, IV to oral medication conversion, dose adjustment, preventative care, and managing duplicate medications ordered as needed. The report identifies coordination between pharmacy team leaders and other healthcare disciplines as instrumental for seamless integration. Additional resources are necessary, including patient throughput action plans and process maps that incorporate pharmacy services, as well as identification of measures and tracking systems to demonstrate the impact of pharmacy interventions. Pharmacy services are highly innovative and process-driven; however, they are often siloed from systemwide interventions for improving patient throughput, which this policy seeks to correct.

2514

ACCURATE AND TIMELY HEIGHT AND WEIGHT MEASUREMENTS

Source: Council on Therapeutics

To encourage the pharmacy workforce to participate in interprofessional efforts to ensure accurate and timely patient height and weight measurements are recorded in the patient medical record to provide safe and effective drug therapy; further,

To advocate that clinical decision support systems and other information technologies be structured to incorporate height and weight to facilitate prescribing, dispensing, and monitoring of drugs for safe and effective dosing; further,

To advocate for laws and regulations that prescribers include either height and weight or weight alone, and date obtained, as a required component of prescriptions for medications that are dosed based on that information.

This policy supersedes ASHP policy 1721.

Rationale

Patients who have clinically significant changes in weight during an admission or between physician visits, or who are at an extreme high or low weight, have a higher risk of medication dosing errors that depend on weight body surface area. Accurate heights and weights in SI units (i.e., kilograms, grams, meters, and centimeters) are an integral part of a physical examination for pharmacists to ensure proper dosing of medications. Certain medications require dosing based on body surface area, and there is a need for healthcare organizations to consistently record patients' height, as estimation of height or weight can contribute to potential over- or underdosing.

Factors such as clinically significant changes in weight due to fluid overload and subsequent diuresis, patient growth, and weight changes due to changes in caloric consumption complicate the picture of an appropriate weight to record for dosing certain medications. Some healthcare organizations default to a dosing weight that is used for dosing medications alone, while other weight fluctuations recorded on a daily basis are not used to dose medications, whereas other organizations alert pharmacists to a clinically significant change in weight. Leveraging technology to ensure such safeguards are in place is essential, and providing interoperability between the patient's recorded dosing weight and smart pumps is ideal.

Pharmacists are also seeing an increase in the number of patients at both extremes of weight, and there is a lack of information regarding dosing medications for these populations. ASHP advocates that the Food and Drug Administration develop guidance for voluntary drug dosing studies in these populations, as the need for this guidance is supported by the complexity of drug dosing that can vary based on drug and patient characteristics. Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies, and to publicly report the results, especially for drugs for which significant weight extremes may have clinical impact.

Dosing medications based on height and weight presents important concerns, particularly for pediatric patients, whose variables can change often, but also for oncology patients and aging populations, for whom toxicities or adverse events are a concern (Lubsch L et al. Patient Weight Should Be Included on All Medication Prescriptions. *J Pediatr Pharmacol Ther.* 2023;28:380–1). Therefore, regulations that mandate recording of height and weight on orders for medications that are dosed based on height and weight would enhance patient safety.

2515

CLINICAL AND SAFETY CONSIDERATIONS OF NAMING DRUG MOIETIES AND COMPLEXES

Source: Council on Therapeutics

To encourage regulatory agencies to incorporate pharmacists when considering clinical, operational, access, and safety factors when approving and classifying medications with different moieties or complexes that are used to deliver the active drug; further,

To oppose the consolidation of existing drug classes that include drugs that have distinct pharmacologic effects and pharmacokinetic/pharmacodynamic profiles; further,

To foster increased public notification when changes in approved drug products with therapeutic equivalence occur.

Rationale

The Food and Drug Administration (FDA) publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, identifies drug products approved by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and contains therapeutic equivalence evaluations for approved multisource prescription drug products.

In May of 2021, the FDA changed four iron-carbohydrate drugs with distinct, established, names with different dosing and administration practices and consolidated them under a singular active ingredient, ferric oxyhydroxide. The intravenous formulations of ferric oxyhydroxide, iron sucrose, sodium ferric gluconate, and iron dextran all have different dosing and administration requirements including test infusions, different infusion rates, doses spread out over multiple days and at different concentrations and different monitoring parameters and safety considerations (Iron dextran has a black box warning due to an increased rate of anaphylaxis than other IV iron therapies), Furthermore, the oral formulation is not used for the treatment of iron deficiency anemia, further complicating the clinical and operational picture.

Additionally, this consolidation introduces several areas of concern including risk for incorrect usage of these medications, formulary considerations, administration of the iron-carbohydrate drug, patient safety, and adverse drug event reporting.

This also creates the potential for the FDA to change labeling of drugs with the same active ingredient but different molecular delivery attributes, such as metoprolol tartrate and succinate which have different frequencies, or liposomal amphotericin B and amphotericin deoxycholate, which have different doses.

In general, the FDA considers an active ingredient to be the active moiety as “the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.” However, because the dosing, administration and monitoring are distinct for different drugs-complexes, even if the active moiety is the same – they should be distinguished by name.

Further, this change was performed under the auspices of a response to a regulatory request in a citizen petition, and therefore did not follow the statue requirement delineated in the FD&C Act that includes an opportunity for comment on this change. While the goal of this consolidation appears to mitigate potential abuse of new chemical entity exclusivity, the negative safety and clinical implications necessitate an examination of this approach, particularly when it is retroactive in nature.

2516

CLINICAL, OPERATIONAL, AND SAFE USE OF MANIPULATED DRUG PRODUCTS AND ALTERNATE ADMINISTRATION ROUTES

Source: Council on Therapeutics

To support clinically appropriate, evidence-based use of manipulated drug-products or alternate drug administration routes when it supports optimal patient care; further,

To promote research that includes pharmaceutics, pharmacokinetics, pharmacodynamics, safety, and efficacy of drugs when manipulated or when given through alternate administration routes; further,

To encourage manufacturers to develop drug products in ready-to-use devices and diverse formulations; further,

To foster pharmacist-led interdisciplinary teams to provide institutional guidance, best practices, and safety recommendations regarding drug products that are manipulated or administered through alternative routes.

This policy supersedes ASHP policies 2041, 2242, and 2314.

Rationale

Administration of drug products through alternative routes of administration including intranasal, nebulization, intrathecal, intraosseous, and enteral routes that deliver medications to alternate sites of absorption are increasingly more prominent in practice as patient needs evolve. For example, novel delivery mechanisms through the nebulization of antibiotics and antifungals that are formulated for intravenous (IV) administration are used adjunctively to treat pulmonary infections in critically ill patients. Intranasal administration is often the route of choice in the emergency department due to access issues, safety concerns, and the characteristics of specific patient populations (e.g., children). Soluble drugs such as naloxone can be converted for intranasal administration without altering the substance simply by use of an aerosolizer. The intranasal route is frequently used to treat pain when oral and intravenous routes are not available or optimal, and intranasal midazolam is often used for sedation in the pediatric population, although that route of administration has not been approved by the Food and Drug Administration.

Manipulation of a drug product can include crushing, splitting, or suspending it in a solvent, which can alter the pharmaceutical properties of the original dosage form. These manipulations are often performed for various reasons including when a patient a) requires the medication administered enterally but is unable to take the medication by mouth, b) requires a dose that is not readily available and so a specific dose requires it to be compounded, or c) is unable to swallow or has a feeding tube placed necessitating manipulation. For patients who lose the ability to swallow easily (e.g., due to stroke or cancer), it is sometimes quite difficult to provide drugs as liquid formulations because they may not be available, thus necessitating crushing them.

Studies reveal that oral drug products pass through the stomach, exposing them to a specific set of pH conditions. The stomach may be bypassed when drug products are administered via feeding tube to organ systems in the body that may have a different pH, affecting the adsorption, metabolism, or distribution of the drug. In addition, the physical properties of the manipulated formulation may also cause obstruction and clogging of enteral tubes used for feeding and medication administration, leading to undesirable outcomes, including supra- or subtherapeutic concentrations in the body, which could lead for example to organ rejection in transplant patients, loss of viral suppression in HIV-positive patients, or toxicities when manipulating an extended-release tablet. When drug products are manipulated or administered through alternative sites or means, consideration for the properties of formulations, including but not limited to drug molecule size, viscosity, surface tension, solubility, stability, osmolality, tonicity, and pH must also be included as these can affect pharmacokinetics and pharmacodynamics.

It is important to recognize that the need to manipulate or administer drug products through an alternate route is because there is not a commercially available formulation and as such, need may require compounding with both sterile and nonsterile ingredients. Due to this variability and potential source for sterile compounding and administration errors, manufacturers should be encouraged to create commercially available formulations to meet clinical needs where there is evidence that supports the use of manipulated drug products or alternate administration methods.

There is also a lack of resources that provide guidance on how manipulation and alternative sites of drug administration may affect the bioavailability of the drug product or whether the manipulated drug product remains bioequivalent with the original dosage form. There is even less research or publicly available information on the clinical effects of manipulated drug products and those administered via alternate routes or delivery systems. ASHP encourages clinical and practice-based researchers to conduct studies on these subjects and to disseminate this information via journal articles and other easily accessible resources. ASHP also encourages education of the pharmacy workforce and other healthcare providers regarding the basic principles of drug dosing for manipulated drug products. Given that the frequency that some of these medications are manipulated or administered is often based on small case studies, consideration for the potential role of artificial intelligence in advancing model development and validation should also be explored.

Manipulation of drug products and alternate administration are also not without risk. Nebulized drugs that are not commercially available may be compounded with both sterile and nonsterile ingredients and that, when possible, should be compounded with preservative- and additive-free formulations to improve patient tolerability and considerations for drug stability, safety for patient and personnel administering nebulized drug products, and methods for preparation and delivery. Drug products administered intranasally often vary in pharmacokinetic and pharmacodynamic properties due to the presence of preservatives and viscosity of the agents and efficacy may depend on the use of additional devices such as atomizers. There are also exposure risks to caregivers preparing or administering manipulated drug products that are carcinogenic or teratogenic. Medications compounded for administration in the epidural space or intrathecal administration also bear consideration for the presence of preservatives. To this end, ASHP strongly recommends that when medications

are manipulated or being considered for alternative administration, a multidisciplinary team that includes a pharmacist is convened to assess clinical, safety and operational needs and provide institutional guidance.

2517
EXPEDITED PARTNER THERAPY
Source: Council on Therapeutics

To affirm that the pharmacy workforce improves patient access to therapies that prevent and treat sexually transmitted infections in all settings; further,

To support legislation that authorizes pharmacists to provide expedited partner therapy (EPT) while addressing barriers; further,

To encourage dispensing entities and payers to adopt internal policies that facilitate dispensing of EPT medications in alignment with public health guidance; further,

To advocate and affirm that drug products for EPT should be provided to individuals in a manner that ensures safe and appropriate use; further,

To encourage surveillance of EPT as a public health effort.

Rationale

Expedited Partner Directed Therapy (EPT) is an approach to treating sexual partners of patients who are seeking therapy for a sexually transmitted infection (STI). According to the Center for Disease Control and Prevention (CDC), chlamydia, gonorrhea, and syphilis are on the rise throughout the United States and are a source of significant morbidity and mortality. EPT has demonstrated to be an effective tool in combating the spread of STIs by treating the sex partners of patients with an STI by providing prescriptions or medications to the patient to take to their partner without the health care provider first examining the partner.

EPT is a generally accepted approach to treating certain STIs, but legislation across the United States varies from state to state with 47 states identifying EPT as permissible and three states that identify it as potentially allowable. "Permissible" is described as allowable for certain practitioners and conditions while "potentially allowable" means that EPT is potentially allowable subject to additional actions or policies. Relevant legal provisions include: existing statutes and regulations that specifically address the ability of authorized health care providers to provide a prescription for a patient's partner(s) without prior evaluation for certain STDs, specific judicial decisions concerning EPT, laws that incorporate via reference guidelines as acceptable practices, and statutory or regulatory provisions that relate to prescription drug laws in each jurisdiction – to the extent they may impact EPT.

Because the variety and complexity of these policies could present potential barriers to care, ASHP supports model legislation that articulates the authorization of a pharmacist to voluntarily offer preventative services, patient assessment, and patient care for sexual and reproductive health conditions, including EPT. When appropriate, pharmacists may recommend a referral to seek a higher level of care through the use of counseling and clinical decision-

making tools. The proposed model legislation authorizes appropriately trained pharmacists to provide these services when consistent with the standard of care.

Finally, ASHP recognizes that any legislation should define these services, provide clear authority for pharmacists to provide person-centered health services independently and through collaboration, create a mechanism for state and commercial insurance companies to pay for these services, include federal preemption and severability language, and should remove any pre-existing state barriers to pharmacist provision of health services.

2518

QUALITY CONSUMER MEDICATION INFORMATION

Source: Council on Therapeutics

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, accessibility, targeting, and simplicity of consumer medication information (CMI); further,

To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level and standardized, patient-focused templates for CMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that the FDA explore alternative models of CMI content development and maintenance that will ensure the highest level of accuracy, consistency, currency, and conformity with health literacy requirements; further,

To advocate that the FDA maintain a highly structured, publicly and easily accessible central repository of CMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for content, format, and distribution of CMI.

This policy supersedes ASHP policy 2005.

Rationale

Providing easy-to-read and accurate information to patients about medications is essential for ensuring their safety and efficacy. Nonadherence to and incorrect use of medications can lead to hospital admissions, treatment failures, and death. Multiple types of written information are provided to patients with prescription medications and biological products, but much of this information can be conflicting, confusing, and incomplete. Furthermore, only 12% of Americans have proficient health literacy skills according to the National Assessment of Adult Literacy, decreasing the likelihood that these patients will comprehend the provided information.

Consumer medication information (CMI) is written information for patients or caregivers about a prescription drug. CMI is developed by individuals or organizations; drug

companies and the FDA do not review or approve CMI. Currently available patient labeling available in the United States include Medication Guides (MG), Patient Package Inserts (PPI), and Instructions for Use. Medication Guides are a type of labeling for patients or caregivers that are required by the FDA if certain criteria are met, for example, when the medication has serious side effects or if following the directions is particularly important for effectiveness or avoiding serious side effects. PPIs provide patient information that can be a part of FDA-approved labeling and are developed by the manufacturer and approved by the FDA. PPI are required for estrogen-containing products and estrogens, but creation of PPI for other prescription medications is voluntary.

In 2023, the FDA proposed a rule that would create a new medication guide called "Patient Medication Information" (PMI) for prescription medications and biological products that are administered, dispensed, or used in an outpatient setting. These manufacturer-developed, FDA-approved, standardized, one-page documents will be provided in either paper or electronic format. PMI would replace the current MG and PPI and will be stored electronically in FDA's labeling repository. The FDA is in the process of reviewing comments and a final rule has not been issued.

The Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health's Healthy People 2030 initiative defines health literacy in two ways: personal health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others; and organizational health literacy is the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Programs that support education and training around self-assessment of health literacy and general communication skills and methods for practitioner assessments of patient health literacy are needed to ensure full adoption and appropriate implementation. Barriers to health literacy include language barriers such as limited English proficiency and communication barriers such as those experienced by the deaf or hard of hearing community. Each of these barriers, along with disability, transportation, and cultural barriers require practice resources to accommodate patients with specific communication needs.

Use of plain-language and patient-centered formats of CMI is essential for optimal health-related outcomes of medication use. Design elements and interventions, however, lack high-quality evidence and are thus unable to be considered "best-practice." Incorporating new methods of providing CMI and innovative practices should be a focus of future investigations.

2519

SUPPORT FOR CAREGIVING RESPONSIBILITIES IN THE PHARMACY WORKFORCE

Source: Council on Education and Workforce Development

To affirm that an individual's life circumstances can change and influence their workplace needs; further,

To foster psychologically safe environments that promote dialogue around individual workplace needs; further,

To advocate for organizational policies and resources that reduce disparities caused by caregiving responsibilities such as eldercare, lactation support, and other life circumstances; further,

To empower individuals to advocate for their own needs related to work-life integration.

Rationale

Throughout an employee's career, work dynamics often shift in response to life changes such as caregiving and lactation responsibilities. These situations introduce unique challenges that can significantly impact an employee's ability to balance personal and professional demands. In the pharmacy profession, organizations and leaders have a critical role in addressing these needs by providing supportive resources, ensuring benefit options are clearly communicated, and fostering an environment where employees feel comfortable discussing their circumstances.

Breastfeeding and lactation support are essential aspects of employee well-being, as breastmilk offers proven health benefits for both individuals and their children. Although the PUMP Act was enacted in 2022, pharmacy workplaces may still lack adequate, clean, and private spaces for expressing breastmilk. Variability in paid parental leave policies further complicates this issue, as many breastfeeding individuals return to work while still nursing and need support to maintain their breastfeeding relationships. Employers of pharmacy personnel must consider how to best support breastfeeding employees, promoting access to resources and lactation-friendly environments.

Eldercare is becoming an increasingly critical issue, particularly as the U.S. population over the age of 65 continues to grow. Unlike childcare, eldercare is not widely supported by current benefits policies, including FMLA. According to the 2022 National Pharmacist Workforce Study, women represent a majority of the pharmacy workforce and may face career disruptions due to caregiving responsibilities. By incorporating eldercare policies and benefits, employers of pharmacy personnel can improve employee retention, reduce absenteeism, and enhance productivity.

Supporting employees with caregiving and lactation needs requires employers of pharmacy personnel to advocate for policies that reduce disparities, ensure flexible work environments, and address the well-being of the workforce.

2520

SAFE TECHNOLOGY IMPLEMENTATION AND EXPANSION OF PHARMACIST SERVICES

Source: Council on Pharmacy Practice

To promote the use of automation and technology with the goal of enabling the pharmacy workforce to dedicate more time to patient care; further,

To affirm the essential role of the pharmacy workforce in the evaluation, implementation, and ongoing assessment of all technology that impacts the medication-use process.

This policy supersedes ASHP policy 1020.

Rationale

Embracing automation and technology in pharmacy practice is essential to enhancing efficiency, reducing medication errors, and allowing pharmacists to focus more on direct patient care. By integrating advanced technologies such as robotics, artificial intelligence, and health information systems, pharmacists can shift their efforts from routine dispensing tasks to providing critical clinical services, including comprehensive medication management. However, successful implementation of these innovations requires active involvement of the pharmacy workforce in evaluating, selecting, and optimizing technology to ensure it aligns with patient safety, operational needs, and organizational priorities. The expertise of the pharmacy workforce in the medication-use process is vital for assessing the effectiveness of automation, refining workflows, and addressing potential risks —with a commitment to ensuring the safety and performance of the technology and compliance with regulatory requirements. Therefore, policies must support the adoption of technology and the leadership role of the pharmacy workforce in shaping its implementation and ongoing assessment to improve healthcare outcomes and operational workflows.

2521

HEALTH CARE QUALITY STANDARDS AND PHARMACY SERVICES

Source: Council on Pharmacy Practice

To advocate that health care quality improvement programs adopt standard quality measures that are developed with the involvement of the pharmacy workforce, are evidence-based, and promote the demonstrated role of the pharmacy workforce in improving patient outcomes.

This policy supersedes ASHP policy 0502.

Rationale

The pharmacy workforce is accountable for ensuring a safe and effective medication use process as an essential component of patient health and quality care standards. Healthcare quality standards and measures are used to evaluate and improve the effectiveness, safety, efficiency, and patient-centeredness of healthcare services across care settings. However, many existing quality improvement programs and measures lack meaningful pharmacy involvement in their development, implementation, and evaluation. The pharmacy workforce should advocate for the adoption of evidence-based quality measures that recognize pharmacy professionals' contributions in patient care. Pharmacy input would promote accountability, support interprofessional collaboration, and drive improvements in medication management – ultimately leading to better health outcomes and more efficient healthcare delivery.

2522

ASHP STATEMENT ON THE PHARMACIST'S ROLE IN SUBSTANCE USE DISORDER PREVENTION, TREATMENT, AND RECOVERY

Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Pharmacist's Role in Substance Use Disorder Prevention, Treatment, and Recovery.

This statement supersedes the ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance dated June 2, 2013.

2024 Policy Positions

2401

ROLE OF THE PHARMACY WORKFORCE IN IMPROVING MENTAL HEALTH

Source: Council on Pharmacy Practice

To advocate for equitable and destigmatized access to mental healthcare services for all patients across their lifespan, including members of the healthcare workforce; further,

To affirm the essential role of pharmacists, as members of the interprofessional care team, in increasing patient access to mental healthcare services; further,

To urge all members of the pharmacy workforce to raise awareness of, screen for, triage, and provide education on mental health conditions; further,

To advocate for expansion of mental health-related comprehensive medication management services provided by pharmacists; further,

To advocate for adequate funding of mental health awareness programs and for funding that promotes equitable access to mental healthcare services.

Rationale

Mental health is a public and population health issue that requires support of mental healthcare needs for patients and members of the healthcare workforce. Mental health is recognized as a global public health issue, worsened by the COVID-19 pandemic. In addition, support for mental health and access to mental health services are important for the healthcare workforce. Despite the high prevalence of patients with mental health issues, access to services is significantly strained. Data prior to the pandemic demonstrated that nearly 6 of 10 people in the U.S. desired access to mental health services for themselves or a loved one. Barriers to access include a limited and constrained healthcare workforce, high cost, insufficient insurance coverage, long wait times, lack of awareness, and stigma.

The pharmacy workforce plays a critical role in improving medication-use outcomes for populations of patients across the continuum of care. This role creates an opportunity for pharmacists with expertise in mental health to increase patient access to mental health services and improve mental health outcomes. Using a comprehensive medication management approach to care, pharmacists can assess mental healthcare needs, manage medication therapy regimens, educate patients and caregivers, monitor patients, and assess outcomes of mental healthcare services. It also creates an opportunity for the pharmacy workforce to engage as members of the interprofessional care team in population health strategies that increase awareness of, screening for, and treatment of mental health issues. The American Psychological Association outlines the following as principles to guide a population health framework for mental health:

- Use data and the best available science to inform policies, programs, and resources.
- Prevent when possible and otherwise intervene at the earliest moment.

- Strategize, analyze, and intervene at the community/population level (in addition to the individual).
- Reach broad and diverse audiences through partnerships and alliances.
- Utilize a developmental approach (e.g., change over time, age-appropriate interventions).
- Consider the "whole person" and the structural/systemic factors impacting individual behavior.
- Be culturally sensitive while also thinking transculturally.
- Recognize that inherent in every community is the wisdom to solve its own problems.
- Champion equity by addressing systemic issues (e.g., social determinants of health, access to treatment).

To ensure that the opportunity to leverage the pharmacy workforce in improving access to and quality of mental health services is realized, there needs to be greater awareness, advocacy and collaboration with other stakeholders, training efforts for building competency and expertise, and reimbursement that supports sustainable services.

2402
SUICIDE AWARENESS, PREVENTION, AND RESPONSE
Source: Council on Pharmacy Practice

To support the goal of zero suicides; further,

To collaborate with key stakeholders in support of suicide awareness, prevention, and response; further,

To acknowledge that optimal suicide awareness, prevention, and response efforts focus both on patients and on the healthcare workforce; further,

To recognize that pharmacists, as key members of the interprofessional care team, are integral to suicide awareness, prevention, and response efforts, and to acknowledge the vital role of other members of the pharmacy workforce in those efforts; further,

To foster the use and development of clinically validated tools to aid the pharmacy workforce in assessing the influence of medications and other factors on suicidality; further,

To advocate for adequate government and healthcare organization funding for suicide awareness, prevention, and response; further,

To enhance awareness of local, state, national, and global suicide awareness, prevention, and response resources.

This policy supersedes ASHP policy 1901.

Rationale

The high and increasing number of suicides in the U.S. has created a call for national action. In 2021, the Centers for Disease Control and Prevention reported that suicide was the eleventh leading cause of death for Americans. Further, a *JAPhA* study showed that pharmacists are at an increased risk of death by suicide when compared to the general public. According to that study, the suicide rate among pharmacists in the United States is 20 per 100,000, which is higher than the general population rate of 12 per 100,000. The U.S. Surgeon General and the National Action Alliance for Suicide Prevention, in the 2012 National Strategy for Suicide Prevention and the 2021 Surgeon General's Call to Action on Suicide Prevention, provided general guidance for various societal approaches, including public awareness and development of effective clinical practices targeting suicide prevention. The National Strategy set an aspirational zero suicides goal for healthcare services, which will require a systemwide effort to improve healthcare's approach to suicide prevention, including clinician training and implementation of better referral systems.

In addition to calls for raising awareness and preventing death by suicide, there also needs an appropriate response in the event of suicide. Postvention, defined as activities that reduce risk and promote healing after a suicide death, is an important term for healthcare workers and communities to factor in response to death by suicide. ASHP partnered with the American Foundation for Suicide Prevention to customize two postvention toolkits for pharmacy residents and student pharmacists. Information in the toolkits is generalizable to the entire pharmacy workforce and aim to ensure a careful and appropriate response to death by suicide.

The responsibility for healthcare professionals to become involved in suicide prevention and response extends beyond those specializing in mental health services, as suicide may be viewed as a response to multiple biological, psychological, interpersonal, environmental, and societal influences that interact with one another and may change over time. Suicide prevention and response, when viewed as the collective efforts of government, public and private organizations, and care providers to reduce the incidence of suicide across the lifespan of a person, requires a correspondingly broad response by healthcare professionals. In 2016, the Joint Commission published a Sentinel Event Alert urging healthcare organizations to develop policies, staff education, and comprehensive care plans to utilize suicide risk assessment tools and support patients with suicide risk factors. The Joint Commission urged all healthcare organizations to develop clinical environment readiness by identifying, developing, and integrating comprehensive behavioral health, primary care, and community resources to assure continuity of care for individuals at risk for suicide.

In addition, concern over drug-associated suicidal ideation and behavior has been increasing over the last decade. In 2012, the Food and Drug Administration (FDA) issued draft guidance on assessing the occurrence of suicidal ideation and behavior in clinical drug trials. Over 800 drugs have been linked to an increased risk of suicidal thoughts and depression, from central nervous system agents to antimicrobials. The ASHP Medications and Suicidality Web Resource Center contains guidelines and publications concerning drug-associated suicidality and maintains links to information on individual drugs associated with depression and suicidality. ASHP encourages continued research on suicidal ideation and behavior in clinical

trials and supports safety measures by manufacturers and FDA (e.g., risk evaluation and mitigation strategies, boxed warnings) when appropriate.

Given the leading role of pharmacists in overseeing safe medication use, the dangers of medications relating to suicide risk, and the high degree of pharmacist interaction with patients, pharmacists are well positioned to play a key role in suicide awareness, prevention, and response efforts. The pharmacist's role could include, for example, ensuring appropriate use of medications in management of mental health and other medical conditions; identifying patients at risk for suicide, and evaluating that suicide risk; and recommending care, making referrals, and following up on referrals with patients and providers. Strategies could range from evaluating patients' prescribed medications and identifying those that increase risk for suicidality; to counseling patients, caregivers, and other healthcare providers about those risks; to educating the public about the dangers of unused medications and the need for proper disposal. Pharmacists trained in behavioral health could also be incorporated into behavioral health programs to offer comprehensive medication management to patients and serve as a resource to the interprofessional care team. Other pharmacy practitioners (student pharmacists and pharmacy technicians) could perform vital services in suicide awareness and prevention efforts as well, such as medication reviews. The goal of zero suicides will also require a combined effort from individual healthcare workers and the healthcare system as a whole to sustain clinician well-being and resilience, as further described in ASHP policy 2329, Clinician Well-Being and Resilience. In 2023, ASHP and partnering pharmacy organizations established the Pharmacy Workforce Suicide Awareness Day to be recognized annually on September 20 as part of September's Suicide Prevention Month.

To ensure that pharmacy practitioners have the competence and confidence to properly fill these key roles, ASHP is committed to providing education and tools to assist pharmacy practitioners in suicide awareness, prevention, and response efforts. Further, ASHP advocates inclusion of suicide awareness, prevention, and response in college of pharmacy curricula and postgraduate educational and training programs, through a multimodal approach. ASHP also advocates universal suicide awareness, prevention, and response training for the health workforce. Adequate government and private-sector funding of suicide awareness and prevention efforts will be required to promote the success of suicide awareness, prevention, and response efforts. ASHP joins other organizations in supporting efforts to promote awareness of local, state, national, and global suicide awareness, prevention, and response resources, including the 988 Suicide & Crisis Lifeline.

Finally, ASHP urges research on suicide awareness, prevention, and response, including research on patient assessment tools, medications that increase the risk of suicidality, and practice models and strategies to identify and manage patients at risk for suicide.

2403

MEDICATION STEWARDSHIP PROGRAMS

Source: Council on Therapeutics

To advocate that pharmacists are foundational members of any medication stewardship program; further,

To affirm that pharmacists bring unique clinical, operational, safety, and financial expertise to help organizations develop and manage medication stewardship programs; further,

To promote pharmacist leadership in medication stewardship teams; further,

To encourage healthcare organizations to develop comprehensive medication stewardship programs that align with applicable laws, regulations, and accreditation standards; further,

To support incorporation and development of the pharmacy workforce in medication stewardship efforts; further,

To enhance awareness that medication stewardship includes disease state management across all levels of care and addresses barriers at the patient and system levels in order to improve the quality, safety, and value of patient care.

Rationale

Stewardship is an approach to patient care whose goals are to improve the quality, safety, and value of care. These goals are achieved through evidence-based therapy to achieve optimal patient outcomes, with selection of the correct drug, appropriate dose, and subsequent optimization, and by reducing costs and barriers to the patient, healthcare system, and payers. The most well-known and successful stewardship programs are those for antimicrobial agents and opioids, because these programs are required by the Centers for Medicare & Medicaid Services. The Joint Commission also requires hospitals or health systems to allocate financial resources for staffing and information technology to support an antimicrobial stewardship program (ASP) and that a pharmacist be a part of the ASP.

As hospitals and health systems transition to value-based care and become more conscious of outcomes data, stewardship has become even more important. Clinical areas that could benefit from stewardship programs include anticoagulation, oncology/anti-cancer therapies, fluid management, pharmacogenomics, and psychiatry; all demonstrate the potential for and necessity of stewardship programs. Additionally, research has firmly demonstrated that programs with pharmacist involvement result in the most improvement in costs, patient outcomes, and safety. Drug selection is typically a collaborative decision between the prescriber and the pharmacist, but pharmacists can add recommendations using several additional lenses. Pharmacists assess the drug to ensure an evidence-based approach is used, ensure the correct dose, assess for drug interactions or comorbidities, and help with dose adjustments, monitoring, and adherence. They also assist with identifying which drugs are restricted by formulary, which biosimilars are preferred, which high-cost drugs have patient-assistance programs, and with other patient-specific insurance issues. Stewardship takes a comprehensive approach to drug management that crosses multiple phases of care. ASHP believes that members of the pharmacy workforce have the clinical skills, training, and financial and operational knowledge that make them foundational members of any new stewardship program and leaders in established programs.

As stewardship programs evolve, so do their needs. The integration of pharmacy technicians is a logical next step for stewardship programs. In the United Kingdom, pharmacy technicians play a large role in ASPs. They conduct antimicrobial virtual chart reviews for de-escalation, review and flag penicillin allergies for the pharmacist, participate in audits, and more. The number of pharmacy technicians that perform clinical roles continues to grow in the United States, and incorporating them into stewardship programs is a natural extension of their evolving roles.

2404
FLEXIBLE WORKFORCE MODELS
Source: Council on Education and Workforce Development

To advocate for flexible workforce models that promote patient safety and continuity of care, optimize pharmacy operations, and enhance recruitment and retention of the pharmacy workforce.

Rationale
Broader advocacy efforts are needed to ensure state laws do not prohibit the development of innovative pharmacy practice models that incorporate flexible approaches, specifically in the areas of telehealth practices and telecommuting. As the healthcare landscape and industry continue to evolve, the entire pharmacy workforce and its stakeholders need to embrace flexible workforce model approaches that optimize operational efficiencies and promote safety in support of patient care. Flexible workforce models may include hybrid, remote, and onsite work. Specific job roles and responsibilities, space, and cost implications must be taken into consideration in any new practice model that incorporates flexible approaches. More importantly, these flexible approaches must ensure continuity of patient care and augment team-based care.

As retention and recruitment grow increasingly challenging, embracing a flexible workforce model may further enhance staff satisfaction and recruitment to the pharmacy profession more broadly.

2405
PHARMACIST ACCESS TO PROVIDER NETWORKS
Source: Council on Pharmacy Management

To advocate for laws and regulations that require healthcare payers to include pharmacists in their provider networks as standard coverage when providing patient care services within their scope of practice and the services are covered benefits; further,

To advocate that payers provide comparative, transparent sharing of performance and quality measure data for all providers in their networks, including pharmacists.

This policy supersedes ASHP policy 2134.

Rationale

As hospitals and healthcare organizations increase their ambulatory care service footprint, pharmacists providing patient care services within those settings may find themselves excluded from healthcare payer networks. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to profitably operate). When creating provider networks, however, payers should include pharmacists providing patient care services within their scope of practice as standard coverage, when the services are covered benefits. ASHP advocates for laws and regulations that require healthcare payer provider networks to consider all qualified pharmacists who apply to participate as a provider in the network and to reimburse all participating providers fairly and equitably for services that are a covered benefit (see ASHP policy 2331, Sustainable Billing, Reimbursement, and Payment Models). To ensure the same level of patient care and equity for healthcare providers within a payer network, payers should be required to (1) disclose to participating providers and those applying to participate in a provider network the criteria used to include, retain, or exclude providers; (2) ensure those criteria are standardized across all network providers; and (3) collect performance and quality measure data on how well providers meet those criteria and report that data to providers. Pharmacist scope of practice is defined at the state level and is highly variable. Provider status recognition is also highly variable. Only a few states formally recognize pharmacists as providers and have established payer mandates to ensure reimbursement in a manner similar to other disciplines that provide patient care. As a result, pharmacy leaders typically have very limited experience regarding how payers manage networks and reimbursement. When pharmacists obtain provider status, health systems will require a substantial amount of infrastructure to support pharmacists as providers. Pharmacy leaders will need to have relationships across a broad range of internal departments and committees, including finance, revenue integrity, provider relations, medical staff services, and credentialing and privileging. They will also need to engage in external collaborations with payers, which often includes departments such as provider relations and contracting that have a very limited understanding of pharmacist patient care services beyond prescription fulfillment and dispensing services. Despite the risk that payer transparency could reduce market competition, comparative, transparent sharing of performance and evidence-based quality measure data could demonstrate to payers and providers how a provider's performance and quality compares to others. Ensuring that qualified pharmacists have access to payer networks improves patient access to pharmacist care, team-based coordination of care, and health outcomes.

2406

RISK ASSESSMENT OF HEALTH INFORMATION TECHNOLOGY

Source: Council on Pharmacy Management

To urge hospitals and health systems to directly involve departments of pharmacy in performing appropriate risk assessment before new health information technology (HIT) is implemented or existing HIT is upgraded, and as part of the continuous evaluation of current HIT performance; further,

To advocate that HIT vendors provide estimates of the resources required to implement and support new HIT; further,

To collaborate with HIT vendors to encourage the development of HIT that improves patient-care outcomes and user experience; further,

To advocate for changes in federal law that would recognize HIT vendors' safety accountability.

This policy supersedes ASHP policy 1418.

Rationale

The adoption of HIT in hospitals has been increasing at a quickening pace. The 2022 ASHP National Survey of Pharmacy Practice in Hospital Settings reports basic analytics (e.g., data from smart pumps, clinical decision support, compounding technology) are used in nearly 85% of hospitals and advanced analytics (e.g., artificial intelligence, machine learning, predictive analytics) are used in 8.7% of hospitals, an increase from 4% in 2021 and 2.6% in 2020. Investing in HIT and properly integrating it within healthcare can prevent and decrease errors, improve quality, and prevent waste.

Before selecting or upgrading health IT, organizations must determine their needs and goals. The Office of the National Coordinator for HIT maintains the Health IT Playbook to help clinicians, administrators, and clinician-practice staff. The Health IT Playbook provides tools to help healthcare organizations choose and implement the right HIT systems for their needs. As hospitals and providers implement HIT within their institutions and practices, however, they often encounter new types of errors and problems. The medical literature is replete with many reports of the unintended consequences of HIT, so continuous monitoring of these systems is required. It has become increasingly important to properly assess the interface between HIT and users to identify whether any new risk has been introduced to the system and implement HIT appropriately, taking into account medication-use processes and human factors. Critical questions hospitals and health systems face include (1) when do HIT advances exceed the capacity for integration into workflow, (2) when does HIT begin to introduce risk into the medication-use process rather than improve patient safety, and (3) what are the accountabilities of HIT providers, regulators, and providers to ensure the necessary product development and assessments are made before implementation of new HIT.

ASHP advocates that the pharmacy department be part of the implementation team for any medication-related technology within an institution. Technology assessment tools should be applied by the pharmacy workforce to proactively determine gaps in function prior to implementation, during upgrades, and as part of the continuous evaluation of HIT performance. The use of failure modes effects analysis (FMEA) and other resources should be considered. Organizations selecting or upgrading HIT should work closely with implementation partners or vendors to ensure the following: (1) products are suited to the organization's needs; (2) HIT will be usable by clinicians and staff; and (3) accurate estimates of resources needed are identified to implement and support new or upgraded HIT. These processes also provide opportunities to examine and optimize care delivery processes. Tailoring both technology and processes around

care pathways takes advantage of the technology's potential to support safer care, inclusive of patient goals, while reducing burdens on healthcare professionals. Risk assessment should also be considered when implementing any new technology to ensure that unintended consequences are minimized. Regulatory and accreditation organizations include components of risk assessment and quality improvement within their criteria, but hospitals need to incorporate these into their overall plans. Such risk assessments could result in less attention on some HIT implementations. Finally, federal law needs to recognize vendors' accountability for the safety of their products as implemented.

2407
UNIT DOSE PACKAGING AVAILABILITY
Source: Council on Pharmacy Management

To advocate that pharmaceutical manufacturers provide all medications used in health systems in unit dose packages or, when applicable, in packaging that optimizes medication safety, improves operational efficiency, and reduces medication waste; further,

To urge that the Food and Drug Administration require pharmaceutical manufacturers to provide stability data to support the repackaging of medications outside of their original manufacturer bulk containers in the interest of public health, healthcare worker and patient safety, and reduced waste.

This policy supersedes ASHP policy 2253.

Rationale

The benefits of unit dose drug administration were well established in the 1960s. Despite these benefits, some drugs are not available from manufacturers in unit dose packages. One reason sometimes cited for this lack of availability is that because unit dose packages make up a relatively small portion of business for many manufacturers, some manufacturers are making a business decision to discontinue this form of packaging. When manufacturers do not provide drugs in unit dose form, the pharmacy must repackage them, introducing opportunities for error and healthcare worker or patient harm. Increasingly, however, pharmaceutical manufacturers are including verbiage on bulk medication bottles and within package inserts that state "dispense in original container" or similar language. These statements are typically declared without any rationale, studies, or analytical support. The statements and the lack of external data regarding stability of medications when repackaged have created hardships for health-system pharmacies trying to provide medications in a ready-to-use form for timely administration. This practice may perpetuate drug shortages and lead to avoidable and costly medication and packaging waste. Although it may not be practical for FDA to mandate unit dose packaging to optimize medication and patient safety, improve operational efficiency, and support the interest of public health, FDA could encourage such packaging in other ways, such as by developing packaging guidelines for the pharmaceutical industry. In cases in which unit dose packaging is not practical, manufacturers should at a minimum provide package sizes or medication stability data that would reduce waste.

2408

SUPPORTING HIGH RELIABILITY IN PHARMACY PRACTICE

Source: Council on Pharmacy Management

To state that a commitment to the principles and science of high reliability, with the goals of zero medication errors and zero harm, are foundational to pharmacy excellence; further,

To encourage hospitals and health systems to commit to high-reliability principles; further,

To encourage research that informs the creation of best practices in high reliability and progress toward implementation of high-reliability principles in all pharmacy services.

Rationale

High reliability is an ongoing process or an organizational frame of mind, not a specific structure. The Agency for Healthcare Research and Quality has outlined practical strategies for healthcare organizations aiming to become highly reliable in their report of practices employed by hospitals in the High Reliability Organization Learning Network. This mindset is supported by five characteristic ways of thinking: preoccupation with failure; reluctance to simplify explanations for operations, successes, and failures; sensitivity to operations (situation awareness); deference to frontline expertise; and commitment to resilience. High-reliability organizations work to create an environment in which potential problems are anticipated, detected early, and virtually always responded to early enough to prevent catastrophic consequences. The Joint Commission suggests that hospitals and healthcare organizations work to create a strong foundation before they can begin to mature as high-reliability organizations. Such foundational work includes developing a leadership commitment to zero-harm goals, establishing a positive safety culture, and instituting a robust process improvement culture. The Joint Commission also provides metrics and tools for assessing the maturity of an organization's leadership, safety culture, and process improvement culture as preconditions to high reliability. Structured analysis of work processes can eliminate inefficiencies, increase value-added time spent with patients, reduce staff stress, and optimize the use of supplies and other resources. Reliable information technology systems are critical to ensure care quality and improve efficiency in administrative and process measures. ASHP's PAI 2030 includes a recommendation that states: "C9. Pharmacy should employ high-reliability principles when designing and selecting health information technology." Given the rising cost of healthcare and internal competition for finite capital dollars, it is important to identify solutions that will improve quality and safety while being fiscally responsible. Research is needed to evaluate tasks and processes to identify better approaches that will reduce waste, improve outcomes, and yield significant savings. Continuous improvement on the delivery of high-value care requires healthcare institutions to continually monitor and improve reliability and performance (see ASHP policy 2206, Continuous Performance Improvement).

2409

ASHP STATEMENT ON THE COMMUNITY PHARMACIST'S ROLE IN THE CARE CONTINUUM

Source: Section of Community Pharmacy Practitioners

To approve the ASHP Statement on the Community Pharmacist's Role in the Care Continuum.

2410

5-HT_2 AGONIST, ENTACTOGEN, AND EMPATHOGEN (PSYCHEDELIC) ASSISTED THERAPY

Source: Council on Therapeutics

To recognize that psychedelic-assisted therapy (PAT) has demonstrated therapeutic potential and should be further researched; further,

To recognize that in PAT there is not a standardized product subject to the same regulations as a prescription drug product, and to support the development of standardized formulations of psychedelics that would provide consistent potency and quality; further,

To encourage state boards of pharmacy, regulatory agencies, and safety bodies with an interest in PAT to promote research best practices and regulatory standards for medication preparation, compounding, and administration to ensure safety and quality; further,

To advocate that when psychedelics are used for PAT, healthcare providers, including pharmacists, should assess patients for medical, pharmacologic, and psychosocial contraindications prior to use and provide medical assistance as needed.

Rationale

There has been growing interest in the therapeutic potential of psychedelic drugs for use in the treatment of conditions such as depression, posttraumatic stress disorder, substance use disorders, and other conditions. The U.S. Food and Drug Administration (FDA) includes among these psychedelic drugs the "classic psychedelics," typically understood to be 5-HT_2 agonists such as psilocybin and lysergic acid diethylamide (LSD), as well as entactogens or empathogens such as 3,4 methylenedioxymethamphetamine (MDMA). As a result of the growing interest, the FDA issued guidance that provides general considerations to sponsors developing psychedelic drugs for treatment of medical conditions.

Many studies report that psychedelic compounds are associated with few adverse events in trials, but the populations studied are not generalizable to the larger population. Psychological safety is a potential concern, and psychological distress is common, though not necessarily harmful in the long term. Increased blood pressure and heart rate due to the distress experienced during the administration session may put individuals with uncontrolled blood pressure or coronary artery disease at risk of ischemic events and may be considered a relative contraindication. Psychiatric illnesses, including schizophrenia, psychosis, and bipolar disorder, are considered a likely contraindication to psychedelic therapy. Drug-drug interactions of psilocybin, including tricyclic antidepressants, monoamine oxidase inhibitors, selective serotonin reuptake inhibitors, and QT interval-prolonging medications, are of concern and underscore the importance of pharmacists in the management of policies and practices related

to the use of psychedelic compounds. Small sample sizes, a lack of diversity in enrollment, a lack of effective blinding, varied doses studied, and selective enrollment are just some of the critiques of trials assessing the use of psychedelic compounds. Psilocybin has been studied mainly in the treatment of psychological distress associated with life-threatening illnesses and major depressive disorder, while MDMA has been studied most extensively in the treatment of posttraumatic stress disorder. Despite promising results of some of the studies, the limitations of the studies prevent firm conclusions from being drawn.

In 2023, the American Medical Association also released new Current Procedural Terminology (CPT) III codes for Continuous In-Person Monitoring and Intervention During Psychedelic Medication Therapy. The codes will provide a mechanism to track and report on the delivery of psychedelic treatments and will cover multiple psychedelic compounds with psychological support models, if approved, as well as various staffing structures, and numbers and credentials of qualified healthcare professionals.

Currently, psychedelic compounds with proposed therapeutic benefit, including psilocybin and MDMA, remain Schedule I substances, with no recognized therapeutic uses. Two states, Oregon and Colorado, have passed laws allowing the legal consumption of psychedelic compounds. Medical organizations have expressed concern about state efforts to circumvent federal laws through this approach, particularly when in the guise of medical treatment. In Oregon, for example, the administration of psychedelics is accompanied by assisted psychotherapy to maximize the possible therapeutic benefits. Prior to administration of the psychedelic compound, the individual will meet with a facilitator in a "preparation" session to review safety and support planning, transportation, and expectations for the administration of the psychedelic compound. The individual is then administered the dose under the supervision of the facilitator. Although these individuals are encouraged to share their past medical histories with the facilitator, it is not required, and the screening needed to ensure an appropriately selected client may fail to detect contraindications or significant drug-drug interactions. Furthermore, facilitators are required to have only a high school diploma and are not required to undergo medical training. This lack of training is of particular concern because individuals who are not trained medical professionals are likely unable to distinguish between medical emergencies and the side effects of the psychedelic compounds.

ASHP policy also aligns with the American Psychiatric Association position that recognizes the emerging scientific evidence for using psychedelic drugs within the context of approved investigational studies and that "clinical treatments should be determined by scientific evidence in accordance with applicable regulatory standards and not by ballot initiatives or popular opinion."

It is important to recognize that mushrooms containing psilocybin have long been used for rituals and religious ceremonies around the world. As those uses fall within indigenous cultural and religious traditions and are not intended as medical treatment, this policy does not address those uses.

2411

PHARMACY RESIDENCY TRAINING

Source: Council on Education and Workforce Development

To continue efforts to increase the number of ASHP-accredited pharmacy residency training programs and positions available; further,

To promote efforts to increase recruitment and retention of residents in ASHP-accredited pharmacy residency programs; further,

To encourage stakeholders to evaluate priority areas within pharmacy for future residency training needs.

This policy supersedes ASHP policy 0917.

Rationale

ASHP is committed to achieving the goal that "pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience" and advocates that "the completion of an ASHP-accredited postgraduate year one residency be required for all new college or school of pharmacy graduates who will be providing direct patient care" (ASHP policy 2027). Furthermore, recommendation B4 of the Practice Advancement Initiative (PAI) 2030 states, "Health systems should require completion of ASHP-accredited residency training as a minimum credential for new pharmacist practitioners." There are opportunities to evaluate recruitment and retention of residents to increase the number of successfully completed residency training programs. In addition, key stakeholders (e.g., colleges of pharmacy, academic medical centers, healthcare organizations, and government agencies) should evaluate priority areas within pharmacy for future training needs, which may include health-system pharmacy administration and leadership, population health management and data analytics, pain and palliative care, medication-use safety and policy, pharmacy informatics, and others.

2412

PREHOSPITAL MANAGEMENT OF MEDICATIONS

Source: Council on Pharmacy Practice

To assert that variation in the prehospital management and use of medications is a risk to patient safety and continuity of care; further,

To advocate for pharmacy workforce involvement in clinical and operational decision-making for prehospital management and utilization of medications; further,

To collaborate with stakeholders involved in prehospital medication-use decisions to improve patient safety, minimize variation, and reduce inefficiencies.

Rationale

ASHP advocates that the pharmacy workforce "assume responsibility for medication-related aspects of ensuring the continuity of care as patients move from one care setting to another"

(ASHP policy 2205). Prehospital management and utilization of medications is within the continuum of care of patients and varies greatly through patient emergency services, transport, and transfers. The pharmacy workforce has established clinical and operational expertise across the spectrum of medication use, which would add value and safety measures to the prehospital management and utilization of medications. Leveraging that expertise will inform decision-making regarding standardization, management of medication shortages, and prevention of medication errors, among other things. Ensuring pharmacy workforce involvement in these medication-related activities and decisions will optimize medication use and thereby improve prehospital care and patient safety during emergent situations and patient transfers.

2413

ROLE OF ARTIFICIAL INTELLIGENCE IN PHARMACY PRACTICE

Source: Council on Pharmacy Practice

To embrace artificial intelligence (AI) as a tool with tremendous potential to improve patient care and the medication-use process through the enhancement of pharmacy practice; further,

To recognize that AI technologies offer innovative ways to gather clinical knowledge, assist learners, enhance educational experiences, and streamline administrative processes; further,

To advocate for standards, policies, and procedures that permit the use of AI in circumstances in which it has proven safe and effective as an augmentation of pharmacy services and to ensure safeguards along with its implementation; further,

To encourage the adoption of policies regarding the use of AI and ongoing surveillance of these tools to maintain professional integrity; further,

To advocate for pharmacy workforce involvement and transparency in the decision-making, design, validation, implementation, and ongoing evaluation of AI-related applications and technologies; further,

To recognize that ethical considerations must guide the development and use of AI in pharmacy practice, and to oppose any use of AI that compromises human interaction or replaces ethical decision-making, professional judgment, critical thinking, or the safety and effectiveness of pharmacy services.

Rationale

Artificial intelligence (AI) is an emerging technology described as intelligent computer programs or software capable of learning human cognition and processes. AI is a valuable tool for hospitals and health systems that can improve healthcare outcomes for the benefit of patients and augment capabilities of the pharmacy workforce. AI falls under two categories: machine learning (ML) for data set analysis and natural learning processes for information extraction from existing data. AI technology has evolved at an immense speed, and healthcare

organizations have been increasingly digitizing data. Therefore, organizations must determine AI's use to improve patient-specific care on a grand scale without compromising patient safety and outcomes, and how to retain the expertise, autonomy, and humanity (e.g., empathy, compassion, and ethical decision making) of the interprofessional care team.

The potential benefits of AI in patient care include, but are not limited to, optimizing patient outcomes, improving implementation of high reliability principles, decreasing process variability, increasing evidence-based practices, streamlining Non-Relative Value Unit (RVU) generating processes, and re-focusing providers on clinical functions. The rapid advancement of generative AI technologies, such as ChatGPT, has also introduced new possibilities in the realm of education. These technologies appear to offer innovative ways to assist learners, enhance educational experiences, and streamline administrative processes.

The pharmacy workforce should collaborate with other healthcare professionals, professional organizations, and stakeholders to research, develop, implement, and improve the quality of AI/ML-based clinical models that affect medication-use processes and tasks. This collaborative team should ensure seamless integration of AI into the broader healthcare ecosystem, promoting the sharing of best practices and knowledge. The pharmacy workforce should maintain competence and continuing education in AI-related technologies that will advance pharmacy practice. Healthcare providers must recognize the need for sufficient purview and monitoring to guarantee patient safety and effective therapy. Risk should be formally assessed and mitigated as necessary. AI vendors and the pharmacy workforce independently have the responsibility to understand how AI solutions are functioning, impacting pharmacy clinical workflows, protecting patient data privacy and security standards, maintaining compliance with all relevant legal statutes, and identifying limitations in supporting practice and clinical services. Additional and applicable expectations for vendors can also be found in ASHP policy 2610, Risk Assessment of Health Information Technology.

Risks of AI use in patient care may include potential for breaches in patient privacy and safety, failure to incorporate ethical and moral decision-making, lack of transparency, automation biases, and narrow algorithm development that does not account for diverse populations and threatens to widen health disparities in underrepresented patient populations. Given these risks, the pharmacy workforce and other healthcare professionals must retain oversight of AI applications and their implementation. The pharmacy workforce should have access to mechanisms to report AI-caused errors or adverse events. Healthcare organizations, hospitals, and colleges of pharmacy should develop policies, procedures, and guidelines to determine which care settings, medications, and patient populations are appropriate candidates for the use of AI. Even if AI technology eventually accounts for every possible variable, final decision-making should be left to the healthcare team to mitigate its inherent risks and biases. Integration of AI tools also raises concerns about academic integrity, plagiarism, and the potential for unethical use that could undermine the educational process. As such, hospitals, health systems, and colleges of pharmacy should adopt policies regarding the appropriate use of AI across the continuum of learning, from didactic to experiential, and within the clinical learning environment.

The pharmacy workforce should consider the transformative potential of AI in pharmacy practice, but also the ethical, professional, and practical considerations associated with its integration. These principles provide the pharmacy workforce a roadmap to navigate the

evolving landscape of AI while upholding the highest standards of patient care and professional responsibilities.

2414
PHARMACIST'S ROLE ON ETHICS COMMITTEES
Source: Council on Pharmacy Practice

To advocate that pharmacists should be included as members of hospital and health-system ethics committees; further,

To encourage pharmacists to actively seek ethics consultations as appropriate; further,

To support continued inclusion of ethics in pharmacy education and encourage pharmacists serving on ethics committees to seek advanced training in healthcare ethics.

This policy supersedes ASHP policy 1403.

Rationale
Many hospitals have a committee or other process by which they consider ethical decisions related to patient care. Many issues that face these committees involve medications, yet often pharmacists do not serve on the committee or are not directly involved in the decision-making process related to ethical issues. The number of ethical issues involving medications is expected to increase, given many new and unique drug products coming into the market. These include patient access to high-cost medications, considerations during medication shortages, and other ethical considerations that surface as part of the formulary process. Pharmacist involvement would better inform these committees and consultations. To effectively contribute to decision-making on ethics, pharmacists will require advanced education on the subject.

2415
ENHANCING THE SAFETY OF HAZARDOUS DRUG PRODUCT HANDLING
Source: Council on Pharmacy Practice

To advocate that pharmaceutical manufacturers and wholesale distributors employ decontamination practices to eliminate surface contamination on packages of hazardous drugs (HDs); further,

To advocate that pharmaceutical manufacturers develop closed-system transfer device compatible, ready-to-administer HD products; further,

To advocate for standardized labeling and package design for HDs that would alert handlers to the potential presence of surface contamination; further,

To advocate for pharmacist involvement in the development of policies, procedures, and operational assessments regarding administration of HDs.

This policy supersedes ASHP policies 1615 and 1902.

Rationale

Hazardous drugs (HDs) present well-known risks to healthcare workers who handle them. Most HDs are administered orally or intravenously; however, other routes of administration are sometimes used, such as intrathecal, intraventricular, or intravesicular administration, or perfusion into a vessel or organ cavity. The protective precautions required for administration through these routes is well described in United States Pharmacopeia (USP) General Chapter 800, the ASHP Guidelines on Handling Hazardous Drugs, the Oncology Nursing Society's *Safe Handling of Hazardous Drugs*, and other sources.

Healthcare providers are required to use personal protective equipment and other protective devices, such as closed-system transfer devices (CSTDs), when the dosage form allows. To reduce the risks to healthcare providers, ASHP encourages device and pharmaceutical manufacturers and the Food and Drug Administration (FDA) to deploy new production and processing standards to mitigate exposures, including label and package design that alerts handlers to the possibility of contamination. In addition, manufacturers and the FDA should develop CSTD-compatible, ready-to-administer HD drug products with the goal that CSTDs be utilized for all routes of administration of HD products as a best practice.

HDs are sometimes administered through other routes (e.g., Ommaya reservoirs, intraperitoneal infusion) for which protective precautions are not as well described or CSTD use is not possible. However, when such use is not possible, an assessment of risk will identify gaps and ensure there are pharmacy-guided policies to address the handling, compounding, and administration for all healthcare staff coming into contact with HDs during administration via nontraditional routes. Such policies should also address any specialized training for staff in procedural areas, or the availability of a staff member with HD-specialized training to assist in the administration of the drug (e.g., a "chemo nurse").

ASHP encourages all healthcare settings to conduct an interprofessional, proactive assessment of the risk of such procedures to evaluate the potential exposure risks for healthcare providers and identify mitigating measures. Given their depth of knowledge regarding the handling of HDs, the pharmacy workforce should be involved in the development of policies, procedures, and operational assessments regarding administration of HDs in such circumstances.

The outer surfaces of vials of HDs have been shown to be contaminated, unwittingly exposing pharmacy and other personnel handling those vials to hazardous substances. ASHP advocates that individuals involved in drug distribution, receiving, and inventory control adhere to safe handling guidelines, including ASHP guidelines and USP General Chapter 800, to avoid undue exposure to hazardous substances. Recognizing the limits of these best practices, pharmaceutical manufacturers have a responsibility to provide vials that are devoid of surface contamination by ensuring adequate vial-cleaning procedures such as using decontamination equipment and protective sleeves during the manufacturing process.

2416
INDEPENDENT DOUBLE CHECKS FOR SINGLE PRACTITIONERS

Source: Council on Public Policy

To advocate for implementation of independent double checks, when feasible, to reduce the risk of error when a single practitioner is solely responsible for ordering, dispensing, administering, and monitoring medication therapy.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

As pharmacy practice has evolved to include more direct patient care services, oversight of these services has not kept pace. This trend was exacerbated by the COVID-19 pandemic, which ushered in new test-to-treat models for pharmacy teams and introduced new flexibilities into telehealth. As care has shifted, pharmacists may be placed in situations in which they are overseeing many aspects of medication use, from independent prescribing to dispensing, without any additional verification checks. Other clinicians, including physicians and nurse practitioners, may also be in similar positions. Regardless of setting, without adequate patient safety safeguards (e.g., high-reliability process, technology and/or human review), placing one clinician in charge of the elements of the medication-use process related to ordering, dispensing and administration, as well as any patient evaluation and monitoring, increases the risk for errors and adverse outcomes. While human checks are preferable for high-risk drugs, nothing in this policy should be considered to oppose appropriate autoverification of orders.

2417

STATE PRESCRIPTION DRUG MONITORING PROGRAMS

Source: Council on Public Policy

To support continued state implementation of prescription drug monitoring programs that collect real-time, relevant, and standard information from all dispensing outpatient entities about controlled substances and monitored prescriptions; further,

To advocate that such programs and states seek adoption into health information exchanges to best integrate into electronic health records and to allow prescribers, the pharmacy workforce, and other practitioners to proactively monitor data for appropriate assessment and dispensing; further,

To advocate that such programs improve their interstate data integration to enhance clinical decision-making and end-user satisfaction; further,

To advocate against unilateral use of these systems that may lead to patient stigmatization or prevent them from seeking appropriate medical care; further,

To encourage policies that allow the pharmacy workforce to gain access to databases without holding licensure in each state; further,

To promote research on the effects of prescription drug monitoring programs and

electronic health record programs on prescribing, dispensing, misuse, morbidity, and mortality.

This policy supersedes ASHP policy 1408.

Rationale

ASHP recognizes the important contributions to public health made by state prescription drug monitoring programs (PDMPs). To be effective, these programs need to be mandatory; must collect standardized, relevant, and real-time information for analysis and comparison among states; and need to be universal and accessible by the pharmacy workforce. However, reporting of information to the PDMP should not be used for the purposes of stigmatizing patients or criminalizing the provision of necessary patient care (e.g., requiring reporting of mifepristone prescriptions).

All states have implemented PDMPs, with the final state, Missouri, implementing its PDMP on January 20, 2023. While this is a great step forward, continued improvement of PDMP utilization is required. A recent review of PDMP reviews by Tay et al. in the *Journal of Drug and Alcohol Dependence* identified the following still-existing barriers: PDMP system-related functionality (i.e., usability, data quality), end-user-related experience (i.e., satisfaction, workflow efficiency), and broader issues (i.e., electronic health record [EHR] integration, data sharing). More importantly, not all states mandate provider use of PDMP prior to controlled substance prescribing, and states that do mandate its use are slow to hold providers/pharmacists accountable for not using it. Due to these factors, it is difficult for practitioners to make relevant clinical decisions.

Improved data sharing between different jurisdictions, enhanced interoperability with EHRs and information exchanges, and increased evidence of PDMPs' impacts on patient outcomes are needed to increase utilization and augment states' PDMPs. Finally, adequate state and federal funding is essential to sustain the viability of these programs and to encourage research, education, and implementation of best practices in PDMPs.

2418

TESTING FOR PREGNANCY STATUS

Source: Council on Therapeutics

To affirm that pregnancy testing should occur only with the patient's informed consent or assent, when feasible, and only when the test results would change medical management; further,

To affirm that a positive pregnancy test should not compromise the integrity of evidence-based, patient-centered care.

Rationale

Screening and testing for the pregnancy status of patients prior to admission to a hospital or surgical center or before initiation of a teratogenic drug therapy has long been a routine practice, as the pregnancy status of a patient has many ethical and legal considerations when medical management is considered for patient care. Chief pharmacy officers often oversee laboratory medicine departments, and pharmacists are often involved in creating protocols and

order sets in which pregnancy testing and screenings are embedded. As a result, pharmacists are key stakeholders in this practice.

It is important to note that this policy pertains to testing without informed consent or assent when therapy may need to be changed due to a positive test. The balance between unnecessary testing and testing when initiating a medication therapy is supported by a 2015 study that found that pregnancy assessment was underutilized in the emergency department when patients were prescribed a pregnancy category D or X drug. This policy does not advocate that healthcare professionals should not include pregnancy screening as a part of a patient history, only that pregnancy testing should occur only with informed consent or assent and not be a requirement for care. The incidence of unknown pregnancy in adult women presenting to a hospital for surgical procedures varies from 0.125 to 1.2%, depending on the procedure. It is important to note that testing should occur when feasible, as care should not be delayed in emergent or urgent scenarios.

This policy also aligns ASHP with the American Society of Anesthesiologists statement that recommends "pregnancy testing may be offered to female sex patients of childbearing age and for whom the result would alter the patient's management, but testing should not be mandatory. Informed consent or assent of the risks, benefits, and alternatives related to preoperative pregnancy testing should ideally be obtained. Best practice may employ shared decision-making between patients and providers."

2419

NONPRESCRIPTION STATUS OF RESCUE AND REVERSAL MEDICATIONS

Source: Council on Therapeutics

To support the nonprescription status of medications intended for evidence-based rescue use or reversal of potentially fatal events, in delivery systems appropriate for administration by lay persons; further,

To promote practices and policies that ensure affordable and equitable access to rescue and reversal medications; further,

To support and foster standardized education and training on the role of rescue and reversal medications and their proper storage, proper administration, safe use, and appropriate follow-up care.

Rationale

As part of public health initiatives, certain medications used for rescue and reversal have moved from prescription to nonprescription status. The opioid reversal agent naloxone is the most recent approval, with naloxone nasal spray approved in March of 2023 to help combat the opioid epidemic in the United States. Rescue and reversal medications such as naloxone and epinephrine require an additional level of action from patients and caregivers because they are used to initially treat life-threatening conditions, in contrast to other nonprescription agents. These patients will often require an additional level of care to monitor for safety and potential adverse events in the event of an opioid overdose or anaphylactic reaction. Therefore, it is important that rescue and reversal medications considered for nonprescription status have

evidence that supports their use.

As barriers to access are removed, patient demand for these life-saving agents will almost certainly skyrocket, aligning with the intended purpose of such initiatives. To forestall the possibility of counterproductive market shortages, efforts to support and enhance manufacturing processes should be bolstered, with the U.S. Food and Drug Administration (FDA) likely being the most effective entity for these interventions.

Similarly, pricing for rescue and reversal medications should be minimized as much as possible, including efforts to eliminate patient cost entirely. Nonprescription status often results in loss of third-party payer coverage, although there are notable exceptions to this trend (e.g., aspirin, vitamin D). The Affordable Care Act established a precedent for requiring insurer coverage of preventive drugs, and similar provisions could be made for rescue and reversal agents. Government efforts could include other related strategies, such as developing manufacturing cost subsidies, supporting tax-exempt status designations, and augmenting the wholesale distribution process and related infrastructure.

Finally, because the use of rescue and reversal medications often occurs in an emergency situation, proper storage and easy-to-understand instructions on how to use these drugs and how to escalate if a person does not respond should be encouraged by all manufacturers. These instructions should be designed, tested, and validated in a similar design to the Drug Fact Label created by the FDA, which is designed to assess whether all the components of the product with which a user would interact could be used safely and effectively as intended.

2420

OPPOSITION TO PHARMACY JURISPRUDENCE EXAMINATION REQUIREMENT

Source: Council on Education and Workforce Development

To advocate for the removal of standalone examination of federal or state pharmacy law as a requirement for licensure to increase interstate practice flexibility; further,

To support ongoing education of the pharmacy workforce on pertinent federal and state pharmacy laws; further,

To acknowledge that it is a professional obligation of the pharmacy workforce to practice in compliance with federal and state laws.

Rationale

National pharmacy associations have recently joined in advocacy for a more portable pharmacist license. Pharmacist interstate movement and practice are inhibited by the state-specific nature of the pharmacy jurisprudence examination. The pharmacist's licensing process includes one clinical knowledge exam (the NAPLEX), and in 48 states a jurisprudence exam is required, typically the Multistate Pharmacy Jurisprudence Examination (MPJE) — a 2.5-hour adaptive and proctored test. In contrast, physicians take three clinical knowledge exams, and only Texas, Oklahoma, Maine, and Oregon require a jurisprudence exam, which is taken online and is open-resource. Nurses are required to take one clinical knowledge exam (the NCLEX), and only Texas and Kentucky require a jurisprudence exam, which is also online and open-

resource. A 2017 working paper from the National Bureau of Economic Research found that pharmacists ranked among the lowest in terms of between-state migration, at -47%, compared to nurses (+5.5%) and physicians (+33%). While licensure in multiple states has always been almost a prerequisite for practitioners whose systems are in multi-state areas (e.g., VA, MD, DC), the advances in telehealth have made multistate licensure compulsory for many more pharmacists. Removal of standalone examinations would inevitably increase interstate practice flexibility.

Accreditation Council for Pharmacy Education accreditation standards require pharmacy law as part of the curriculum, but student pharmacists may not practice in the state in which they receive their education, and support of ongoing education on pertinent federal and state pharmacy laws should be provided to the pharmacy workforce. Even absent the state law exams, continuing education requirements and professional responsibility require the pharmacy workforce to know the laws in the state(s) in which they are licensed.

2421

DOCUMENTATION OF PATIENT-CARE SERVICES IN THE PERMANENT HEALTH RECORD

Source: Council on Pharmacy Management

To advocate for public policies that support documentation of patient-care services provided by the pharmacy workforce in the permanent patient health record; further,

To advocate for the design and use of electronic health records with a common documentation space to accommodate all healthcare team members.

This policy supersedes ASHP policy 1419.

Rationale

Documentation in the patient record is critical for a complete record for patient care and communication among members of the healthcare team. Documentation should be done within an electronic health record (EHR) to the fullest extent possible. ASHP supports the use of post-licensure credentialing, privileging, and competency assessment, in a manner consistent with other healthcare professionals, to practice pharmacy as a direct patient-care practitioner (ASHP policies 2011, Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice, and 1415, Credentialing, Privileging, and Competency Assessment). Pharmacy technicians, within their scope of practice, have documented activities (e.g., medication history documentation) in the record as part of team-based care documentation. When documenting electronically, use of standardized and coded formats allows for improved measurement of patient outcomes.

2422

SAFE MEDICATION SOURCING, STORAGE, PREPARATION, AND ADMINISTRATION IN ALL SITES

OF CARE

Source: Council on Pharmacy Management

To advocate that all sites of care be required to meet the same regulatory standards for medication sourcing, storage, preparation, and administration to ensure safety and quality.

This policy supersedes ASHP policy 1914.

Rationale

Payers have implemented strategies that fragment providers' comprehensive care management of the patient. These strategies include but are not limited to site-of-care (SOC) optimization, which shifts care away from hospitals, and payer-directed drug distribution models (ASHP policy 2309, Payer-Directed Drug Distribution Models), which undermine hospitals' patient safety protections and jeopardize patient care. The payers' overarching goal is cost containment, while maintaining access to the prescribed therapy. Cost containment efforts have shifted beyond the traditional pharmacy point-of-sale management intended for self-administered medications under the pharmacy benefit, such as formulary tiering, prior authorization requirements, drug exclusions, and step therapy implementation. Payer strategies targeting provider-administered medications under the medical benefit present risks to patient care and safety. Patients are increasingly being required to receive care at lower-cost nonhospital SOCs, rather than at traditional venues, such as hospital outpatient infusion centers. Alternative or nonhospital SOCs include nonhospital-affiliated outpatient infusion centers, physicians' offices, ambulatory infusion centers, or patients' homes. Payer-imposed SOC restrictions and policies jeopardize the continuity of care for the patient by introducing incongruent providers and systems (ASHP policy 2502, Pharmacy Access to Payer Networks). These same policies also create additional logistical challenges for the patient to navigate and can impede timely access to care for patients who require additional special assistance or services, such as access to emergency staff in the event of an adverse reaction. Further, the level of infrastructure required to adequately address regulatory and accreditation requirements focused on quality and safety (e.g., United States Pharmacopeia General Chapters <797> and <800>, Drug Supply Chain Security Act, state board of pharmacy regulations, and the standards of accreditors such as The Joint Commission and Det Norske Veritas Healthcare) varies across SOCs, with hospitals carrying the greatest administrative burden and costs. As a result, health systems should collaborate with pharmacy leadership when exploring ways to optimize medication access and appropriate utilization in nonhospital SOCs.

2423

INDEPENDENT PRESCRIBING AUTHORITY

Source: Council on Pharmacy Practice

To affirm that pharmacists are highly trained medication experts on the interprofessional care team who make evidence-based decisions; further,

To advocate that pharmacists have independent authority to initiate, monitor, modify, and deprescribe all schedules and classes of medications, commensurate with the pharmacist's training and in accordance with the standard of care; further,

To encourage healthcare delivery organizations to establish credentialing and privileging processes for pharmacists that delineate scope of practice, support pharmacist prescribing, and ensure that pharmacists who prescribe are accountable, competent, and qualified to do so; further,

To advocate that pharmacists be recognized as authorized providers by payers, pharmacies, and industry.

This policy supersedes ASHP policies 2236 and 2251.

Rationale

Pharmacists are highly trained medication experts skilled in providing comprehensive medication management (CMM) services across the continuum of care. As such, pharmacists are core members of the healthcare team, well-positioned to provide high-quality, cost-effective care that increases patient access and reduces the burden on other healthcare providers. Hundreds of studies published in peer-reviewed literature, conducted throughout a variety of organizations and health systems, have consistently demonstrated the benefits of pharmacist-directed patient care across a variety of clinical practice settings.

Independent, or autonomous, prescribing allows pharmacists to be responsible and accountable and fully execute CMM treatment plans. Independent medication therapy decision-making by pharmacists is already common and accepted by other licensed practitioners (e.g., physicians, physician assistants, and nurse practitioners). Practitioners participating in interprofessional teams that include pharmacists rely on the knowledge, demonstrated competency, and expertise of those pharmacists for CMM. Pharmacists in specialty practice areas such as anticoagulation management, solid organ transplant, and nutrition support have long functioned in roles in which independent prescriptive authority has improved clinical outcomes in the management and monitoring of medication therapy. In settings such as the Indian Health Service and Veterans Health Administration systems, prescriptive authority for pharmacists providing CMM services has been in place for over 40 years and has demonstrated positive clinical impact and increased patient access across the continuum of care.

Enabling state and institutional policy are critical in ensuring that pharmacists can seamlessly provide CMM services as members of the interprofessional team and at the top of their training and education. States authorize pharmacists to independently or collaboratively prescribe or initiate medications at varying degrees. Many health systems authorize pharmacists to manage medication therapy by enacting pharmacy and therapeutics committee policies that require use of medical staff delegation protocols and physician oversight for pharmacist-initiated orders. Pharmacist autonomous prescriptive authority should be the gold standard for practice, especially when appropriate credentialing and privileging is in place and there is a separation of duties to ensure that a prescribing pharmacist is not responsible for the processing and dispensing of that medication order, except during extenuating circumstances.

Credentialing and privileging of individual healthcare providers is essential for determining who is authorized to prescribe and should ensure the appropriate evaluation of

the quality of care provided. The credentialing procedures used to establish pharmacists' competency to prescribe must ensure that patients receive treatment from highly qualified caregivers. In addition to verifying appropriate education, licensure, and certification, the process should include:

- the same transparency and rigor applied to other prescribers,
- criteria used to measure patient care quality, and
- peer review by similar or higher-level peers (i.e., pharmacist prescribers or other licensed practitioners who are authorized to prescribe).

Healthcare organizations should use privileging methods that establish the scope of practice and clinical services that pharmacists are authorized to provide commensurate with their demonstrated competency within an area or areas of clinical expertise. The practice of credentialing and privileging should be consistent between hospitals, health systems, accountable care organizations, and other organizations where pharmacists function as a part of the interprofessional team.

ASHP Policy 2011, Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice, stipulates that pharmacists who prescribe must be recognized by payers and receive equitable payment for performing these advanced practice services. All pharmacist prescribers must possess a National Provider Identifier to monitor the care provided and should be reimbursed for services rendered. Finally, interprofessional education and training programs should incorporate the standard of pharmacist prescribing to ensure consistency and acceptance of pharmacist prescribing in similar practice settings and with similar levels of responsibilities.

2424

ADDITIONAL EDUCATION REQUIREMENTS FOR PHARMACY TECHNICIANS IN ADVANCED ROLES

Source: Council on Education and Workforce Development

To recognize that highly trained and skilled pharmacy technicians working in advanced roles regularly perform complex and critical medication-use procedures, and that a safe and effective medication-use process depends significantly on the skills, knowledge, and competency of those pharmacy technicians to perform those tasks; further,

To reaffirm that all pharmacy technicians should complete an ASHP/ACPE-accredited training program, be certified by the Pharmacy Technician Certification Board, and be licensed by state boards of pharmacy; further,

To advocate that pharmacy technicians working in advanced roles have additional training, such as an associate degree, and demonstrate ongoing competencies specific to the tasks to be performed, to ensure patient safety.

This policy supersedes ASHP policy 1203.

Rationale

Pharmacy technician roles have undergone a significant transformation within health systems throughout the years. In today's intricate healthcare landscape, these pharmacy technicians take on advanced responsibilities beyond their traditional duties. These extended roles include managing information systems, sterile product preparation, handling logistics, and implementing cutting-edge technology. According to the 2022 ASHP National Survey, more advanced pharmacy technician roles are emerging, including 340B Drug Pricing Program management, responsibility for USP General Chapter 797 (USP 797) compliance, initiation of medication reconciliation, and supervision of other technicians. Pharmacy administrators have also reported a range of functions that health-system technicians perform, including sterile and nonsterile compounding, inventory management, purchasing, hazardous drug handling, controlled substance system management, medication order distribution, supervisory responsibilities, billing and reimbursement, and technician education and training. These advanced roles will require different skills and competencies, and pharmacy technicians should demonstrate competency before being allowed to perform such tasks, which will require additional, task-specific training.

The advancement of the pharmacy technician workforce includes credentialing, licensing, and on-the-job training. Moreover, engaging in formal education such as an associate degree equips pharmacy technicians with the necessary skill set to excel in these multifaceted roles, aids human resources departments in assigning an appropriate job code and pay grade, and elevates the pharmacy profession more broadly. Furthermore, other technical personnel in the healthcare sector (e.g., radiology technicians, respiratory therapists, laboratory technicians) are moving towards requiring a minimum of an associate degree and completion of an accredited training program, and aligning pharmacy technician requirements with other professions provides another pathway for enhanced remuneration. It is recognized that these measures are synergistic with, and should not replace, existing educational requirements for pharmacy technicians working in advanced roles including the ASHP/ACPE-accredited training program, certification by the Pharmacy Technician Certification Board, state board of pharmacy licensure, professional certificate programs, and institution-based programs such as those from the military and armed services. It is the intent that these collective measures would promote recruitment and retention of the pharmacy technician workforce within hospitals and health systems.

2425

LIABILITY PROTECTION

Source: Council on Public Policy

To advocate that the pharmacy workforce be able to provide services consistent with the standard of care to patients without fear of legal consequences, harassment, or liability; further,

To advocate that protection against liability extend to referrals for out-of-state care and for providing services consistent with the standard of care to patients from another state.

This policy was revised in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

Rationale

In some states, pharmacists face potential civil or criminal liability for providing certain patient care services consistent with the standard of care, including services related to reproductive health, gender-affirming care, and prevention and post-prophylaxis for HIV. Subjecting pharmacists to such liability for providing patient services consistent with the standard of care not only inappropriately infringes on the practice of pharmacy, it increases risks to patients. Given the chilling effect of the laws impeding certain patient care services, patient access to services may be reduced or eliminated. Treatment delays, particularly for time-sensitive care related to reproductive health and provision of post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP), adversely impact patient care and outcomes and may result in patient or fetal mortality. Further, fear of prosecution could not only unduly limit the number of pharmacists willing or able to provide these services, but also significantly hinder training and specialization in these areas in the next generation of clinicians, damaging our nation's clinical pipeline. This policy is meant to apply only to care provided consistent with the standard of care and would not extend to protect against liability associated with negligence or malpractice.

2426

ACCESS TO REPRODUCTIVE HEALTH SERVICES

Source: House of Delegates

To recognize that reproductive healthcare includes access to and safe use of medications; further,

To recognize that reproductive health services include pre-conception, conception, post-conception, and termination of pregnancies; further,

To advocate for access to safe, comprehensive reproductive healthcare for all patients, including historically underserved patient groups such as patients of color, those with limited means, and those living in rural areas; further,

To advocate that medications related to reproductive health not be reclassified as controlled substances and that dispensing of those medications not be required to be reported to prescription drug monitoring programs; further,

To affirm that healthcare workers should be able to provide reproductive healthcare per their clinical judgment and their conscience without fear of legal consequence, workplace sanctions, social stigmatization, harassment, or harm.

This policy supersedes ASHP policy 2250.

Rationale

Reproductive health has been defined as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes," and reproductive healthcare has been defined as "the constellation of methods, techniques and services that contribute to reproductive health and well-being by preventing and solving reproductive health problems." (International Conference on Population and Development Programme of Action, Twentieth Anniversary Edition, United Nations Population Fund, Sep 2014). In the U.S., the term "reproductive health services" is defined in 18 USC § 248(e)(5) as "medical, surgical, counselling or referral services relating to the human reproductive system, including services relating to pregnancy or the termination of a pregnancy." Reproductive health services include pre-conception, conception, post-conception care, including termination of pregnancies, and reproductive healthcare includes access to and safe use of medications.

ASHP advocates for access to safe, comprehensive reproductive healthcare for all patients, including historically underserved patient groups. Studies show that there have been longstanding disparities in access to and outcomes from reproductive health services in the U.S., especially for racial and ethnic minorities. For example, black women have the highest maternal morbidity and mortality rates in the country. These disparities include contraceptive use, reproductive cancers, preterm deliveries, and maternal morbidity and mortality. (Sutton MY, Anachebe NF, Lee R et al. Racial and ethnic disparities in reproductive health services and outcomes, 2020. Obstet Gynecol. 2021; 137:225–33.)

The reproductive health medications misoprostol and mifepristone have been reclassified as Schedule IV controlled substances in Louisiana, effective October 1, 2024 (Louisiana Act 246, 2024). The classification of controlled substance is typically reserved for medications with potential for abuse that may lead to physical or psychological dependence and safety liability. There is no evidence suggesting that misoprostol and mifepristone have a likelihood for abuse or physiological dependence, despite decades of approved use in the U.S. The improper classification of reproductive health medications burdens providers and patients and can lead to a dangerous stigma for patients prescribed the medications for purposes other than abortion, such as mifepristone for managing the effects of miscarriage or misoprostol for treating or preventing stomach ulcers. Prescription drug monitoring programs require reporting of dispensed controlled substances, often across state lines, which could increase risks of prosecution for both providers and patients who seek or provide these medications.

On June 24, 2022, the Supreme Court of the United States overturned *Roe v. Wade*, freeing states to restrict or outlaw abortion. Thirteen states had implemented trigger laws that would outlaw abortion almost immediately, and 26 states were expected to ban or severely restrict access to abortion. These state laws are likely to impact patient access to necessary treatments, including medications, and the practice of pharmacy, in the following ways:

- *Access to necessary treatments:* Pharmacists are involved in treating patients with ectopic pregnancy or pregnant women with cancer diagnoses. These laws could limit patient access to lifesaving treatments because of the risk of legal liability for providers. Pharmacists have a role in providing medications for these treatments as well as supporting patients' mental health and well-being related to reproductive health.

- *Access to medications:* A number of companies have formed that provide telehealth access to medications used to induce abortion. There are likely to be challenges to interstate mail order of these medications. In addition, some overseas companies also provide these medications, which raises questions about foreign importation of medications. ASHP opposes wholesale importation of medications from other countries due to supply chain security concerns but does not object to patients ordering from legitimate foreign pharmacies for their personal needs. Further, medications (e.g., misoprostol) that are used off-label as abortifacients but have other clinical uses may become harder for patients to access because providers fear the legal liability for prescribing or dispensing these medications. Finally, access to medications is a national security issue. For examples, the Department of Defense is required by law to make contraceptive services available to all female active-duty servicemembers.
- *Clinician judgment:* Restrictions on medication abortion function as limitations on clinicians' professional judgment. As noted above, because some medications can be used off-label as abortifacients, it is possible that there will be increased scrutiny of the prescribing and dispensing of certain medications. Further, some states are pursuing laws that would allow citizens a private right of action against a clinician who assists in an abortion (i.e., "bounty laws"). These laws could create civil and/or criminal liability against clinicians who prescribe or dispense abortion medications.

In addition to these concerns, other procedures that are not abortion but might result in destruction of an embryo (e.g., in vitro fertilization therapy) could fall into an uncertain legal zone. Medications used to induce labor to protect a pregnant woman could be restricted. Because the decision in *Roe v. Wade* was based on a constitutional right to privacy, other privacy-related rulings are now in question, including *Griswold v. Connecticut*, which allowed access to contraception.

The decision to terminate a pregnancy is a complicated, difficult, and often extremely emotional choice for patients and healthcare providers, and it often involves weighing the risks to the pregnant woman. Under some state laws, pregnant women could be prosecuted for seeking lifesaving treatment, and healthcare providers involved in these difficult decisions and providing necessary treatments could be subject to unjust criminal prosecution. ASHP believes that healthcare workers should be able to provide reproductive healthcare per their clinical judgment and their conscience without fear of legal consequence, workplace sanctions, social stigmatization, harassment, or harm.

2427

USE OF TWO PATIENT IDENTIFIERS IN THE PROVISION OF PATIENT CARE

Source: Council on Pharmacy Practice

To encourage the use of two unique identifiers during the provision of patient care.

This policy supersedes ASHP policy 2010.

Rationale

Errors caused by dispensing or administering medications to the wrong patient are largely

preventable. The Institute for Safe Medication Practices reports that dispensing a correctly prepared prescription to the wrong patient in community pharmacies is the most common complaint reported to the National Consumer Medication Errors Reporting Program, with approximately 25% of events resulting in patient ingestion of the wrong medication. The Joint Commission (TJC) recognizes that wrong-patient errors occur in all stages of diagnosis and treatment in hospitals and health systems. Both organizations call for a standard approach to verify a patient's identity using at least two patient identifiers.

TJC defines a patient identifier as "Information directly associated with an individual that reliably identifies the individual as the person for whom the service or treatment is intended. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, date of birth, or other person-specific identifier." ASHP supports the consistent use of two patient identifiers in the dispensing and administration of medications during the provision of care in all care settings. ASHP also believes that bar code medication administration is important for verification of medication use, however, should not be a replacement for verifying a patient's identity with two patient identifiers.

2428

ASHP STATEMENT ON ARTIFICIAL INTELLIGENCE IN PHARMACY

Source: Section of Pharmacy Informatics and Technology

To approve the ASHP Statement on Artificial Intelligence in Pharmacy.

This statement supersedes the ASHP Statement on the Use of Artificial Intelligence in Pharmacy dated May 20, 2020.

2023 Policy Positions

2301
EDUCATION AND TRAINING IN DIGITAL HEALTH
Source: Council on Education and Workforce Development

To acknowledge that digital health is a growing modality that supports the pharmacy workforce in providing patient care; further,

To support training and education for the pharmacy workforce in innovative models that support digital health services; further,

To advocate for involvement of the pharmacy workforce in research on digital health services and outcomes.

Rationale
Continuous development of digital health technology is rapidly redefining the provision of healthcare. Digital health is a broad, multi-faceted term used to describe a wide category of practices, products, and processes. The U.S Food and Drug Administration has stated that "the broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine."

To ensure that pharmacists are involved in the care of patients using digital health technologies, training and education must be developed that supports the pharmacy workforce. The interoperability and integration of digital health technologies into electronic health records is crucial. Research supporting digital health technologies for improved patient outcomes, while maintaining security and improving interoperability with electronic health records, is needed to foster continued development of these technologies and applications.

2302
DIGITAL THERAPEUTICS PRODUCTS
Source: Council on Pharmacy Management

To affirm the essential role of the pharmacist in the team-based evaluation, implementation, use, and ongoing assessment of digital therapeutic products to ensure the safety, effectiveness, and efficiency of medication use; further,

To encourage the pharmacy workforce to promote broader and more equitable use of digital therapeutic products by identifying and addressing barriers to patient and healthcare worker access to those products; further,

To encourage clinicians and researchers to establish evidence-based frameworks to guide use of digital therapeutic products; further,

To advocate that insurance coverage and reimbursement decisions regarding digital therapeutic products be made on the basis of those evidence-based frameworks.

Rationale

Digital health is a broad, multi-faceted term used to describe a broad category of practices, products, and processes. The Food and Drug Administration (FDA) describes digital health as "the broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine." The Digital Therapeutics Alliance describes digital therapeutics products, a component of digital health, as products that "deliver evidence-based therapeutic interventions that are driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes." Generally, digital therapeutic products are used to monitor indicators of a patient's condition (e.g., blood pressure, hemoglobin A1c) or encourage behaviors (e.g., adherence to medication or behavioral therapies) and share several similar features: a digital interface used by patients, clinicians, and sometimes medical devices; wearable devices that provide information about a patient's conditions to patients, clinicians, or medical devices; integration of disparate sources of data; enhanced patient engagement with their data and treatment; and automated or live digital coaching features to improve patient adherence with medication and/or behavioral therapies. The Access to Prescription Digital Therapeutics Act of 2022 would expand Medicare coverage to prescription digital therapeutics products and would help ensure that these products are tested for safety and efficacy and have a defined FDA approval process.

The proliferation of digital therapeutics products has the potential to create fundamental shifts in patient care. When digital therapeutics products impact medication use, pharmacists can and should participate in the evidence- and team-based decision-making about how those products are selected and used. Pharmacist expertise is essential in the team-based evaluation, implementation, use, and ongoing assessment of those products to ensure the safety, effectiveness, and efficiency of medication use. Pharmacists' medication-use expertise can assist in appropriate patient selection, product prescribing and ordering, and patient education regarding product use.

Appropriate use of digital therapeutics products will require healthcare decision-makers (e.g., clinicians, researchers, pharmacy and therapeutics committees, and payers) to establish evidence-based frameworks to guide use of and coverage and reimbursement decisions regarding use. Although evidence used in the approval process for these products should inform these decisions, ongoing research will be required to assess the absolute and comparative safety and effectiveness of digital therapeutics products. In addition, to promote optimal use, members of the pharmacy workforce will require education and training in the evaluation and use of digital therapeutics products.

Finally, one of the major drivers of societal inequities is the digital divide that separates those with access to technology from those without. ASHP encourages the pharmacy workforce to promote broader and more equitable use of digital therapeutic products by identifying and addressing barriers to patient and healthcare worker access to those products.

2303

INTEROPERABILITY OF PATIENT-CARE TECHNOLOGIES

Source: Council on Pharmacy Management

To encourage interdisciplinary development and implementation of standards that foster foundational, structural, semantic, and organizational interoperability of health information technology (HIT); further,

To encourage the integration, consolidation, and harmonization of medication-related databases used in patient-care technologies to reduce the risk that outdated, inaccurate, or conflicting data might be used and to minimize the resources required to maintain such databases; further,

To encourage healthcare organizations to adopt HIT that utilizes industry standards and can access, exchange, integrate, and cooperatively use data within and across organizational, regional, and national boundaries.

This policy supersedes ASHP policy 1302.

Rationale

The interoperability of patient-care technologies should be a standard across any hospital or health system. The development and implementation of standards would promote timely and seamless portability of information and optimize patient-care technologies that utilize medication-related databases. The installation of these technologies will aid pharmacy data, data analytics, and support activities that mitigate medication errors, medication diversion, and other health outcomes. This form of uniformity in information sharing will increase workflow efficiency and reduce delay in duties for pharmacy and other healthcare workers.

Although it is important to recognize the differences among technologies used in patient care, there is a need to have both a standardized format to describe medications as well as means for efficiently managing the medication databases in order to safely populate and update the different technologies that rely on drug information. Coalitions such as the Pharmacy e-Health Information Technology Collaborative are important in providing expertise, organizing and participating in stakeholder events, and advocating for best practices. It may, however, be necessary for other organizations to convene stakeholders to develop standards for the harmonization of medication-related databases.

2304

PATIENT MEDICATION DELIVERY SYSTEMS

Source: Council on Pharmacy Practice

To foster the clinical and technical expertise of the pharmacy workforce in the use of medication delivery systems; further,

To advocate for key decision-making roles for the pharmacy workforce in the selection, implementation, maintenance, and monitoring of medication delivery systems; further,

To urge hospitals and health systems to directly involve departments of pharmacy and interprofessional stakeholders in performing appropriate risk assessments before new medication delivery systems are implemented or existing systems are upgraded; further,

To advocate that medication delivery systems employ patient safety-enhancing capabilities and be interoperable with health information systems; further,

To encourage continuous innovation and improvement in medication delivery system technologies; further,

To foster development of tools and resources to assist the pharmacy workforce in designing and monitoring the use of medication delivery systems.

Rationale

Technological advances in medication delivery systems and administration devices frequently enable improved control of medication administration. Smart infusion pumps are becoming the standard of care for delivering intravenous fluids and medications because they allow for a greater level of control, accuracy, and precision with drug delivery. They are designed to provide users with clinical decision support for programmed doses and infusion rates in order to identify errors before medications or fluids are infused. Smart pump technology and data systems can help improve safety practices by recording and offering reports regarding pump-related errors, alerts, compliance to the institution's drug library, and overrides. ASHP advocates that to enhance patient safety, medication delivery systems interface with information systems, allow interoperability with the electronic health record, and employ dose error reduction software, including but not limited to standardized medication drug libraries with dosing limits, clinical advisories, and other patient safety-enhancing capabilities.

The design, maintenance, monitoring, and continuous quality improvement of medication delivery systems is an interdisciplinary process that requires ongoing collaboration among many disciplines. The pharmacy workforce has an integral role in ensuring the safe and effective management of medication delivery systems, including advising the interprofessional care team on their use. Pharmacists are a resource for education, therapy selection, monitoring, and troubleshooting of smart pump and other drug delivery systems to help improve patient safety and reduce medication errors. In efforts to optimize drug use, pharmacists should participate in organizational and clinical decisions with regard to these systems and devices.

2305

EDUCATION ABOUT PERFORMANCE-ENHANCING SUBSTANCES

Source: Council on Pharmacy Practice

To encourage pharmacists to engage in and advise community outreach efforts informing the public on the risks associated with the use of performance-enhancing substances, including but not limited to medications; further,

To educate patients on the importance of disclosing the use of performance-enhancing substances that may or may not be prescribed for legitimate medical indications; further,

To encourage pharmacists to advise athletic authorities, athletes, the community, and healthcare providers on the dangers of performance-enhancing substances and other products that are prohibited in competition; further,

To advocate for the role of the pharmacist in all aspects of performance-enhancing substances control.

This policy supersedes ASHP policy 1305.

Rationale

The risks of using performance-enhancing substances (PES) are well documented in sports medicine journals and other biomedical literature. The U.S. Anti-Doping Agency (USADA) maintains a comprehensive list of performance-enhancing substances that are banned for U.S. athletes competing in the Olympics. In addition to anabolic steroids, the list includes hormones and hormone-like substances (e.g., insulin, tamoxifen); beta-2 agonists; diuretics; red blood cells (RBC) in any form and RBC enhancers; agents that alter genes or genetic expression; stimulants (including caffeine and nicotine); narcotics; cannabinoids; and glucocorticoids. Certain dietary supplements that are known to contain prohibited substances are also banned. The U.S. Food and Drug Administration has also identified dietary supplements that contain pathogens (e.g., Salmonella), contaminants (e.g., lead or mercury), or undeclared prescription drug ingredients (e.g., ephedrine, sildenafil, or dexamethasone).

Although such authorities as the National Collegiate Athletic Association and the USADA have implemented bans on use of these agents and drug testing policies to enforce them, these strategies have been only partially effective in curbing the use of PES. In addition, use of PES has spread beyond professional athletes to military personnel, recreational body builders, professional entertainers, and others wishing to lose weight, increase muscle mass, improve alertness, and increase stamina.

Pharmacists, as medication-use experts and the most-accessible healthcare provider in many communities, can play an important role in community outreach efforts to provide education regarding the use of performance-enhancing substances, including medications, and the importance of disclosing any such use to their healthcare providers.

2306

SUPPORT FOR FDA EXPANDED ACCESS (COMPASSIONATE USE) PROGRAM

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) Expanded Access (Compassionate Use) Program be the primary mechanism for patient access to drugs for which an investigational new drug application (IND) has been filed, in order to preserve the integrity of the drug approval process and assure patient safety; further,

To advocate for broader patient access to such drugs under the FDA Expanded Access Program; further,

To advocate that IND applicants expedite review and release of drugs for patients who qualify for the program; further,

To advocate that the drug therapy be recommended by a physician and reviewed and monitored by a pharmacist to assure safe patient care; further,

To advocate for the patient's right to be informed of the potential benefits and risks via an informed consent process, and the responsibility of an institutional review board to review and approve the informed consent and the drug therapy protocol; further,

To support the use of the Right-to-Try pathway in instances in which all other options have been exhausted, provided there is (1) a robust informed consent process, and (2) institutional and clinical oversight by a physician and a pharmacist.

This policy supersedes ASHP policy 1508.

Rationale

Patient access to drugs for which an investigational new drug application (IND) has been filed is made available on a limited basis to individual patients under a compassionate-use program regulated by the FDA. With information about clinical trials and drugs under development readily available to patients, there is an increased demand for access to these therapies. In addition, three states have passed laws to permit patients who have exhausted approved drugs and treatment to have access to these potentially lifesaving drugs. Other states may follow suit in the future, and the FDA has begun to respond to this growing patient demand by streamlining its application process for individual patient expanded access. In order to respond to state legislative proposals, ASHP advocates preserving the integrity of drug development through strengthening the evidence-based clinical trial process and expanded patient access.

In 2018, Congress passed Right-to-Try legislation, which, per FDA, “is one pathway for patients diagnosed with life-threatening diseases or conditions who have exhausted all approved treatment options and are unable to participate in a clinical trial to access certain drugs that have not been approved by the Food and Drug Administration (FDA).” The program functions outside of FDA control, with patients and their physicians coordinating directly with manufacturers for access to investigational new drugs. ASHP advocates that the FDA’s Compassionate Use Program remain the primary access point for investigational new drugs, but supports the use of Right-to-Try for patients who have exhausted all other options. Furthermore, ASHP advocates for additional patient safety requirements related to informed consent and clinician monitoring for patients accessing investigational new drugs through the Right-to-Try pathway.

2307
BIOSIMILAR MEDICATIONS
Source: Council on Public Policy

To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,

To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,

To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore supports substitution for the reference product without the intervention of the prescriber; further,

To oppose the implementation of any state laws restricting biosimilar interchangeability; further,

To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed; further,

To require postmarketing surveillance for all biosimilar medications to ensure their continued safety, effectiveness, purity, quality, identity, and strength; further,

To advocate for adequate reimbursement for biosimilar medications that are approved by the FDA; further,

To promote and develop education of pharmacists, providers, and patients about biosimilar medications and their appropriate use within hospitals and health systems; further,

To advocate for patient, prescriber, and pharmacist choice in selecting the most clinically appropriate and cost-effective therapy.

This policy supersedes ASHP policy 1816.

Rationale

A provision in the Patient Protection and Affordable Care Act created a new pathway for the FDA to approve biosimilar products. The FDA approved its first biosimilar application in March 2015 for filgrastim-sndz, and others (e.g., adalimumab-adbm, adalimumab-atto, bevacizumab-awwb, etanercept-szzs, infliximab-abda, infliximab-dyyb) have followed. The FDA defines a biosimilar drug as “a biologic that is highly similar to and has no clinically meaningful differences from another biologic that is already approved by the FDA (known as the reference product).” During the FDA approval process, a new biosimilar undergoes tests to assess structural and functional components as well as limited pre-clinical and clinical studies. In order for a biosimilar to be considered interchangeable with its reference product, the FDA requires

the manufacturer to additionally show that their biosimilar produces the same clinical result and switching to their biosimilar does not result in any additional risks or diminished efficacy. This typically requires additional trials, which are time consuming and costly. As of 2022, there are over 30 biosimilars approved, not all of which are commercially available, but only a select few have qualified as interchangeable due to these extensive regulatory processes.

At the state level, legislation has been proposed and enacted requiring patient and/or prescriber notification that a biosimilar medication has been interchanged. It is important to note that pharmacists cannot substitute a biosimilar medication unless the FDA has deemed that biosimilar to be interchangeable. As of 2019, 46 states and Puerto Rico have passed biosimilar substitution laws. In some states the prescriber/patient notification is similar to what is required for generic substitution, but in others it goes further. For example, Georgia's biosimilar law requires the pharmacist to notify the prescriber within 48 hours of dispensing the medication (excluding weekends and holidays).

Despite the lack of interchangeable biosimilars, insurance companies have started requiring use of "preferred" biosimilars, leading to issues when attempting to maintain reasonable hospital formularies, patients being required to switch between biosimilar products for nonmedical reasons, and increased burden on the dispensing process when pharmacists have to contact the prescriber with every required biosimilar switch. Therefore, while health systems appear to acquire the biosimilars at lower costs, most are forced to maintain extensive formularies with all of the biosimilars in order to provide the payers preferred biosimilar for a patient. Additionally, this requirement extends into logistical burdens associated with storing, handling, and dispensing multiple similar products and increases the potential for medication errors. Due to lack of interchangeable biosimilars and payers requiring certain biosimilars to be used, a pharmacist is required to contact a prescriber each time a biosimilar needs to be changed. This interrupts workflows and prolongs the process of the patient receiving the drug. Inadvertently dispensing the wrong product to a patient may actually lead to higher cost to the patient if their payer will not cover the dispensed product. Initially identifying which product is covered for a patient, in addition to maintaining documentation about which product is needed for future dispenses, is a time-consuming task on an already strained healthcare system.

ASHP recognizes FDA's authority to determine biosimilar interchangeability, and in cases in which biosimilar products are deemed interchangeable, supports substitution for the reference product without the intervention of the prescriber. Further, ASHP opposes the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance and opposes any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed. FDA's determination of interchangeability should be all that is needed in order to substitute the biosimilar with the reference product. Although FDA guidances are distinct from FDA regulations, they often have profound impacts on healthcare decisions and delivery, so ASHP encourages the FDA to include healthcare practitioners in their development.

ASHP recognizes that postmarketing surveillance and pharmacist evaluation as part of the formulary system before biosimilar use are required to guarantee safe use of biosimilar medications. ASHP also advocates for adequate reimbursement for biosimilars approved by the FDA. This includes opposing payer ability to dictate preferred biosimilars. ASHP encourages payers to work with health systems to align their preferred biosimilar products and for payers

to cover multiple biosimilars in order to allow health systems to maintain cost-effective formularies.

2308
PHARMACOGENOMICS
Source: Council on Therapeutics

To advocate that pharmacists take a leadership role in pharmacogenomics-related patient testing, based on current or anticipated medication therapy; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage health systems to support an interprofessional, evidenced-based effort to implement appropriate pharmacogenomics services and to identify and determine appropriate dissemination of actionable information to appropriate healthcare providers for review; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To advocate that all health insurance policies provide coverage for pharmacogenomic testing to optimize patient care; further,

To advocate that drug product manufacturers and researchers conduct and report outcomes of pharmacogenomic research to facilitate safe and effective use of medications; further,

To encourage research into the economic and clinical impact of preemptive pharmacogenomic testing; further,

To encourage pharmacy workforce education on the use of pharmacogenomics and its application to therapeutic decision-making.

This policy supersedes ASHP policy 2113.

Rationale
Clinical pharmacogenomics is the practice of using genetic information to guide optimal drug selection and drug dosing for patients to maximize therapeutic effects, improve outcomes, and minimize toxicity. Currently, pharmacogenomic testing is used for specific drug-gene pairs in patients currently taking a medication associated with gene or prior to initiating therapy. Pharmacists are especially prepared to take a leadership role in selecting appropriate tests as

they have an understanding of pharmacokinetic and pharmacodynamics properties of drugs in specific diseases and patient populations.

Over the past 10 years, the Clinical Pharmacogenetics Implementation Consortium (CPIC) has published over 23 guidelines that cover 19 genes and 46 drugs across several therapeutic areas as well as resources to facilitate the implementation of pharmacogenomics into routine clinical practice and the electronic health record. These guidelines include indications for which drugs and genes are most likely to be clinically useful based on current evidence. However, barriers such as prioritizing testing, interpretation for actionable results, incorporation of genomic data into the electronic health record, and reimbursement remain. Furthermore, there is also the challenge of how to ensure that the results of pharmacogenomic tests stay with the patient throughout their health journey. Implementation of pharmacogenomic testing has the potential to improve patient care by decreasing failed treatment attempts due to medication ineffectiveness or adverse effects and by increasing effectiveness of improperly dosed medications.

The advent of widely available pharmacogenomic tests, many of which are also marketed to the public, introduces another layer of complexity. The Food and Drug Administration (FDA) has alerted patients and healthcare providers that claims for many genetic tests to predict a patient's response to specific medications have not been reviewed by the FDA and may not have the scientific or clinical evidence to support their use. Changing drug treatment based on the results from such a test could lead to inappropriate treatment decisions and potentially serious health consequences for the patient. It is imperative to identify clinically significant drug-gene pairs, as these may prevent adverse events, and such identification should be performed preemptively, as with DPYD genotyping prior to starting patients on fluoropyrimidines. There may also be a role for the FDA to provide incentives for manufacturers to conduct pharmacogenomic testing to optimize drug-gene patient paring.

Another barrier that many providers and patients encounter is insurance coverage of pharmacogenomic testing. A 2019 JAPhA article found that coverage and payments of pharmacogenomics varied by the company and gene-drug pairs and remain suboptimal. The article found that, of gene-drug indication group (GDIG), 50% were mentioned in policies but were covered less than 20% of the time. When mentioned in a policy, 7 GDIGs were uniformly covered, and 11 GDIGs were uniformly not covered. Overall, insurance companies covered approximately 40% of GDIGs mentioned in their policies. Additionally, preemptive pharmacogenomics suffers from a lack of economic and outcomes data supporting its more widespread adoption into practice. Such data would provide impetus for reimbursement from third-party payers. The number of genes tested in preemptive testing is typically greater than for reactive testing, meaning the number of actionable pharmacotherapeutic interventions made will increase. To ensure a sustainable preemptive pharmacogenomic testing system, clinical decision support is crucial for the implementation of evidence-based treatment decisions because it will become less feasible for a clinician specializing in pharmacogenomics to provide a recommendation for each pharmacogenomically actionable medication.

Furthermore, the ASHP Statement on the Pharmacist’s Role in Clinical Pharmacogenomics states that pharmacogenomics has an essential place in pharmacy education because pharmacists should be educated to be able to recommend pharmacogenomic testing for drug and dosage selection; design patient-specific drug and dose

regimens based on the patient's pharmacogenomic profile and other pertinent information; educate patients, pharmacists, and other healthcare professionals about pharmacogenomic principles and appropriate indications for clinical pharmacogenomic testing; and communicate pharmacogenomic-specific drug therapy recommendations to the healthcare team.

2309
PAYER-DIRECTED DRUG DISTRIBUTION MODELS
Source: Council on Pharmacy Management

To advocate that insurers and pharmacy benefit managers be prohibited from mandating drug distribution models that introduce patient safety and supply chain risks or limit patient choice.

This policy supersedes ASHP policy 2248.

Rationale
Hospitals and health systems have a responsibility to confirm drug product integrity and pedigree to ensure safe and appropriate administration of drug products. Drug products supplied to a hospital or health system without an institution's direct oversight raise questions about the product's proper storage and pedigree. These drug products include patients' home drug products, including clinician-administered pharmaceuticals (i.e., brown bagging) brought in by the patient or caregiver, and clinician-administered pharmaceuticals shipped from an external pharmacy directly to the location where they are being administered (i.e., white bagging).

Due to patient safety and supply chain risks, hospitals and health systems should advocate for action from boards of pharmacy to directly address payer-mandated drug distribution models and encourage state policymakers to prohibit insurers and PBMs from mandating white and brown bagging, including prohibiting insurers and PBMs from steering patients away from hospitals and health systems that refuse to accept potentially dangerous white-bagged or brown-bagged drug products.

2310
USE OF SOCIAL DETERMINANTS OF HEALTH DATA IN PHARMACY PRACTICE
Source: Council on Pharmacy Management

To encourage the use of patient and community social determinants of health (SDoH) data in pharmacy practice to optimize patient care services, reduce healthcare disparities, and improve healthcare access and equity; further,

To educate the pharmacy workforce and learners about SDoH domains, including their impact on patient care delivery and health outcomes; further,

To encourage research to identify methods, use, and evaluation of SDoH data to positively influence key quality measures and patient outcomes.

This policy supersedes ASHP policy 2249.

Rationale

Social determinants of health (SDoH) are defined by the Centers for Disease Control and Prevention (CDC) as the "conditions in the environments where people are born, live, learn, work, play, worship and age." These conditions can have a significant impact on healthcare outcomes, health equity, and quality of life for individuals and communities. SDoH have been found to account for 80-90% of modifiable contributors to health outcomes. From a third-party payer perspective, the recent shift of many organizations from fee-for-service to value-based reimbursement models places more emphasis on SDoH, screening, and evidence-based decision-making to prioritize long-term health outcomes. Healthy People 2030, a national program developed by the Office of Disease Prevention and Health Promotion within the U.S. Department of Health and Human Services, includes 355 measurable, data-driven, national objectives to improve the health and well-being of the American public by the year 2030. Health People 2030 recognizes five distinct SDoH domains: Economic Stability, Education Access and Quality, Healthcare Access and Quality, Neighborhood and Built Environment, and Social and Community Context. Patient screenings and data collection from multiple data sources to ascertain SDoH would be optimized through the use of standardized codes (e.g., ICD-10-CM Z codes, SNOMED-CT value sets) that are consistent, discrete data elements that are reportable and can be shared with other technologies, leading to actionable intelligence to enhance quality improvement initiatives. To support this goal, there is a need for broader implementation of SDoH health information technology (IT) tools into general practice and development of policies for how to appropriately use SDoH in clinical decision-making. The Office of the National Coordinator for Health Information Technology has identified four priority areas for advancing interoperability and use of SDoH data: standards and data, infrastructure, policy, and implementation. Many health IT and electronic health record (EHR) vendors have invested significant resources in development of SDoH tools and products. Among these products are screening tools, population health metrics, referral and care transition tools, and analytic and reporting tools. Health systems must have access to appropriate technology-based platforms to exchange SDoH data and make referrals for patients at discharge or transfer to another institution. Lack of standardization of data and reporting across health systems makes sharing of best practices and metric goal-setting difficult.

Efforts to address SDoH through pharmacy practice have varied. A 2018 survey of postgraduate pharmacy residents and their program directors found that only 1% of residents and 4% of residency program directors stated they had received education and training on Healthy People 2020. (Chandra RN. Pharmacists' knowledge of social determinants of health in post-graduate pharmacy residency programs. Wright State University; Dayton, OH; 2018.) The pharmacy workforce has opportunities to advance the use of SDoH in pharmacy practice (e.g., consults, medication reconciliation, patient assistance programs) to improve health outcomes.

Tools available within some EHR platforms include those measuring quality of life, suicidal ideation rating, community service referral capabilities, and use of secondary survey data in conjunction with the CDC/ATSDR social vulnerability index to further evaluate population health at a community level. SDoH tools can be categorized as either single domain, such as the Hunger Vital Sign tool to evaluate food insecurity, or multiple domain, such as the WE CARE survey to evaluate education, employment/income, food insecurity, and housing/utility domains. The validity of each tool should be considered before implementing

into practice, and more research is needed to determine the utility of specific tools in pharmacy practice. The Pharmacy Quality Alliance (PQA) has developed a Medication Access Framework for Quality Measurement and is evaluating a pharmacy measure concept to address the social determinants of health that hinder patient medication access and contribute to poor health outcomes.

2311
PHARMACY ACCREDITATIONS, CERTIFICATIONS, AND LICENSES
Source: Council on Pharmacy Management

To advocate that healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidence-based principles of patient safety and quality of care; further,

To advocate that health-system administrators allocate the resources required to support medication-use compliance and regulatory demands.

This policy supersedes ASHP policy 1810.

Rationale
Pharmacy leaders have years of experience managing the demands and challenges of ensuring that pharmacy services meet the standards of accreditation organizations. In the past, this responsibility was predominantly achieved through accreditation by The Joint Commission (TJC) and compliance with state laws and Board of Pharmacy regulations, as well as with federal requirements (e.g., those of the Drug Enforcement Administration). The number of accreditation standards pharmacy leaders needed to be knowledgeable about was limited. Healthcare organizations with ambulatory care services (e.g., home infusion, specialty pharmacy) have had to manage the additional accreditation process for these business units. Recent changes in healthcare have increased this challenge for pharmacy leaders: (1) TJC is no longer the only accreditor for hospitals and health systems; (2) healthcare organizations are developing or acquiring new business units that have their own accreditation processes that need to be integrated into existing ones; and (3) new accreditation, certification, or licensure processes have been created for services and businesses that fall under the responsibility of pharmacy leaders.

The expansion of healthcare organizations and the growth of the pharmacy enterprise are creating a new environment with multiple accreditors and regulators, presenting pharmacy leaders with the growing challenge of compliance with overlapping accreditation, certification, and regulatory standards. Examples include the Michigan Board of Pharmacy requirement to obtain certification to conduct compounding and the California Board of Pharmacy requirement that each IV hood have its own pharmacy license. In addition, community pharmacy accreditation processes and standards are being implemented that pharmacy leaders need to consider as well.

ASHP recognizes the difference between certifications that are the sole responsibility of and have a direct impact on a pharmacy and certifications of a healthcare organization's service line (e.g., stroke or transplant services) that are the responsibility of the organization but have

medication management components that need to be addressed by the pharmacy. Pharmacists and pharmacy departments are being challenged by a growing number of required accreditations, certifications, and licensures, which result in increased need for pharmacist-in-charge designations, workforce fatigue, and direct and indirect costs. Health-system administrators need to recognize this changing environment and allocate the resources required to support medication-use compliance and regulatory demands.

2312

ASHP STATEMENT ON LEADERSHIP AS A PROFESSIONAL OBLIGATION

Source: Council on Pharmacy Management

To approve the ASHP Statement on Leadership as a Professional Obligation.

This statement supersedes the ASHP Statement on Leadership as a Professional Obligation dated June 12, 2011. Originally published in 2023, this statement has been republished to incorporate non-substantive edits approved by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

2313

REDUCING HEALTHCARE SECTOR CARBON EMISSIONS TO PROMOTE PUBLIC HEALTH

Source: Council on Pharmacy Practice

To promote reducing carbon emissions from the healthcare sector through collaboration with other stakeholders; further,

To encourage members of the pharmacy workforce to seek out opportunities to engage in efforts to reduce carbon emissions in their workplaces and communities.

Rationale

ASHP acknowledges the scientific consensus on the adverse impact of carbon emissions on human health and the environment and recognizes the need to reduce carbon emissions, including from the healthcare sector. Climate change negatively impacts human health and increases strain on the healthcare system. Health-related consequences of climate change that lead to increased morbidity and mortality include but are not limited to heat-related illnesses, respiratory illnesses, and vector-borne diseases. The 2015 Lancet Commission on Health and Climate Change concluded that addressing climate change is the greatest public health opportunity of the 21st century and that failure to adequately address climate change could undo most of the past century's progress in global health.

Carbon emissions are a target for addressing climate change. It has been estimated that the healthcare sector is responsible for 8.5% of carbon emissions in the U.S. Sources of healthcare carbon emissions rank as follows: healthcare facility operations (estimated to account for 7% of healthcare sector emissions); purchased sources of energy, heating, and cooling (11%); and healthcare sector procurements or supply chain for services and goods (>80%).

Healthcare organizations have been called upon to reduce their carbon footprint ("decarbonize") as a measure to promote patient and public health. The federal government has goals to decrease carbon emissions by 50% by 2030 and to achieve net-zero levels by 2050.

Many healthcare-related organizations have made climate change and decarbonization pledges, including the members of the Medical Society Consortium on Climate & Health and organizations engaged in the National Academy of Medicine (NAM) Action Collaborative on Climate Change and as. In the fall of 2021, NAM launched the Action Collaborative on Decarbonizing the U.S. Health Sector (the "Climate Collaborative"), mobilizing four work groups: healthcare supply chain and infrastructure; healthcare delivery; health professional education and communication; and policy, financing, and metrics.

The pharmacy workforce has an important role in reducing carbon emissions from healthcare-related sources (Beechinor RJ et al. Climate change is here: what will the profession of pharmacy do about it? *Am J Health-Syst Pharm.* 2022; 79:1393-6). ASHP encourages collaboration with stakeholders that share a commitment to reducing carbon emissions from the healthcare sector and encourages members of the pharmacy workforce to seek out opportunities to engage in efforts to reduce carbon emissions in their workplaces and communities. To fill their roles in reducing carbon emissions, the pharmacy workforce will require education, training, and resources on emissions-reduction strategies. The development of evidence-based strategies will require research and dissemination of information on ways to reduce carbon emissions.

2314
MANIPULATION OF DRUG PRODUCTS FOR ALTERNATE ROUTES OF ADMINISTRATION

This policy was superseded by ASHP policy 2516.

2315
RESPONSIBLE MEDICATION-RELATED CLINICAL TESTING AND MONITORING
Source: Council on Therapeutics

To recognize that overuse of clinical testing leads to unnecessary costs, waste, and patient harm; further,

To encourage the development of standardized measures of appropriate clinical testing to better allow for appropriate comparisons for benchmarking purposes and use in research; further,

To promote pharmacist accountability and engagement in interprofessional efforts to promote judicious use of clinical testing and monitoring, including multi-faceted, organization-level approaches and educational efforts; further,

To promote research that evaluates pharmacists' contributions and identifies opportunities for the appropriate ordering of medication-related procedures and tests; further,

To promote the use of interoperable health information technology services and health information exchanges to decrease unnecessary testing.

This policy supersedes ASHP policy 1823.

Rationale

As the prevalence of collaborative practice grows and as pharmacist care expands into direct patient care services, so too do the responsibilities held by these practitioners. In many institutions, pharmacists' responsibilities now include ordering blood draws as a part of initiating a medication regimen, assessing drug levels, monitoring for adverse effects, or ordering imaging such as ultrasound for evaluating a deep vein thrombosis or an electrocardiogram to evaluate a QTc interval.

Overuse of medical care is a long-recognized problem in clinical medicine, and more spending and treatment do not translate into better patient outcomes and health. The number of articles on overuse nearly doubled from 2014 to 2015, indicating that awareness of overuse is increasing, despite little evidence of improved practice, which may mean that the overuse of diagnostic tests and lab monitoring is leading to patient harm and could outweigh benefits. Healthcare continues to be enthralled by high-technology innovation, including both therapies and tests. Once practice norms are established, clinicians are slow to de-implement services, even those that are found to be potentially dangerous. Reasons for excessive ordering of tests by healthcare providers include defensive behavior, fear, uncertainty, lack of experience, the use of protocols and guidelines, routine clinical practice, inadequate educational feedback, and clinician's lack of awareness about the cost of examinations. Inappropriate testing causes unnecessary patient discomfort, may lead to iatrogenic anemia from over-testing, entails the risk of generating false-positive results and unnecessary treatment, leads to overloading of diagnostic services, wastes valuable healthcare resources, and is associated with other inefficiencies in healthcare delivery, thus undermining the quality of health services. Furthermore, ordering unnecessary tests may also disproportionately affect vulnerable populations, including pediatric patients; trigger unnecessary therapies, such as for asymptomatic bacteriuria; and introduce bias, such as when screening for illicit drugs is performed but not as part of a differential diagnosis. A multi-faceted approach is recommended to reduce waste and support the judicious use of clinical testing. Key strategies include use of interoperable health information technology services and health information exchanges; optimization of test ordering through use of clinical decision support systems; provider and pharmacist education; benchmarking; and organization-level guidance, such as through establishment of a laboratory formulary committee that includes formulary control. Additionally, a key limitation of current literature surrounding appropriateness of clinical testing is a lack of standardized definitions of "appropriateness." Guideline and professional organization-endorsed standards may be used to benchmark clinical testing, although variations by country or institutional practices may confound these definitions.

Choosing Wisely is a national program designed to help raise provider and public awareness and garner support for appropriate test utilization, with the goal of promoting conversations between providers and patients about choosing appropriate care in order to reduce both harm and waste. In 2016, ASHP announced its partnership with the ABIM Foundation on the Choosing Wisely campaign, and in 2017 became the first pharmacy organization to contribute recommendations to the campaign. ASHP has continued to support this partnership through regular review and updates of its recommendations.

2316
ASHP STATEMENT ON PRECEPTING AS A PROFESSIONAL OBLIGATION
Source: Section of Pharmacy Educators

To approve the ASHP Statement on Precepting as a Professional Obligation.

2317
EMERGENCY MEDICAL KITS
Source: Council on Pharmacy Practice

To recognize the importance of standardized and readily accessible emergency medical kits (EMKs) in locations with inconsistent emergency medical services; further,

To advocate for the inclusion of pharmacist expertise in policy and regulations for the interprofessional decisions related to the contents, storage, and maintenance of medications in EMKs; further,

To collaborate with other professions and stakeholders to standardize the contents of and locations for EMKs, and to develop guidelines and standardized training for proper use of EMK contents by designated personnel employed in those settings.

Rationale
A social media movement called attention to the lack of standardization in emergency medical kits (EMKs) during an in-flight medical emergency. U.S. CFR 121.803 – Emergency Medical Equipment – requires certain medications and supplies for flights in case of medical emergencies but does not require the stocking of naloxone for reversing opioid overdoses or epinephrine auto-injectors for ease of administration, among many other medications and supplies. Many locations with inconsistent access to emergency medical services, such as airplanes, contain a stock of emergency supplies and medications that are not standardized and may not be adequate to manage some emergencies. In 2019, the Aerospace Medical Association Air Transport Medicine Committee sent recommendations to the Federal Aviation Administration regarding the contents of emergency medical kits, including recommendations to add naloxone and an epinephrine auto-injector (EpiPen).

The World Health Organization (WHO) has developed standardized health kits of medicines and medical supplies to meet different health needs in humanitarian emergencies and disasters. These kits are developed to provide reliable and affordable medicines and supplies quickly to those in need. The kits are used by United Nations agencies, nongovernmental organizations, and national governments. The contents of these kits are based primarily on the WHO's Essential Medicines list and guidelines on treatment of specific medical conditions. The contents of the kits are frequently reviewed and updated to adapt to changing needs based on experience in emergency situations. However, the WHO List of Essential Medicines does not specify an auto-injector for use in anaphylaxis.

There is growing concern regarding the need to standardize requirements set by a governing body to ensure that EMKs contain appropriate medications and supplies that are easy to use in an emergency, have been audited to ensure they contain the required items, have been

stored appropriately, and do not contain expired products. Standardization of EMK contents would simplify training requirements for those using the kits, which should include what products are contained within the EMKs, how to use them (when appropriate), and when to provide the kits in the case of an emergency. Finally, it is critical to collect and track incident and outcomes data to promote improvement in emergency response, and pharmacist involvement in the interprofessional evaluation of that data is essential.

2318

RAISING AWARENESS OF THE RISKS ASSOCIATED WITH THE MISUSE OF MEDICATIONS

Source: Council on Pharmacy Practice

To support the pharmacy workforce in outreach efforts to provide education to authorities, patients, and the community on the risks associated with use of medications for nonmedical purposes or from nonmedical sources.

Rationale

Misuse of medications involves the use of prescription and over-the-counter medications in ways that are not prescribed or directed. The use of medications for nonmedical purposes is also a category of misuse. Misuse may lead to serious consequences, such as emergency department visits, hospitalization, and death. While most of the evidence regarding medication misuse is related to opioids, central nervous system depressants, and stimulants, misuse of any medication may result in patient harm. As such, efforts to raise awareness of the risks of misusing any medication needs to prioritized, in addition to specific medications and medication classes. Pharmacists, as medication experts, can identify red flags and patterns of medication misuse and support community outreach efforts to help patients understand the risks associated with the misuse of medications.

2319

STANDARDIZATION OF MEDICATION CONCENTRATIONS, DOSING UNITS, LABELED UNITS, AND PACKAGE SIZES

Source: Council on Pharmacy Practice

To support adoption of nationally standardized medication concentrations, dosing units, labeled units, and package sizes for medications administered to adult and pediatric patients, and to advocate that the number of standard concentrations, dosing units, labeled units, and package sizes be limited as much as possible; further,

To encourage interprofessional collaboration on the adoption and implementation of these standards across the continuum of care; further,

To encourage manufacturers and registered outsourcing facilities to provide medications in those standardized concentrations, labeled units, and package sizes.

This policy supersedes ASHP policy 1306.

Rationale

Standardization and simplification are widely accepted methods for reducing variability in processes and risk for error. With increased adoption of intelligent infusion devices, use of standard concentrations has enhanced infusion safety by eliminating most dosing and rate calculations. Standardizing concentrations reduces the potential for errors, particularly during transitions of care; simplifies ordering by providing fewer choices, which decreases provider uncertainty; reduces operational variations, which enhances provider efficiency; and streamlines manufacturing, which accelerates production and allows for the formulation of premixed medications. In addition, broader use of standard concentrations might stimulate industry to offer a broader array of ready-to-administer infusions and facilitate the development of drug libraries.

To improve patient safety and availability of products, units of measure used for ordering, labeling, and administration of medications need to be standardized as well, as do package sizes for liquid formulations. All liquid formulations, including intravenous, oral, and topical formulations, need to be included in the standardization process, and standards specific to pediatric and adult populations are needed and should be limited in number to the extent possible. Development of these standards requires a holistic view of the medication-use process that considers all these aspects, as they all intersect and impact patient safety and the interoperability of automated systems.

In 2015, ASHP launched the Standardize 4 Safety (S4S) initiative. Funded by the U.S. Food and Drug Administration (FDA) and helmed by ASHP, S4S is the first national, interprofessional effort to standardize medication concentrations to reduce errors resulting from confusion over nonstandardized drug concentrations and errors that result from concentration differences when patients transition their care from one setting to another. To date, the expert committees have developed four lists—standardized concentrations for adult continuous infusions, pediatric continuous infusions, compounded oral liquids, and PCA/epidural infusion—and the S4S Initiative offers the pharmacy workforce other resources to help implement standardized concentrations.

2320

PHARMACOEQUITY

Source: Council on Pharmacy Practice

To raise awareness that disparities in clinical practice negatively impact healthcare outcomes and compromise pharmacoequity; further,

To recognize the impact of social determinants of health on pharmacoequity and patient outcomes; further,

To advocate for drug availability, drug pricing structures, pricing transparency, and insurance coverage determinations that promote pharmacoequity; further,

To advocate that the pharmacy workforce identify and address risks and vulnerabilities to pharmacoequity as part of comprehensive medication management services; further,

To advocate for resources, including technology, that improve access to care for marginalized and underserved populations where pharmacy access is limited; further,

To encourage the pharmacy workforce to identify and mitigate biases in healthcare decision-making that compromise pharmacoequity.

Rationale

Pharmacoequity aims to ensure that all individuals, regardless of socioeconomic status or availability of resources, have access to the highest quality medications required to manage their health needs. Barriers contributing to the lack of pharmacoequity include decreased access to care, increased costs of care, and differences in care based on provider bias (Essien UR, Dusetzina SB, Gellad WF. A policy prescription for reducing health disparities—achieving Pharmacoequity. *JAMA*. 2021;326(18):1793. doi:10.1001/jama.2021.17764). These barriers have helped raise awareness of the ABCs of solutions for promoting pharmacoequity: access, bias, and costs.

Decreased access to care may be due to insufficient prescription drug coverage or residing in a pharmacy desert. The current trends in the price of prescription drugs, combined with lack of insurance or underinsurance, results in lower use of prescribed medications and nonadherence.

Ensuring that all individuals, regardless of socioeconomic status or availability of resources, have access to the highest quality medications required to meet their needs will require a multifaceted approach. Promotion of culturally competent structures through increased awareness of disparities, in addition to improving medication affordability and pharmacy access, are all steps needed to attain pharmacoequity.

2321

MEDICATION ADMINISTRATION BY THE PHARMACY WORKFORCE

Source: Council on Pharmacy Practice

To support the position that the administration of medications is within the scope of pharmacy practice; further,

To advocate that states grant pharmacists and appropriately supervised student pharmacists and pharmacy technicians the authority to administer medications; further,

To support the position that pharmacists should be participants in establishing procedures in their own work settings with respect to the administration of medications (by anyone) and monitoring the safety and outcomes of medication administration.

This policy supersedes ASHP policy 9820.

Rationale

Laws, regulations, and local policies on medication administration vary greatly. Medications are routinely administered by many different practitioners, including nurses, physicians, radiology and nuclear medicine technologists, nurses aides, laboratory technologists, dental hygienists,

respiratory therapists, and physical therapists. ASHP believes that administration of medications is within the scope of pharmacy practice and supports laws, regulations, and local policies that allow for it and for medication administration by appropriately trained and supervised student pharmacists and pharmacy technicians. Decisions about pharmacists' involvement in medication administration should be made by individual healthcare organizations, which have an awareness of their resources and the adequacy of their medication administration processes. Patient need should be the primary factor in deciding who administers medications in any institution, and pharmacists should be involved in the institution's decision-making process regarding procedures used to administer medications.

2322

AVAILABILITY AND USE OF FENTANYL TEST STRIPS

Source: Council on Therapeutics

To affirm that fentanyl test strips (FTS) have a place in harm reduction strategies for people who use drugs; further,

To support legislation that declassifies FTS as drug paraphernalia; further,

To promote public availability of and access to FTS, including zero-cost options; further,

To support the pharmacy workforce in their roles as essential members of the healthcare team in educating the public and healthcare providers about the role of FTS in public health efforts.

Rationale

In April 2021 the National Center for Health Statistics reported that in the past 12-month period there were over 100,000 drug overdose deaths in the United States, with fentanyl responsible for over two thirds of those deaths. Fentanyl, a synthetic opioid, is 50 to 100 times more potent than morphine, and therefore the risk of overdose is higher than with other opioids, particularly when the person consuming the fentanyl is not aware of its presence or has not developed a tolerance to it.

Studies have shown that fentanyl test strips (FTS) are used by people who use drugs (PWUD) to check their drugs for the presence of fentanyl and mitigate overdose risk by making informed decisions about their safety when consuming. The findings of a 2018 study suggest that the distribution and use of rapid fentanyl test strips are a feasible and PWUD-accepted harm reduction tool to detect the presence of fentanyl in illicit drugs. As a result, as part of the effort to reduce overdoses and promote harm reduction, state and county health departments and community organizations across the United States have started to distribute FTS as a low-barrier, inexpensive drug-checking strategy. Through the SUPPORT Act, the Centers for Disease Control and Prevention, the U.S. Department of Health and Human Services, and the Substance Abuse and Mental Health Services Administration are permitted to provide funding to be used to purchase FTS as a part of harm reduction efforts.

Currently, a little more than half the states in the U.S. have laws that declassify FTS as drug paraphernalia. Laws in the remaining states that designate FTS as drug paraphernalia may

prevent states and organizations from applying for those grants or using their own funds to purchase FTS. Although many states have legislation in the works to remove this barrier, some states are reluctant to make this change, due to the perception that the use of FTS as quality control devices could encourage PWUD to seek out a stronger high rather than reduce the use of fentanyl, reinforcing risky behavior.

The pharmacy workforce is well equipped meet the needs of PWUD and the use of FTS. For example, in June of 2022, the Illinois General Assembly passed H.B. 4556, which expands the ability of pharmacists and other healthcare professionals to distribute FTS. The Ohio State University School of Pharmacy offers a naloxone and FTS training and distribution event as an effort to reduce harm, to meet patients where they are, and to provide services along a continuum of care. Legislation and programs like these demonstrate the value of the pharmacy workforce and should be expanded throughout the United States.

2323

DEA SCHEDULING OF CONTROLLED SUBSTANCES

Source: Council on Therapeutics

To advocate that the Drug Enforcement Administration (DEA) establish clear, measurable criteria and a transparent process for scheduling determinations; further,

To urge the DEA to use such a process to re-evaluate existing schedules for all substances regulated under the Controlled Substances Act to ensure consistency and incorporate current science-based evidence concerning scheduling criteria; further,

To advocate that the U.S. Congress, with input from stakeholders, enact clear definitions of the terms *potential for abuse*, *currently accepted medical use*, and *accepted safety for use* in the Controlled Substances Act; further,

To advocate for monitoring of the impact of DEA scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) on patient access to therapy and on healthcare provider workload; further,

To advocate for the elimination of federal and state laws that create barriers to research on therapeutic use of Schedule I substances.

This policy supersedes ASHP policy 1315.

Rationale

Since its passage in 1970, the Controlled Substances Act (CSA) has served as the foundation of modern drug control policy by regulating the manufacture, importation, possession, use, and distribution of certain substances. The CSA lists eight factors to be considered by the Drug Enforcement Administration (DEA) when deciding if a molecular entity should be scheduled: (1) the potential for abuse; (2) scientific evidence of its pharmacological effect; (3) state of current scientific knowledge regarding the substance; (4) history and current pattern of abuse; (5)

scope, duration, and significance of abuse; (6) risk to public health; (7) its psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled. The CSA then specifies that the three criteria used to determine the schedule of a substance include (1) its potential for abuse, (2) whether it has a medical use, and (3) its safety and risk of dependence. Several limitations of the aforementioned factors and criteria are worth noting. First, the eight factors are redundant and lack clarity. Second, the CSA does not specify the relationship between the eight factors and the three criteria for scheduling, and the DEA has not yet clarified this matter.

Additionally, the CSA does not explicitly define the terms *potential for abuse* or *accepted medical use,* giving the DEA much discretion to apply the scheduling criteria. The DEA has maintained broad discretion when scheduling substances according to their abuse potential, through court rulings that have upheld the DEA's comparison of the substance in question to already-scheduled substances. The DEA has formally defined the term *currently accepted medical use* in response to repeated litigation regarding the classification of Schedule I substances. The criteria under this definition include: (1) the drug's chemistry must be known and reproducible; (2) adequate safety studies; (3) adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.

The lack of regulatory clarity of the CSA has led to a complicated process and inconsistent scheduling of substances. The language of the CSA implies that for a substance to be placed into a particular schedule, it must fulfill all three criteria. It is entirely possible, however, for one substance to fail to meet all three criteria of one schedule. Nonetheless, the DEA maintains that all scheduled substances without an accepted medical use must be classified as Schedule I, illustrating the conflicting scheduling practices used.

Furthermore, the existing schedules do not take into account evolving evidence about the abuse potential of these drugs. For example, gabapentin and pregabalin are structural analogues of gamma-aminobutyric acid, with pregabalin being classified as Schedule V under the CSA. Gabapentin, however, remains federally uncontrolled. An increase in its abuse has led some states to classify this medication as a Schedule V substance and/or mandate prescription reporting.

Finally, the CSA also places many restrictions on medical research into Schedule I substances, creating barriers that hinder the discovery of their potential therapeutic uses. Therefore, ASHP first recommends that the U.S. Congress use its legislative authority to define, with the input of stakeholders, the aforementioned terms in the CSA to provide a statutory basis for regulatory decision-making that will simplify the scheduling process. ASHP also advocates that the DEA establish clear, measurable criteria, to the extent possible for this complex subject, and a transparent process for scheduling determinations. Further, the DEA is encouraged to use those criteria to re-evaluate current schedule assignments for all controlled substances based on recent evidence. Finally, federal and state legislators are urged to eliminate laws that create barriers to research on Schedule I substances.

2324

POINT-OF-CARE TESTING AND TREATMENT BY PHARMACISTS

Source: Council on Therapeutics

To advocate for laws, regulations, and development of specific, structured criteria that include performing diagnostic point-of-care testing (POCT), interpreting test results, prescribing, dosing, and dispensing as clinically indicated by POCT within pharmacists' scope of practice, or referral; further,

To support the tracking of reportable diseases through pharmacist-managed POCT and reporting to public health agencies when appropriate; further,

To promote training and education of the pharmacy workforce to competently engage in POCT and related patient care services; further,

To foster research on patient access and public health improvements, cost savings, and revenue streams associated with pharmacist-managed POCT and related patient care services.

This policy supersedes ASHP policy 2229.

Rationale

Point-of-care testing (POCT) is laboratory testing that takes place at or near the site where the patient is located. These tests are quality-assured pathology services using analytical tools such as blood gas; critical care analyzers; and meters for glucose, urinalysis, and other metabolites. They can be used for both communicable and noncommunicable disease states, including influenza A and B, strep throat, diabetes mellitus, hypertension, anticoagulation, congestive heart failure, and stroke. POCT can be performed by patients in their home, using for example a device that monitors international normalized ratio (INR) for warfarin management, or in the field by healthcare providers, such as rapid strep testing in community pharmacies. POCT devices fall under the Federal Food, Drug, and Cosmetic Act and therefore are also subject to pre- and post-marketing surveillance and review.

As the shortage of primary care providers continues and POTC technology improves, there is ample opportunity to expand the pharmacy workforce's roles in disease screening, identification, and management. POCT provides fast results, which can reduce the time to therapeutic intervention through test-to-treat services, often at a lower cost to patients than an office visit. Pharmacists are well positioned to conduct risk assessments, provide appropriate treatment and referrals when necessary, provide disease state monitoring services, and in turn, improve adherence and identify unnecessary or inappropriate medications. For example, the availability of rapid influenza tests allows pharmacists to quickly diagnose and recommend treatment for influenza A and B, which has been found to reduce the time to first dose of antiviral drugs among individuals with influenza-like illness, compared to those referred to other providers. The combined benefits of telehealth and test-to-treat services should not be discounted. Newer technology that patients can use in the home, including smart scales that monitor changes in weight for congestive heart failure patients, home blood glucose monitoring systems for diabetic patients, and INR monitoring have already demonstrated improved patient outcomes in conjunction with pharmacist care. Numerous studies demonstrate that home POCT can be implemented to streamline healthcare services to patients with chronic and acute disease states and also limit hospital admissions, readmissions,

and delays in care and can ultimately lead to better outcomes as well as cost savings for patients and providers.

State legislation concerning pharmacist-managed POCT varies widely. For example, in California, pharmacists are able to perform routine patient assessment procedures through POCT that includes testing for human immunodeficiency virus (HIV) antibodies, total cholesterol, glucose and hemoglobin A1c levels, opiates, blood ketones, thyroid-stimulating hormone, hematocrit, and prothrombin time. Most common is legislation that permits pharmacists in collaborative practice agreements to perform rapid testing to diagnose group A streptococcal pharyngitis and prescribe antimicrobial therapy when a test is positive. This practice model has been shown to decrease the cost of diagnosis and treatment for children and adults and has demonstrated increased patient satisfaction.

ASHP advocates development of specific and structured criteria for pharmacist prescribing, dosing, and dispensing of antimicrobials for this purpose, under a variety of models (e.g., autonomous prescribing authority for pharmacists, delegation protocols, or collaborative practice agreements). A 2018 study found that 69% of pharmacists are willing to perform POCT in a community pharmacy setting, and 86% either strongly agreed or agreed to be willing to recommend appropriate treatment for influenza and group A streptococcal pharyngitis. With collaborative practice agreements in place, patients can bypass visiting a primary care provider, empowering pharmacists to assume an active role not only in treating patients but also in promoting public health by reporting positive cases to local health departments, should rapid testing and reporting be a requirement of dispensing. A Washington State University study demonstrated that after a POCT training module, student pharmacists were not only able to proficiently perform POCT for group A streptococcal pharyngitis, influenza, and HIV, but also showed an increased willingness to perform and recommend the tests, which could expand access.

2325

NONPRESCRIPTION AVAILABILITY OF SELF-ADMINISTERED INFLUENZA ANTIVIRALS

Source: Council on Therapeutics

To support a behind-the-counter practice model that expands access to self-administered influenza antivirals.

This policy supersedes ASHP policy 2116.

Rationale

Oseltamivir (Tamiflu), zanamivir (Relenza), and baloxavir (Xofluza) are self-administered drugs used for the treatment and chemoprophylaxis of influenza. ASHP supports the availability of self-administered influenza antivirals via a behind-the-counter practice model. Use of this practice model, which has already been adopted for medications such as pseudoephedrine and emergency contraception, would facilitate appropriate use of those antivirals and provide patients with an opportunity to receive assessment and professional consultation from a pharmacist.

There are several perceived advantages and disadvantages of the nonprescription designation for self-administered influenza antivirals. Potential benefits include quicker and

improved access for patients, public health value by reducing exposure of sick individuals at provider visits, unlikely development of antiviral resistance (based on currently available data), and experience with oseltamivir as a nonprescription medication in New Zealand since 2007. Potential concerns include stockpiling, shortages, questionable effectiveness, adverse effects, potential reduction of influenza vaccination rates because of perceived antiviral availability, dosing considerations (e.g., renal function, pediatric weight-based dosing), costs, reimbursement for clinical services provided by pharmacists (e.g., point-of-care influenza testing, questionnaire screening tool for oseltamivir dispensing), blunting of other more severe underlying conditions without a provider visit, and overextension of pharmacist responsibilities and duties. Furthermore, potential public health benefits and risks of expanded access must also be considered. With availability over or behind the counter, patients may bypass visiting their primary care providers to obtain antivirals, and pharmacists will therefore need to assume an active role in promoting public health by reporting positive cases to local health departments, should rapid testing and reporting be a requirement of dispensing.

Given the interest in expanding patient access to self-administered influenza antivirals, ASHP advocates that any reclassification should not result in increased costs to patients or pharmacies. Modifications to national, regional, and local drug coverage decisions are needed to ensure that payer policies do not unintentionally restrict or prevent access. In addition, the reclassification will likely result in an increased workload and potential liability associated with pharmacist provision of this care, which includes patient screening (and point-of-care testing, if applicable), patient education, dosing, counseling, and documentation of the care provided in the pharmacy and medical record.

2326

OVER-THE-COUNTER AVAILABILITY OF HORMONAL CONTRACEPTIVES

Source: Council on Therapeutics

To advocate that hormonal contraceptives be available over the counter (OTC) without age restriction only under conditions that ensure safe use, including the availability of pharmacist consultation to ensure appropriate self-screening and product selection, and that maintain patient confidentiality; further,

To encourage the Food and Drug Administration to require manufacturers to include all patients of childbearing age, including adolescents, in studies to determine the safety and effectiveness of OTC hormonal contraceptives; further,

To advocate that all insurers and manufacturers maintain coverage and limits on out-of-pocket expenditure so that patient access is not compromised.

This policy supersedes ASHP policy 1410.

Rationale

There have been repeated calls to make hormonal contraceptive products more widely available, with the intent of expanding access to women's reproductive health therapies and reducing unintended pregnancies. The American College of Obstetricians and Gynecologists

(ACOG) advocates over-the-counter (OTC) access to hormonal contraception, including oral contraceptive pills, the contraceptive patch, contraceptive vaginal rings, and depot medroxyprogesterone acetate injections, without age restrictions. The American Medical Association (AMA), and the American Academy of Family Physicians (AAFP) support OTC access to oral contraceptives. ASHP agrees with ACOG and AMA that there is no clinical justification to restrict access to hormonal contraceptives by adolescents past menarche.

As with other OTC medications, there is recognition that both progestin-only and combined oral contraceptive use carries a very small amount of risk of adverse events and should be determined to be safe and effective for self-use. Progestin-only hormonal methods are generally safe and carry no or minimal risk of venous thromboembolism (VTE), and the VTE risk with combined oral contraceptive use is small compared with the increased risk of VTE during pregnancy and the postpartum period. ASHP advocates that OTC hormonal contraceptives should therefore be available where a patient has access to a pharmacist. Patient self-screening and product selection would be improved through pharmacist-provided consultation that assists patients in identifying absolute and relative contraindications (e.g., hypertension, heart or kidney disease), assessing other patient-specific factors (e.g., adherence practices), and determining when to recommend a referral to seek a higher level of care through the use of counseling and clinical decision-making tools. This process would guide the determination of which contraceptive product would be most safe and effective for an individual patient. ASHP does not believe that the current model for behind-the-counter access to some drug products (e.g., pseudoephedrine, emergency contraception) is appropriate for hormonal contraceptives because such a model would place the pharmacist in a gatekeeping rather than the clinical role that is necessary to ensure safe and effective use of these therapies.

Manufacturers will need to submit a supplemental new drug application for conversion from prescription to OTC status, including post-marketing surveillance reports and studies of consumer behaviors. It is critical that adolescents be included in these studies to assess their label comprehension, aptitude to self-select, and ability to effectively use the OTC hormonal contraceptives.

Given the intent to expand access to these therapies, ASHP advocates along with ACOG and AAFP that the proposed reclassification to OTC should not result in increased costs to patients and should include full insurance coverage without cost sharing. Modifications to national, regional, and local drug coverage decisions may be needed to ensure that payer policies do not unintentionally restrict or prevent access to OTC oral contraceptives.

2327

THERAPEUTIC AND PSYCHOSOCIAL CONSIDERATIONS OF PATIENTS ACROSS THE GENDER IDENTITY SPECTRUM

Source: Council on Therapeutics

This policy was discontinued in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

2328

REMOVAL OF INJECTABLE PROMETHAZINE FROM HOSPITAL FORMULARIES

Source: Council on Therapeutics

To advocate that injectable promethazine be removed from hospital formularies; further,

To encourage regulatory and safety bodies to review patient safety data and conduct research on adverse events related to administration of injectable promethazine; further,

To encourage manufacturers to produce injectable promethazine in package sizes and concentrations that reduce risk.

This policy supersedes ASHP policy 1831.

Rationale

In its 2020-2021 Targeted Medication Best Practices for Hospitals, the Institute for Safe Medication Practices (ISMP) included a recommendation to eliminate injectable promethazine from hospitals. This recommendation includes removal of injectable promethazine from all areas of the hospital, including the pharmacy; classification of injectable promethazine as a nonstocked, nonformulary medication; implementation of a medical staff-approved automatic therapeutic substitution policy; conversion of all injectable promethazine orders to another antiemetic; and removal of injectable promethazine from all computerized medication order screens and from all order sets and protocols. In 2018, only 56% of ISMP Survey respondents believed promethazine to be a high-alert medication, which was a *decrease* from 59% in 2014. The 2018 survey also found that 54% of respondents also thought that "IV promethazine" should be changed to "injectable promethazine," also underscoring the need for broader protections from intravenous administration use. This recommendation reiterated the identical 2018-2019 ISMP Best Practice recommendation, which was a change from previous ones in which ISMP promoted safe use by raising awareness about risks associated with intravenous (IV) promethazine administration. Despite the efforts to improve the safety of injectable promethazine use, sporadic and significant patient harm continues to occur.

Promethazine is a known vesicant that can cause tissue damage and necrosis when extravasation occurs during IV administration, and it has negative effects on cardiac conduction. Although therapeutic alternatives are available for most indications, the alternative therapies are also not without risk and may not be as effective in some clinical situations. Processes to limit the potential for patient harm when IV administration of promethazine is indicated include but are not limited to use of therapeutic alternatives (e.g., 5-HT_3 receptor antagonists, antipsychotic agents, antihistamines); use of alternate routes and modalities of administration (e.g., oral, rectal); and restrictions on use (e.g., nonformulary, nonstocked status and removal from order sets and protocols). While prior guidance provided practice recommendations to mitigate the risk of injectable promethazine use (e.g., minimum drug dilution, continuous nurse monitoring of infusion, administration through a running IV line), a 2006 ISMP survey of hospitals revealed poor adherence to these recommendations, despite the well-documented risks of circumventing them. Although medication regimens for some specific patient populations may include injectable promethazine, many guidelines for management of

disease states in which promethazine may have a role do not recommend injectable promethazine as an agent of initial choice, indicating it should be used as last line/salvage therapy. Often, these guidelines do not include injectable promethazine as a therapeutic option at all; given the number and variety of suitable alternatives, the risks of using this medication outweigh the benefits.

In addition, because ISMP has recommended injectable promethazine's removal from formularies, there is not much data on its safety and efficacy, as implementation of the recommendation has varied across the U.S., and what data is available has been mostly anecdotal or case-based reports. ASHP encourages regulatory and safety bodies to review patient safety data and conduct research on adverse events related to administration of injectable promethazine. Finally, ASHP encourages manufacturers to produce injectable promethazine in package sizes and concentrations that reduce risk in a similar manner to those recommended by ISMP for administration of electrolytes (e.g., use of prediluted standardized solutions).

2329

WELL-BEING AND RESILIENCE OF THE PHARMACY WORKFORCE

Source: Council on Education and Workforce Development

To affirm that occupational burnout adversely affects an individual's well-being and healthcare outcomes; further,

To acknowledge that the healthcare workforce encounters unique stressors throughout their education, training, and careers that contribute to occupational burnout; further,

To declare that healthcare workforce well-being and resilience requires shared responsibility among healthcare team members and between individuals and organizations; further,

To provide resources to empower individuals and institutions to embrace well-being and resilience as a priority supported by organizational culture; further,

To promote that pharmacy leadership collaborate with their institutions to assess the well-being and resilience of the pharmacy workforce and identify effective prevention and intervention strategies; further,

To encourage hospitals and health systems to invest in the development and assessment of interprofessional programs that prevent occupational burnout while supporting well-being, and to support nonpunitive participation in these programs.

This policy supersedes ASHP policy 1825.

Rationale

Clinician burnout can have serious, wide-ranging consequences on individual clinicians and learners, health care organizations, and patient care. Occupational burnout is a syndrome

characterized by a high degree of emotional exhaustion, high depersonalization (e.g., cynicism), and a low sense of personal accomplishment from work due to both internal and external factors. The results follow a 2018 study in the *American Journal of Health-System Pharmacy* (*AJHP*) that found 53 percent of health-system pharmacists self-reported a high degree of burnout caused by increasing stresses and demands. Occupational burnout affects today's pharmacy workforce at unprecedented rates. At the individual level, pharmacy staff burnout can result in medication errors and increased patient harm. At the hospital or healthcare system level, the consequences of occupational burnout include disengagement, loss of productivity, and employee turnover, which can lead to inefficiency and financial problems for healthcare organizations. Stress in our clinical learning environment can affect all healthcare learners, with negative outcomes ranging from poor well-being to substance abuse to depression, even suicide. A 2017 *AJHP* article reported that pharmacy residents working more than 60 hours per week reported high levels of stress, depression, and hostility.

ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience in 2017. The goals of the Collaborative are to:

1. Raise the visibility of clinician anxiety, burnout, depression, stress, and suicide.
2. Improve baseline understanding of challenges to clinician well-being.
3. Advance evidence-based, multidisciplinary solutions to improve patient care by caring for the caregiver.

The NAM Action Collaborative Conceptual Model depicts both individual and external factors affecting well-being and resilience and indicates that it requires a combined effort from the individual and the system to address and prevent occupational burnout.

Studies suggest that burnout is a problem of the entire healthcare organization as well as individual clinicians, so maintaining clinician well-being and resilience requires a combined effort by the individuals and their employers. To be successful, interventional programs must promote prevention, recognition, and treatment of burnout, and healthcare organizations must foster a culture that supports not just nonpunitive participation in these interprofessional programs but a sense of personal empowerment for developing and maintaining resilience. A healthcare organization with a resilient workforce will provide the best healthcare outcomes.

Supporting the well-being of the pharmacy workforce requires sustained attention and action at organizational, state, and national levels, as well as investment in research and information sharing to advance evidence-based solutions. A pharmacy workforce with the ability to thrive during adversity—a resilient workforce—is essential to combat burnout and support higher-quality care, increased patient safety, and improved patient satisfaction.

2330

PHARMACIST PRESCRIBING AUTHORITY FOR ANTIRETROVIRAL THERAPY FOR THE PREVENTION OF HIV/AIDS

Source: Council on Therapeutics

To affirm that drug products for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for human immunodeficiency virus (HIV) infection prevention should be provided to individuals in a manner that ensures safe and appropriate use; further,

To oppose reclassification of currently available drugs used for PrEP and PEP to nonprescription status; further,

To advocate for legislation and regulation that expands pharmacist scope of practice to encompass initiation of PrEP and PEP therapy; further,

To advocate that the therapies and associated care for PrEP and PEP are available to patients with zero cost-sharing; further,

To support establishment of specific and structured criteria to guide comprehensive pharmacist interventions related to PrEP and PEP; further,

To support the research, education, and training of the pharmacy workforce on the therapeutic, psychosocial, and operationalization considerations of pharmacist-provided PrEP and PEP therapy; further,

To support educating the public regarding the public health benefits of PrEP and PEP.

This policy was revised in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

Rationale

Increasing access to pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for human immunodeficiency virus (HIV) infection prevention is a public health priority. The *Ending the HIV Epidemic in the U.S.* initiative, for example, includes expanded access to PrEP and PEP in its whole-of-society plan coordinated among agencies across the U.S. Department of Health and Human Services to end the HIV epidemic in the United States by 2030. Despite the increase in the availability of antiretroviral therapies for such prophylaxis, much of the patient population that would benefit from access has been limited by stigma and other barriers, including a requirement for a prescription in many parts of the U.S. One of those barriers to access is that many states do not provide pharmacists independent authority to order and initiate PrEP and PEP therapy. Given the time-sensitive nature of these therapies, patients and their partners would benefit from being able to access them at community pharmacies. Those forced to seek medications through a physician's office or other site of care may struggle to find a timely appointment, especially if they do not have an established primary care provider. In contrast to physicians, community pharmacists are often available without an appointment and pose a potential solution to expanding access to therapy. Through policy, education, and infrastructure changes, pharmacists can be an alternate source for PrEP, expanding availability and further reducing HIV transmission.

ASHP advocates expanding pharmacists' scope of practice to include initiation of PrEP

and PEP therapy, including associated screening, testing, monitoring, referrals, product selection, and counseling, as well as the establishment of specific and structured criteria for prescribing, dosing, and dispensing of PrEP and PEP by pharmacists. As one example, California Bill 159, approved in October 2019, authorizes pharmacists who undergo a board-approved training program to supply PrEP and PEP every two years, with a 60-day supply cap and certain conditions under which the therapies can be prescribed. In addition, insurance companies are not allowed to require prior authorization for these drug products. The goal of this law is to get patients on PrEP and then direct them to a prescriber for further care management. Other states, including New York, Colorado, Missouri, and New Hampshire, are exploring similar programs. As these practices and programs vary from state to state, ASHP also recommends structured criteria be set that optimizes patient care and access to these drug products.

Expanding collaborative practice, in which pharmacists are permitted under an agreement with a prescriber to prescribe a defined list of medications along with associated monitoring, provides an effective way to advance the scope of pharmacy practice nationwide. A Seattle pharmacy operationalized such a program by forming a clinic in which pharmacists perform a history, risk assessment, lab testing, and education before dispensing PrEP. Implementation of a standing order for pharmacists to furnish PrEP for their patients may provide longitudinal benefit, and infrastructure for pharmacists to bill for these services, as well as the facilities to see patients, must accompany such policy changes. To ensure that patients who present for HIV prophylaxis receive comprehensive care, pharmacists should be allowed to order tests for other sexually transmitted infections at the patient's request when possible, as some community pharmacies and other sites of care may not have the ability to provide certain tests onsite.

ASHP opposes reclassification of currently available drugs used for PrEP and PEP (tenofovir and emtricitabine) to nonprescription status, because existing models for nonprescription dispensing do not provide the safeguards required to ensure safe and effective use.

Other barriers to access include a lack of insurance coverage and high out-of-pocket costs, insurers' refusal to cover brand medications when necessary, and insurers failing to cover all formulations, including pediatric formulations. Modifications to national, regional, and local drug coverage decisions are needed to ensure that payer policies do not unintentionally restrict or prevent access. To promote the broadest possible access, ASHP advocates that PrEP and PEP be available to patients with zero cost-sharing, regardless of income or insurance coverage.

Pharmacist initiation of PrEP and PEP therapies will likely result in an increased workload and potential liability associated with provision of this care, which includes patient screening (including point-of-care testing, if applicable), patient education, dosing, counseling, and documentation of the care provided in the pharmacy and medical record.

A survey of community pharmacists revealed that education and training are needed to advance pharmacy practice in PrEP and PEP therapy. Training in necessary laboratory testing, trauma-informed care, destigmatizaton, and appropriate follow-up should be done to ensure an adequate knowledge base for pharmacists unfamiliar with the procedures. Finally, ASHP supports public education regarding the public health benefits of PrEP and PEP therapy.

2331

SUSTAINABLE BILLING, REIMBURSEMENT, AND PAYMENT MODELS

Source: House of Delegates

To advocate for reimbursement, pay parity, and financially sustainable models related to cognitive services of pharmacist-accountable services, regardless of site of care; further,

To educate the pharmacy workforce and stakeholders about financially sustainable models of care; further,

To advocate that compensation for healthcare services be commensurate with the level of care provided, based on the needs of the patient; further,

To advocate for the development of consistent, transparent billing, reimbursement, and alternative payment model policies and practices by both government and commercial payers.

Rationale

The National Academy of Sciences recommends that payers, including Centers for Medicare & Medicaid Services (CMS), commercial insurers, and self-insured employers shift payment for healthcare services toward a hybrid model that includes fee-for-service and capitated payments, and that these models pay prospectively for interprofessional, integrated, team-based care. Due to lack of federal provider status for pharmacists and subsequent inability to directly bill Medicare as care providers, organizations and practices have become creative in maintaining financial sustainability of pharmacist services. Financial sustainability for services provided by pharmacists has been achieved using a variety of models. Some settings utilize indirect funding, while others take advantage of some of the limited direct insurance billing opportunities to fund pharmacist patient care. Direct billing opportunities vary based on the setting (e.g., hospital-based versus physician-based practices) as well as state-specific laws and regulations. Medicare, Medicaid, and commercial health plans may reimburse pharmacists for certain services, while some will require direct contracting with the health plan. Several states have passed pharmacist state provider status laws or reimbursement parity laws allowing for reimbursement for direct patient care pharmacist services by state Medicaid or commercial plans.

2332

BARCODING OF LOT NUMBER AND EXPIRATION DATE

Source: House of Delegates

To advocate that the Food and Drug Administration and organizations that develop barcode standards require barcodes contain lot number and expiration date on all immediate product packages to enable automated collection and validation of this information during medication preparation, dispensing, and administration processes; further,

To educate regulatory and safety organizations that barcode scanning versus manual logging of lot numbers and expirations is critical for patient safety and preparation sterility and improves data visibility for medication recalls; further,

To advocate that state boards of pharmacy, regulatory agencies, and accrediting bodies delay punitive action on rules requiring logging of lot number and expiration dates during sterile product preparation until this information is made available on immediate product barcodes.

Rationale

The current Food and Drug Administration (FDA) barcode rule requires the National Drug Code (NDC), lot number, and expiration date on all saleable medication packages. FDA created an exception for immediate packages, which include unit dose packages and individual vials sold as lots in boxes. More than 90% of products dispensed in a hospital are immediate packages. The FDA exception requires that the barcodes on these immediate packages be linear (1D) barcodes. Due to the technology of 1D barcodes, it is difficult to fit the larger barcode containing additional characters needed to code lot number, expiration date, and NDC on labels of inner packages. As a result, the 1D barcodes required on inner packages only contain the NDC. 2D barcodes require less label space than 1D barcodes, and 2D scanners can read 1D and 2D barcodes. Many products dispensed are saleable packages that only contain 2D barcodes, and 2D barcode readers are significantly less expensive and more reliable than the 1D laser scanners used in the past. Hospitals have responded by widely adopting use of 2D scanners.

A proposed FDA rule will allow but not require 2D barcodes and require only the inclusion of the NDC in the barcode. The FDA states that the reason for these requirements is that the expansion of the NDC to 12 digits will create issues for manufacturers that code a 10-digit NDC number in the barcode and don't have the label space to expand the 1D barcode to 12 digits. The proposed rule will not guarantee that barcodes on inner products contain lot number and expiration date. FDA has stated that they are addressing the immediate package requirements in the revised rule, but this is only true for the NDC 12-character expansion and not for the encoding of lot and expiration date.

Multiple state boards of pharmacy, including California and Texas, require hospitals to log the NDC, lot number, and expiration dates on all intravenous (IV) products that are compounded or repackaged. United States Pharmcopeia (USP) Chapter 797 is adding the same requirements, effective November 1, 2023. The logging of lot numbers and expiration dates is not a second check but an attempt to track medications all the way to the patient in the case of recalls and event reporting. With IV workflow systems and barcodes with lot number and expiration dates, an IV product can be prepared and documented with only two barcode scans. Current linear barcodes require scans of the NDC, multiple mouse clicks, and many keystrokes on a keyboard to enter the data. For example, a two-component IV product with a base solution and one additive was reported to require 22 keystrokes and 2 mouse clicks at a minimum if lot number and expiration date are not in the barcode. In addition, putting a keyboard into the sterile environment or pulling hands in and out of the sterile field threatens sterility. Dispersing this data entry work in the middle of a complicated IV workflow will not only create data entry or transcription errors but will increase the potential for computation errors, as the preparer keys in or handwrites a long series of seemingly random numbers while computing, measuring, and verifying doses.

Software vendors have acknowledged that their systems already have the functionality to capture lot number and expiration dates, if available, through barcode scanning, replacing

numerous keystrokes. This functionality has not only been added to IV preparation functions but also to dispensing and medication administration functions as well. In addition, many systems allow barcode scans to be initiated by foot switches, permitting users to avoid touching scanners, therefore minimizing potential impacts on sterility. One vender has reported that they are in the process of adding automatic checks for expired medications and recalled lot numbers during all medication barcode scanning functions throughout the medication-use process. Significant safety improvements and time savings can be realized through automated checking of expiration dates and recalls throughout the medication-use process, including automated dispensing cabinet restocking.

Although state boards of pharmacy and USP are considering and implementing rules to track medications to the patient and validate expiration dates, there is a general lack of understanding how these rules impact IV preparation workflows and corresponding medication safety and sterility of IV preparation. It is important that rulemakers understand these impacts and implement rules to require the inclusion of lot number and expiration date on immediate product barcodes. Healthcare organizations should communicate the need for NDC, lot number, and expiration date on all immediate products, including repackaged products and investigational medications, to the FDA and GS1, the barcode standards organization that defines medication barcode standards, to assure the resulting barcodes meet the needs of health systems.

2333

END-OF-LIFE TREATMENT AND CARE

Source: Council on Pharmacy Practice

To support the position that end-of-life treatment and care is part of the continuum of care that the pharmacy workforce should provide to patients; further,

To support the position that the pharmacy workforce has a professional obligation to work in a collaborative and compassionate manner with patients, family members, caregivers, and other professionals to help fulfill the care needs, especially the quality-of-life needs, of patients of all ages receiving end-of-life treatment and care; further,

To support research on the needs of patients receiving end-of-life treatment and care; further,

To provide education and continuing education to the pharmacy workforce on end-of-life treatment and care, including education on clinical, managerial, professional, and legal issues; further,

To urge the inclusion of such topics in the curricula of colleges of pharmacy and pharmacy technician education and training programs.

This policy supersedes ASHP policy 0307.

Rationale

The National Cancer Institute defines end-of-life care as care provided to people near the end of life who have stopped treatment aimed at curing or controlling their disease. It includes physical, emotional, social, and spiritual support for the patient and their family. End-of-life care may also be referred to as palliative care, supportive care, comfort care, and hospice care. As medication-use experts across the continuum of care, the pharmacy workforce is expected to encounter patients requiring end-of-life treatment and care. The pharmacy workforce therefore needs to be competent, collaborative, and compassionate in the provision of care for patients at the end of life.

In 2016, ASHP published the ASHP Guidelines on the Pharmacist's Role in Palliative and Hospice Care. The guidelines outlined essential and desirable administrative and clinical roles of the pharmacy workforce as well as practice development, advocacy, and advancement initiatives. The guidelines support pharmacists providing direct patient care, medication order review and reconciliation, and education and medication counseling within hospice programs. The guidelines also include pharmacist support of transitions of care (including from aggressive treatment to comfort care), student and clinician training in the unique needs of this population, and contribution to the body of knowledge via writing, speaking, or research to improve treatments and processes.

2334

PHARMACIST LEADERSHIP OF PHARMACY PRACTICE

Source: Council on Pharmacy Management

To affirm the importance of an organizational structure in hospitals and health systems that places administrative, clinical, and operational responsibility for pharmacy practice under a pharmacist leader; further,

To affirm the role of the pharmacist leader in oversight and supervision of all pharmacy personnel; further,

To recognize the role of other members of the pharmacy workforce in leadership and management roles within pharmacy departments.

This policy supersedes ASHP policy 0918.

Rationale

The ASHP Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems sees a growing role for other members of the pharmacy workforce, to include nonpharmacists, in management and leadership positions in hospitals and health systems. Many factors are fueling this expansion, including a shortage of experienced pharmacist leaders, pharmacists' salaries, and the growing complexity of the pharmacy enterprise. There are many functions in the pharmacy department that can be led or managed by nonpharmacists, including management of technological, business, or financial matters. Although nonpharmacists fill many important supporting leadership and management roles within pharmacy departments, a pharmacist should lead the pharmacy enterprise, supervise and manage all pharmacy personnel, and be responsible for the administrative, clinical, and operational functions of pharmacy departments

in hospitals and health systems. Specifically, a pharmacist leader should have operational decision-making authority related to pharmacy practice. The intrinsic value a pharmacy executive brings to an organization's enterprise and executive leadership is further described in the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive. Use of other specialized members of the pharmacy workforce expertise will vary, depending on the size and complexity of the pharmacy enterprise. These roles will be more prevalent in large facilities and less so in small or rural facilities, where there is likely to be less specialization in pharmacy functions.

2335
PHARMACEUTICAL DISTRIBUTION SYSTEMS
Source: Council on Pharmacy Management

To support pharmaceutical distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products; further,

To oppose manufacturers, distributors, and wholesalers restricting or making availability of products contingent on how those products are used or through exclusive distribution channels; further,

To encourage selection of a wholesale distributor that (1) purchases products only from a manufacturer before distribution to the purchasing end user; (2) is licensed in the state where it is conducting business; (3) complies with the requirements of the Drug Supply Chain Security Act; (4) is accredited under the National Association of Boards of Pharmacy Drug Distributor Accreditation program; and (5) uses information systems that are interoperable with common types of pharmacy systems.

This policy supersedes ASHP policy 1913.

Rationale
Wholesalers and distributors have traditionally contracted with hospitals and health systems for pharmaceutical product distribution and other services. Many wholesalers have made a large portion of their revenue through speculative buying and other business practices that are no longer desirable because of requirements for pedigrees, the risk of buying counterfeit or adulterated products, demands by manufacturers to limit product transactions leading to supply chain disruption, and the need to manage recalls. These changes, plus the vast diversification of many wholesaler distributors, have resulted in new business models that will affect how hospitals acquire and manage pharmaceutical products. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient. ASHP supports support drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products (e.g., that minimize short-term outages and long-term product shortages, disclose disruptions in product availability, manage and respond to product recalls, foster product-handling and transaction efficiency, preserve the integrity of

products as they move through the supply chain, and provide affordable service costs).

Additionally, some manufacturers and distributors have required that pharmacies ensure certain products are not used or sold for use for particular purposes, and there are concerns that this practice could grow. ASHP supports wholesaler and distribution business models that meet the requirements of hospitals and health systems, which includes the ability for pharmacies to obtain products for established patient care uses without restriction.

ASHP supports using strict vendor vetting policies to prevent sales from nonreputable or gray market vendors. Vendors should purchase products only from a manufacturer, not a secondary source; be licensed in the state in which it operates; comply with the requirements of the Drug Supply Chain Security Act; be accredited under the National Association of Boards of Pharmacy (NABP) Drug Distributor Accreditation program; and use information systems that are interoperable with common types of pharmacy systems. NABP accreditation requires a rigorous criteria compliance review.

2336

PROMOTION OF THE PHARMACY PROFESSION

Source: Council on Education and Workforce Development

To promote the professional image of the pharmacy workforce and collaborate with stakeholders to enhance public understanding of the pharmacy profession's important roles in patient care and its many professional and personal rewards; further,

To promote diverse careers in pharmacy to attract applicants with skills and attributes aligned with the needs and demands of the pharmacy workforce and professional identity formation; further,

To develop and disseminate resources that provide insight into the diverse career opportunities within the pharmacy profession; further,

To encourage educators and counselors in primary and secondary education or trade schools to make students aware of the benefits of careers in the pharmacy workforce.

This policy supersedes ASHP policy 1828.

Rationale

The success of ASHP's advocacy efforts relies on public perception of the pharmacists, student pharmacists, and pharmacy technicians we represent. Promoting the image of pharmacy, which consistently ranks among the most trusted professions, to the general public, public policymakers, payers, other healthcare professionals, and healthcare organization decision-makers is an ongoing priority for ASHP. As stated in the ASHP Statement on Professionalism, one of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession's ideals and mission. Moreover, professional identity formation is defined as the process of internalizing a profession's core values and beliefs. The recruitment of pharmacists and pharmacy technicians is essential to meet current and future healthcare

demands and needs to begin in high school or even earlier, when students are exploring potential careers. ASHP is committed to highlighting opportunities for pharmacy careers in all health-system settings to maintain a pool of quality candidates for those careers.

2022 Policy Positions

2201
STATE-SPECIFIC REQUIREMENTS FOR PHARMACIST AND PHARMACY TECHNICIAN CONTINUING EDUCATION
Source: Council on Education and Workforce Development

To advocate for the standardization of state pharmacist and pharmacy technician continuing education requirements; further,

To advocate that state boards of pharmacy adopt continuing professional development as the preferred model to maintain competence.

This policy supersedes ASHP policy 1111.

Rationale

All 50 states require continuing education for pharmacists as a means of maintaining their competence, and many states have similar requirements for pharmacy technicians. State requirements for continuing education differ, in numbers of hours and the time frame within which they must be collected and reported, for example. Some state boards of pharmacy have established specific educational requirements for individual topic areas they concluded should be mandatory. These initially included topics such as state-specific pharmacy law and human immunodeficiency virus and acquired immune deficiency syndrome, but more recently, states have included requirements for education on topics such as medication and patient safety, pain and palliative care, patient management, and administration of injectables. Some states also specify the number of hours that must be obtained by "live" presentation rather than home-study courses. As more states develop unique requirements, many pharmacists who are licensed in multiple states are finding it difficult to meet the unique requirements of each individual state.

Pharmacy technician license and continuing education requirements vary widely by state, depending on whether the state requires national certification through the Pharmacy Technician Certification Board (PTCB), completion of a state board-approved or accredited pharmacy technician training program, on-the-job training, or some other measure of competence. To maintain PTCB certification, pharmacy technicians must complete specific continuing education requirements including law, patient safety, or sterile compounding, depending on their level of certification.

For over a decade, ASHP has encouraged individuals, healthcare organizations, and states to embrace continuing professional development (CPD) as a means of maintaining and demonstrating competence. CPD involves personal self-appraisal, educational plan development, plan implementation, documentation, and evaluation, and has been endorsed by the Accreditation Council for Pharmacy Education and other pharmacy organizations for use by pharmacists and pharmacy technicians. Broader adoption of CPD into state CE requirements would facilitate its use and improve pharmacy practice.

2202
ASHP STATEMENT ON PROFESSIONALISM
Source: Council on Education and Workforce Development

To approve the ASHP Statement on Professionalism.

This statement supersedes the ASHP Statement on Professionalism dated June 26, 2007.

2203
PRECEPTOR SKILLS AND ABILITIES
Source: Council on Education and Workforce Development

To collaborate with pharmacy organizations and colleges of pharmacy on the development of standards to enhance the quality of experiential education and pharmacy residency precepting; further,

To provide tools, education, and other resources to develop and evaluate preceptor skills.

This policy supersedes ASHP policy 1201.

Rationale
The quality and effectiveness of the pharmacy workforce can be positively influenced by the quality of pharmacy preceptors. Growth in the number and size of colleges of pharmacy has increased demand for teaching sites and for qualified preceptors to provide experiential training and residency rotations at those sites. Although nearly all colleges of pharmacy endeavor to provide robust preceptor training, efforts to develop preceptors may be inconsistent or ineffective due to resource constraints. In addition to improved training of preceptors, the profession needs a mechanism for evaluating the skills of preceptors and educators.

2204
MOBILE HEALTH TOOLS, CLINICAL APPS, AND ASSOCIATED DEVICES
Source: Council on Pharmacy Management

To advocate that patients, pharmacists, and other healthcare professionals be involved in the selection, approval, and management of patient-centered mobile health tools, clinical software applications ("clinical apps"), and associated devices used by clinicians and patients for patient care; further,

To foster development of tools and resources to assist pharmacists in designing and assessing processes to ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices; further,

To advocate that decisions regarding the selection, approval, and management of mobile health tools, clinical apps, and associated devices consider patient usability,

acceptability, and usefulness and should further the goal of delivering safe and effective patient care that optimizes outcomes; further,

To advocate that mobile health tools, clinical apps, and associated devices that contain health information be interoperable and, if applicable, be structured to allow incorporation of health information into the patient's electronic health record and other essential clinical systems to facilitate optimal health outcomes; further,

To advocate that pharmacists be included in regulatory and other evaluation and approval of mobile health tools, clinical apps, and associated devices that involve medications or medication management; further,

To encourage patient education and assessment of competency in the use of mobile health technologies; further,

To enhance patient awareness on how to access and use validated sources of health information integrated with mobile health tools, clinical apps, and associated devices.

This policy supersedes ASHP policy 1708.

Rationale

Digital health technologies, including mobile health (mHealth) applications (apps), hold great potential to improve health and healthcare. There is nearly ubiquitous use of smartphones and an ever-growing and increasingly sophisticated suite of health apps. These apps are providing a wide range of medical functions that span the care continuum from prevention to diagnosis to care management. The adoption of these digital solutions is further amplified by their accessibility, low cost, and personalized features. In addition, their ability to provide practical functions such as health education, tracking of symptoms and side effects, appointment management, and social support make them compelling healthcare tools. With the proliferation of mHealth tools, clinical apps, and associated devices, healthcare organizations need to address the potential barriers and risks of application use. Particular concerns include (1) assessing the quality of mHealth tools, clinical apps, and associated devices; (2) standardizing choices and use across the organization; (3) ensuring the security of data and data storage; and (4) patient usability, acceptability, and usefulness (e.g., generational differences in acceptance of technology). To maximize the effectiveness of mHealth tools, clinical apps, and associated devices, they must be selected, approved, and managed with the goal of improving care and with input from representatives of all affected parties, including patients, physicians, pharmacists, and other healthcare professionals. In addition, their effectiveness is enhanced when they are interoperable (as described in ASHP policy 2303, Interoperability of Patient-Care Technologies) and the data stored within them can be incorporated into the patient's electronic health record (EHR) and other essential clinical systems.

Providers and patients currently have little guidance regarding use of these resources or the management of the data they provide. The Food and Drug Administration and other

regulatory agencies are just beginning to determine the scope of their oversight regarding standardized evaluation and validation processes. As medication-use experts, pharmacists can contribute to the regulatory evaluation and approval of mHealth tools, clinical apps, and associated devices that involve medications or medication management. For example, pharmacists can help assess the quality of information presented (e.g., incorrect or incomplete information, variation in content, incorrect or inappropriate response to patient needs) and mitigate inconsistencies with patient education resources provided by an organization (e.g., discharge education). ASHP is committed to fostering development of resources to help pharmacists ensure safe, accurate, supported, and secure use of mHealth tools, clinical apps, and associated devices. Patient engagement strategies include patient education and competency assessment and enhanced patient awareness of how to access and use validated sources of health information integrated with mHealth tools, clinical apps, and associated devices. Product customer assistance teams for mHealth tools, clinical apps, and associated devices should be leveraged to provide direct support to sustain these efforts. Patient engagement with these tools will: (1) increase communication between patient and providers, leading to increased patient satisfaction; (2) enhance sharing of health information using EHRs; and (3) enable patients to have access to their health data, which empowers them with the knowledge of their health conditions and helps them make informed treatment choices.

2205
TRANSITIONS OF CARE
Source: Council on Pharmacy Management

To encourage the pharmacy workforce to assume responsibility for medication-related aspects of ensuring the continuity of care as patients move from one care setting to another; further,

To encourage the development, optimization, and implementation of technologies that facilitate sharing of patient-care data across care settings and interprofessional care teams; further,

To advocate that health systems provide sufficient resources to support the important roles of the pharmacy workforce in supporting transitions of care; further,

To encourage payers to provide reimbursement for transitions of care services; further,

To encourage the development of strategies to address the gaps in continuity of pharmacist patient care services, including effective patient engagement.

This policy supersedes ASHP policy 1208.

Rationale
Continuity of patient care is a vital requirement in the appropriate use of medications. Changes in healthcare reimbursement have resulted in an increasing focus on transitions of care from the acute care environment to other settings (e.g., ambulatory care to inpatient care to home

care or specialty settings). Pharmacy workforce engagement, as integral members of interprofessional care teams, is pivotal to support health systems focus on reducing readmissions, improving patient satisfaction, and effectively educating patients about their medications. It is important that ASHP advocate for improvements in technologies that facilitate sharing of patient information across various care settings. Further alignment of financial incentives and sufficient resource allocation that encourage and support patient care roles of the pharmacy workforce in the transition of care are also required.

2206
CONTINUOUS PERFORMANCE IMPROVEMENT
Source: Council on Pharmacy Management

To encourage the pharmacy workforce to establish multidisciplinary continuous performance improvement (CPI) processes within their practice settings to assess the effectiveness and safety of patient care services, adherence to standards, and quality and integrity of practice; further,

To encourage the pharmacy workforce to use contemporary CPI techniques and methods for ongoing improvement in their services; further,

To support the pharmacy workforce in their development and implementation of CPI processes.

This policy supersedes ASHP policy 0202.

Rationale
Pharmacy departments should continually strive for medication safety and quality by identifying and prioritizing quality improvement efforts that align with national and health-system goals. The pharmacy workforce can make use of a variety of methods to ascertain goals, aims, and interventions for the system and to influence medication-related goals, aims, and interventions in the pursuit of high-value care and improved patient outcomes. Some of these process improvement methodologies include Six Sigma, Lean Management, Lean Six Sigma, Agile Management, Total Quality Management, and Kaizen. All the process improvement tools share many common features and the philosophy that processes can always be improved. They share the assumption of measurement and statistics being a key to improvement and the faith in the power of the workers closest to a process to be able to improve it. The continuous performance or quality improvement program is structured to assess the effectiveness and safety of patient care services, adherence to standards, and quality and integrity of the practice. It is aligned with the health system's overall plan and system for performance and quality improvement, accrediting organizations, and with payer contractual obligations for quality reporting. Pharmacy departments must have internal procedures for ongoing surveillance and reporting to assess overall appropriateness of services and implement quality improvements as needed to integrate quality metrics that drive quality improvement and refocus efforts on areas of need. The pharmacy department should have process and feedback

loop in place that translates analysis to initiatives and initiatives to measured and improved outcomes using appropriate tools derived from implementation science.

2207
INSTITUTIONAL REVIEW BOARD AND INVESTIGATIONAL USE OF DRUGS
Source: Council on Pharmacy Practice

To support mandatory education and training on human subject protections and research bioethics for members of institutional review boards (IRBs), principal investigators, and all others involved in clinical research; further,

To advocate that principal investigators discuss their proposed clinical drug research with representatives of the pharmacy department before submitting a proposal to the IRB; further,

To advocate for the pharmacist's roles in ethical clinical research, including but not limited to serving as a principal investigator, developing protocols, executing research, determining rational-use decisions for the off-label use of drug products, and publishing research findings, and for adequately resourced, sustainable models for filling those roles; further,

To advocate that IRBs include pharmacists as voting members; further,

To advocate that IRBs inform pharmacy of all approved clinical research involving drugs within the hospital or health system; further,

To advocate that pharmacists act as liaisons between IRBs and pharmacy and therapeutics committees in the management and conduct of clinical drug research studies; further,

To support pharmacists' management of drug products used in clinical research.

This policy supersedes ASHP policy 0711.

Rationale
The Food and Drug Administration (FDA), under its regulations, defines an institutional review board (IRB) as a group of people that have been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. Human subjects research is codified in 45 CFR Section 46, and 45 CFR Section 46.102(e)(1) states that a human subject is:

> a living individual about whom an investigator (whether professional or student) conducting research:
> (i) Obtains information or biospecimens through intervention or interaction with the

individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Evidence-based healthcare decisions are highly dependent on sound principles of research and investigation. ASHP believes the healthcare workforce needs to be competent in understanding the research process and the protection of human subjects involved in research trials. In addition, hospitals and health systems are home to investigational drug services that support the conduct of clinical trials involving medication use. Pharmacists are critical to the successful management of these trials and therefore need to be engaged in decisions related to developing, conducting, and evaluating research within their institutions.

2208
PHARMACIST'S ROLE IN TEAM-BASED CARE
Source: Council on Pharmacy Practice

To recognize that pharmacists, as core members and medication-use experts on interprofessional healthcare teams, increase the capacity and efficiency of teams for delivering evidence-based, safe, high-quality, and cost-effective patient-centered care; further,

To advocate to policymakers, payers, and other stakeholders for the inclusion of pharmacists as care providers within team-based care and as the provider of comprehensive medication management services; further,

To assert that all members of the interprofessional care team have a shared responsibility in coordinating the care they provide and are accountable to the patient and each other for the outcomes of that care; further,

To urge pharmacists on healthcare teams to collaborate with other team members in establishing and implementing quality and outcome measures for care provided by those teams.

This policy supersedes ASHP policy 1215.

Rationale

There is a growing consensus among healthcare providers and payers that patient-centered care by a collaborative team is the optimal model of care. A collaborative care model provides pharmacists with an opportunity to contribute their expertise in medication use to improving patient outcomes.

The pharmacy profession appears to be struggling, however, with implementation of this care model. Not unexpectedly, there is a wide variation in the way "team-based care" is interpreted and applied. Therefore, states currently in the process of rewriting practice acts have been challenged to find guidance on the fundamental roles and responsibilities of pharmacists in various care settings. This policy recommendation builds on concepts in ASHP policy 1114, Pharmacist Accountability for Patient Outcomes; sets the expectation for other providers that teams with

pharmacists will improve the quality, safety, and efficiency of care; and supports advocacy to the broader healthcare community on the value of care delivery by teams that include pharmacists.

2209
DRUG TESTING AS PART OF DIVERSION PREVENTION PROGRAMS
Source: Council on Public Policy

To advocate for the use of pre-employment and random or for-cause drug testing during employment based on defined criteria and with appropriate testing validation procedures; further,

To support employer- or government-sponsored drug diversion prevention programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that employers use validated testing panels that have demonstrated effectiveness detecting commonly abused or illegally used substances.

This policy supersedes ASHP policy 1717.

Rationale
Controlled substance diversion and abuse has reached the attention at the highest levels in the U.S., with even the White House weighing in on the crisis. In the past 4-5 years, the Drug Enforcement Administration has levied large fines on chain drugstores, drug wholesalers, and even major hospitals. Pharmacy managers and pharmacists-in-charge have increasing responsibility of ensuring controlled substance management and storage across large healthcare organizations. There is an increased risk to organizations as acquisitions of physician office practices, clinics, and other nonhospital-based business units continue, and many challenges exist for healthcare institutions in managing controlled substances.

ASHP recognizes that drug testing job applicants and employees whose responsibilities may bring them into contact with controlled substances is an essential element of diversion prevention programs and promotes worker well-being. Pre-employment and random or for-cause drug testing should be performed based on defined criteria, with appropriate testing validation procedures, and have demonstrated effectiveness detecting commonly abused or illegally used substances. In addition, drug testing should be supported by an employee addiction recovery program, as outlined in the ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance.

2210
DRUG SAMPLES
Source: Council on Public Policy

To oppose drug sampling or similar drug marketing programs that circumvent appropriate pharmacy oversight or control.

This policy supersedes ASHP policy 9702.

Rationale

Drug marketing or sampling programs that involve physical samples can create a number of drug supply and patient risks if they are not subject to strict pharmacy control. However, "virtual" programs that allow pharmacy management of the supply (e.g., situations where a limited amount of drug is dispensed from the pharmacy's supply) are not problematic if proper controls are in place. Specifically, workable drug sampling programs must (1) provide the elements of pharmaceutical care, (2) result in careful drug control, ensuring patients receive only properly labeled and packaged, unexpired, and recorded drugs, (3) provide access to prescription drugs only through authorized, trained personnel, (4) discourage inappropriate prescribing habits, or (5) do not increase the cost of treatment for all patients.

2211

NALOXONE AVAILABILITY

Source: Council on Therapeutics

To recognize the public health benefits of naloxone for opioid reversal; further,

To support efforts to safely expand patient and public access to naloxone through independent pharmacist prescribing authority, encouraging pharmacies to stock naloxone, supporting availability of affordable formulations of naloxone (including zero-cost options), and other appropriate means; further,

To advocate for statewide naloxone standing orders to serve as a prescription for individuals who may require opioid reversal or those in a position to aid a person requiring opioid reversal; further,

To support and foster standardized education and training on the role of naloxone in opioid reversal and its proper administration, safe use, and appropriate follow-up care, and dispelling common misconceptions to the pharmacy workforce and other healthcare professionals; further,

To support the use of objective clinical data, including leveraging state prescription drug monitoring programs and clinical decision-making tools, to facilitate pharmacist-initiated screenings to identify patients who may most benefit from naloxone prescribing; further,

To encourage the co-prescribing of naloxone with all opioid prescriptions; further,

To support legislation that provides protections for those seeking or providing medical help for overdose victims.

This policy supersedes ASHP policy 2014.

Rationale

According to the Centers for Disease Control and Prevention (CDC), prescription drug abuse is a national epidemic. Deaths from prescription opioid overdose number 10,000 per year; in

contrast, deaths from heroin overdose number 2000. People at risk for opioid overdose include not only substance abusers, but also opioid-naive patients, such as those being admitted for or discharged from ambulatory surgery.

Naloxone is a competitive opioid antagonist that rapidly rescues patients from opioid overdose by displacing mu2 opioid receptors in the central nervous system. Naloxone has an excellent safety profile. The World Health Organization includes naloxone on its model list of essential medicines.

Evidence has demonstrated a clear public health benefit from expanding access to naloxone. Naloxone is currently distributed without a prescription via standing orders, collaborative practice agreements, or pharmacist prescribing authority in all 50 states to ensure liberal access to this lifesaving drug. Several states have also started to permit pharmacy technicians to dispense naloxone under these provisions as well.

Currently there are several formulations of naloxone on the market, which vary in strength and route of administration, including subcutaneous injection (which caregivers or peers may have difficulty administering properly) and intranasal formulations. Studies have shown that intranasal naloxone is as effective as injectable routes in rapid opioid reversal. However, its cost ($130-300 per kit) presents a barrier to widespread use. ASHP encourages the Food and Drug Administration to explore ways to get more user-friendly and less-costly formulations to the market for patients and caregivers. Recognizing that naloxone should not be cost-prohibitive, efforts should be made to fully subsidize the cost of this lifesaving medication.

Despite expanded access to naloxone, there are still significant barriers to its widespread use, including hesitancy among pharmacists to dispense naloxone. Uniform education for those administering the drug, training on safe administration, and recommendations on follow-up care with abuse treatment programs for treated individuals is needed.

Furthermore, although great strides have been made in many areas to improve naloxone access, it is necessary to recognize areas of practice where such efforts are inadequate as a one-size-fits-all model. While pharmacists in all 50 U.S. states now have the ability to participate in naloxone prescribing in some form, barriers to access may still exist, such as in rural communities with no physician willing to participate in a collaborative practice agreement, or indeed, perhaps no physician whatsoever. To that end, pharmacists' naloxone prescribing authority should be independent (i.e., not requiring a protocol or collaborative practice agreement to be in place). Where there are barriers to such independent authority, ASHP should advocate for legislation that promotes standing orders for naloxone as a part of patient care, much as ASHP advocates for pharmacists' independent prescribing authority for medication-assisted treatment (ASHP policy 1909).

Pharmacists should make every effort to intervene on behalf of their patients' safety; therefore, pharmacist education regarding use of naloxone should begin in the didactic curriculum in schools of pharmacy and be part of an ongoing effort for pharmacists as lifelong learners. Current literature suggests that one key barrier to expanded pharmacist involvement in naloxone prescribing is a lack of confidence — which may be addressed by increased education — and also by persistent misconceptions, such as the notion that increased naloxone availability will promote opioid misuse. Because the pernicious nature of this idea is so harmful,

it should be highlighted for targeted educational efforts.

Significant access and racial prescribing disparities have been noted in clinical literature regarding naloxone (Dayton L et al. Racial Disparities in Overdose Prevention among People Who Inject Drugs. *J Urban Health* 2020; 97:823–30). Encouraging pharmacists to be proactive in making clinical interventions is important, but safeguarding patients to protect them from the harms of bias is essential in ensuring equitable access to this medication. Whenever possible, pharmacists should use objective measures (e.g., history of overdose, polypharmacy including multiple CNS-depressing agents, high morphine milligram equivalents per day) to identify high-risk patients and make proactive interventions to provide naloxone to them.

Finally, encouraging co-prescribing of naloxone with every opioid prescription aligns ASHP with the American Medical Association, CDC guidelines, and other organizations that recommend prescribing or co-prescribing naloxone to reduce the risk of overdose deaths. Laws, including medical amnesty and those that provide protection against legal liability for persons administering naloxone (i.e., Good Samaritan laws), are needed as well as laws protecting individuals who call for help for someone who has overdosed from prosecution from minor drug possession or drug paraphernalia.

2212

SAFE AND EFFECTIVE THERAPEUTIC USE OF INVERTEBRATES

Source: Council on Therapeutics

To recognize use of medical invertebrates (e.g., maggots and leeches) as an alternative treatment in limited clinical circumstances; further,

To educate pharmacists, other providers, patients, and the public about the risks and benefits of medical invertebrates use and about best practices for use; further,

To advocate that pharmacy departments, in cooperation with other departments, provide oversight of medical invertebrates to assure appropriate formulary consideration and safe procurement, storage, use, and disposal; further,

To encourage independent research and reporting on the therapeutic use of medical invertebrates.

This policy supersedes ASHP policy 1724.

Rationale

Medical invertebrates, including leeches and maggots, are used as a therapeutic intervention for various indications, including in treatment of extravasation injury, post-plastic-surgery salvage, relief of vascular congestion, macroglossia, compartment syndrome, pain management, and debridement therapy. The use of medical invertebrates is not without risk. There have been reports of local and systemic infections with use of leeches and transmission of communicable disease if not handled properly, and use may mask coagulopathies. Antimicrobial prophylaxis may be required, and there are also drug-invertebrate interactions that may impact the effectiveness of invertebrate therapy. There is also limited research on the

efficacy of these therapies that lead to varied practice and unsubstantiated claims. In addition, leeches may present a biohazard. Application or manipulation may require expulsion of blood to encourage reattachment, and there have been cases in which engorged leeches have fallen off patients, potentially exposing caregivers and other patients to blood.

To promote safe use of medical invertebrates, pharmacy departments, in cooperation with other health-system departments, should assure appropriate formulary consideration and safe procurement, storage, use (e.g., control, prescribing, preparation, dispensing, administration, application, manipulation, documentation, consideration for antimicrobial prophylaxis, clinical and regulatory monitoring), and disposal.

2213

CRITERIA FOR MEDICATION USE IN GERIATRIC PATIENTS

Source: Council on Therapeutics

To support comprehensive medication management, including assessment of physiologic and pharmacokinetic factors, as a central component of providing safe and effective medication therapy to geriatric patients; further,

To oppose use of the Beers criteria or similar criteria by the Centers for Medicare & Medicaid Services, other accreditation and quality improvement entities, and payers as the sole indicator to assess the appropriateness of prescribing for geriatric patients based on known limitations in the evidence evaluating the association between use of medications listed in such criteria and subsequent adverse drug events; further,

To advocate for the development, refinement, and validation of new criteria that consider drug-, disease-, and patient-specific factors, and criteria and quality measures that demonstrate the ability to decrease the occurrence of adverse drug events in geriatric patients; further,

To support research to assess the clinical application of existing and proposed criteria, including assessment of their correlation to patient outcomes and strategies for implementation; further,

To encourage inclusion of validated criteria in clinical decision support systems and other information technologies to facilitate prescribing and deprescribing for geriatric patients; further,

To acknowledge that such criteria are intended as a guide and should not replace the clinical judgment of pharmacists and other clinicians.

This policy supersedes ASHP policy 1221.

Rationale

Criteria have been developed to identify high-risk drugs that should be avoided in geriatric patients (i.e., those 65 years of age or older) based on the potential for these therapies to cause

adverse drug events that can result in falls, hospitalizations, and other incidents that lead to significant morbidity and mortality in this patient population. Those criteria include the 2019 iteration of the Beers criteria and the Screening Tool of Older Persons' Potentially Inappropriate Prescriptions, or STOPP (version 2 of the STOPP/START criteria was published in 2015). Although ASHP supports the intent of these criteria to prevent patient harm, safe and effective use of medications in geriatric patients requires the more thorough assessment associated with pharmacist-provided comprehensive medication management. ASHP opposes adoption of the Beers criteria by the Centers for Medicare & Medicaid Services (CMS) and other accreditation and quality improvement organizations as a tool to assess prescribing in long-term care and other settings, noting concerns about the development and validation of that tool. More importantly, studies evaluating the clinical application of the 2003 iteration of the Beers criteria have not demonstrated a reduction in adverse events when that tool is used. The American Geriatric Society publishes an update every three years, with the most recent update occurring in 2019. Although the update addressed some concerns (e.g., removal of drugs no longer available, drug-drug interactions), some of the criteria's shortcomings (e.g., lack of validation) remain unresolved. In that regard, STOPP, which is based on organ systems and accounts for patients' concomitant disease, is considered more useful. Studies evaluating STOPP, though small in number and consisting of heterogeneous study populations and implementation plans, project a favorable impact on patient outcomes. ASHP encourages additional work to develop, refine, and validate this and similar evidence-based criteria.

Quality indicators for appropriate medication use in older adults were identified as part of the Assessing Care of Vulnerable Elders (ACOVE) project. The indicators provide suggestions for improving prescribing practices and identify medications that require monitoring or should be avoided in vulnerable elders. Practical indicators that can be reviewed from patient encounters and transitions of care include maintenance of a medication list, periodic drug therapy review, assessing response to therapy, drug monitoring, and patient education. Review of these indicators may facilitate benchmarking and consideration of discontinuing unnecessary medications, dose reduction, and consideration of nonpharmacologic alternative strategies.

Further, there is a need for practice-based research to evaluate the application of such criteria and inclusion of validated criteria in clinical decision support systems and other information technologies is necessary to facilitate the use of these criteria in clinical practice. Finally, these tools are intended to serve as a guide or screening tool and should not replace the clinical judgment of pharmacists and other clinicians.

2214
MEDICATION ADHERENCE
Source: Council on Therapeutics

To recognize that medication adherence improves the quality and safety of patient care when the following elements are included: (1) assessment of the appropriateness of therapy, (2) provision of patient education, and (3) confirmation of patient comprehension of information necessary to support safe and appropriate use of prescribed therapies; further,

To advocate that the pharmacy workforce take a leadership role in interdisciplinary efforts to improve medication adherence; further,

To recognize that clinicians, patients, and caregivers share accountability for the outcomes of medication therapies, and that the central role patients and their caregivers have in disease management includes responsibility for following instructions for safe and effective medication use; further,

To encourage development, evaluation, and dissemination of models and tools that improve adherence, including those that combine existing strategies that have demonstrated effectiveness; further,

To oppose misinformation or disinformation that leads patients to decline education and clinical information regarding their medication therapy; further,

To support the development of mechanisms to document medication adherence interventions, including information technology solutions; further,

To advocate for payment models that facilitate an expanded role for the pharmacy workforce in and provide reimbursement for medication adherence efforts.

This policy supersedes ASHP policy 1222.

Rationale

The need to improve medication adherence as a cornerstone of efforts to improve patient care outcomes is widely recognized. A 2010 *New England Journal of Medicine* editorial issued a call to action to improve adherence based on estimates that 50% of all patients are non-adherent, resulting in an estimated $100 billion spent annually on avoidable hospitalizations. ASHP supports programs to improve adherence, but such efforts are not useful, and are perhaps harmful, if they fail to (1) assess the appropriateness of therapy, (2) provide patient education, and (3) ensure patient comprehension of information necessary to support safe and appropriate use of prescribed therapies. Because of their distinct knowledge, skills, and abilities, pharmacists are the ideal clinician to lead interdisciplinary efforts to develop, implement, monitor, and maintain effective strategies for improving medication adherence, and other members of the pharmacy workforce can have important roles in those efforts. Other members of the interdisciplinary team could include physicians, nurses, health psychologists, and social workers. Patients and their caregivers must share accountability with clinicians for medication therapy outcomes, including the responsibility for following instructions for safe and effective medication use. Otherwise, the results from efforts of pharmacists and other clinicians would be negligible. Some interventions to improve medication adherence have shown favorable results, but the greatest success is achieved by models that incorporate multiple strategies reinforced over time. Therefore, the development, evaluation, and dissemination of models that use multimodal approaches are encouraged. The development of information technology solutions and other mechanisms (e.g., digiceuticals) to document interventions intended to improve medication adherence is also recommended. Further,

payment models that support an expanded role for the pharmacy workforce in medication adherence efforts should be pursued.

2215
ASHP STATEMENT ON THE PHARMACY TECHNICIAN'S ROLE IN PHARMACY INFORMATICS
Source: Section of Pharmacy Informatics and Technology

To approve the ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics.

This statement supersedes the ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics dated June 3, 2013.

2216
CAREER COUNSELING
Source: Council on Education and Workforce Development

To advocate that structured student-centered career counseling begin early and continue throughout college of pharmacy curricula; further,

To urge pharmacists to partner with colleges of pharmacy for participation in structured and unstructured student-centered career counseling; further,

To encourage colleges of pharmacy to provide professional development opportunities for faculty and other pharmacy professionals to promote student-centered career counseling approaches; further,

To urge colleges of pharmacy to develop an assessment process to evaluate their career counseling.

This policy supersedes ASHP policy 8507.

This policy was revised in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

Rationale
To ensure students are exposed to the increasing number of postgraduate opportunities and ensure their success in obtaining those opportunities, a structured student-centered career counseling approach must be taken.

2217
WORKFORCE DIVERSITY
Source: Council on Education and Workforce Development

This policy was discontinued in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

2218

PHARMACY EXECUTIVE OVERSIGHT OF AREAS OUTSIDE PHARMACY

Source: Council on Pharmacy Management

To advocate for opportunities for pharmacy leaders to assume healthcare executive leadership roles outside the pharmacy department; further,

To urge pharmacy leaders to seek out formal and informal opportunities to provide such leadership; further,

To encourage pharmacy leaders to use tools, resources, and credentialing identified by national pharmacy and professional healthcare organizations to demonstrate competence and readiness for healthcare executive leadership; further,

To encourage pharmacy leaders to support development of leaders with a broader scope of executive responsibilities by balancing generalization and service-line specialization in their career development and the career development of rising pharmacy leaders; further,

To advocate for healthcare organization structures that provide pharmacy leaders with opportunities to assume leadership responsibilities outside the pharmacy department; further,

To promote continuing professional development opportunities in executive leadership to provide pharmacy leaders with evidence of a commitment to lifelong learning and leadership excellence.

Rationale

In health systems, pharmacy operations often span multiple practice settings, and pharmacists contribute to many different interdisciplinary teams. ASHP's Statement on the Roles and Responsibilities of the Pharmacy Executive notes there is need for a "strategic and innovative pharmacy executive who plans and oversees the design and operation of the entire and complex medication-use process throughout the system." As each health system is unique in the size and range of services offered to patients, there is significant variability of the scope for the pharmacy executive's position. The role of the pharmacy executive, as it originated, was to provide cohesive oversight of the entirety of the medication-use process, including medication-use policy considerations. However, as practice has evolved, medication use and pharmaceutical management has as well. Recent areas of expansion related to medication management in health systems include drug shortages, medication safety and quality, 340B Drug Pricing Program oversight, investigational drugs, and patient assistance support. Some areas for which health systems have sought pharmacy executive oversight that are less directly related to medication management include compliance and regulatory assurance, transitions of care, supply chain, laboratory operations, and dietary services. Pharmacy executives also manage relationships with stakeholders, evaluate quality and outcome metrics, support medication access, and provide leadership in optimizing reimbursement.

Health-system pharmacy leaders possess skills that have often made them candidates for positions outside pharmacy. As senior leadership teams become smaller to reduce labor

costs, pharmacy leaders may be asked to take on additional responsibilities. Over 70% of the 2020 ASHP Foundation Pharmacy Forecast panelists indicated this will be a likely occurrence in many organizations within five years. Adding to a pharmacy leader's portfolio of responsibility creates opportunities for sharing experience and resources across multiple departments. Placing multiple departments under the leadership of one executive also makes it easier to reduce silo budgeting by identifying and implementing interventions that may increase cost in one department while reducing cost to a greater degree in another. Pharmacy leaders who accept responsibility for other service lines must exploit the strengths of their other departments, drive collaboration across all areas they lead, and avoid undermining authority entrusted to subordinate service-line leaders.

Pharmacy executive leaders should strive to demonstrate a commitment to achieving and maintaining excellence in pharmacy and healthcare leadership to communicate value to colleagues, healthcare administrators, and the public. This goal could be achieved by seeking national recognition of core competencies (e.g., leading people and processes, professionalism, financials) identified by national pharmacy and professional healthcare organizations (e.g., American College of Healthcare Executives fellowship program, 360 evaluations, career coaching, professional leadership certificates, ASHP Certified Pharmacy Executive Leader credential). Pharmacy executive leaders should continually seek opportunities for professional development to demonstrate their competence, leadership, and commitment to the profession and to enhance their essential executive knowledge, skills, and abilities in order to facilitate team success.

A key driver enabling a pharmacy executive leader the ability to devote the time and energy for expanded roles includes striking a balance with service-line personnel breadth and depth. This balance is of particular importance when establishing a talent pipeline of capable leaders that will keep the service lines running with little to no interruption. In some health systems, pharmacists hold roles such as chief executive officer, chief operating officer, and senior vice president. Some institutions include oversight of additional service lines within the purview of their highest-ranking pharmacist administrator, such as combining "Pharmaceutical and Nutrition Care," or appointing a pharmacist to manage all "intravenous admixture services."

To achieve maximum performance in an expanded leadership role, the conditions for success must exist. Organizational structure (e.g., hierarchal, matrix, divisional) aligns and defines the relationships of parts of an organization, and the structure chosen affects an organization's success in carrying out its strategy, goals, and objectives. Leadership should understand the characteristics, benefits, and limitations of various structures in aligning organizational structure with the enterprise's business strategy.

2219

HOSPITAL-AT-HOME CARE

Source: Council on Pharmacy Practice

To affirm that patients treated in the hospital-at-home (HAH) setting are entitled to the same level of care as those treated in an inpatient hospital setting; further,

To support HAH care models that provide high-quality, patient-centered pharmacist

care, including but not limited to: (1) clinical pharmacy services that are fully integrated with the care team; (2) a medication distribution model that is fully integrated with the providing organization's distribution model and in which the organization's pharmacy leader retains authority over the medication-use process; (3) information technology (IT) systems that are integrated or interoperable with the organization's IT systems and that allow patient access to pharmacy services, optimize medication management, and promote patient safety; and (4) ensuring the safety of the pharmacy workforce throughout the HAH care delivery process; further,

To advocate that pharmacists be included in the planning, implementation, and maintenance of HAH programs; further,

To advocate for legislation and regulations that would promote safe and effective medication use in the HAH care setting, and for adequate reimbursement for pharmacy services, including clinical pharmacy services, provided in the HAH care setting; further,

To provide education, training, and resources to empower the pharmacy workforce to care for patients in HAH care settings and to support the organizations providing that care; further,

To encourage research on HAH care models.

Rationale

Hospital-at-home (HAH) care is a patient care model that provides acute-level care to patients in their own homes. The first described HAH program was originally developed by the Johns Hopkins Schools of Medicine and Public Health over 25 years ago, and the HAH care model has seen broader adoption by other hospitals and health systems in recent years. HAH care models have been shown to improve clinical outcomes, reduce length of stay, provide higher patient satisfaction, and reduce costs and medical complications.

The COVID-19 pandemic forced hospitals and health systems to explore new and innovative care models, with a heightened focus on remote care. In March 2020, the Centers for Medicare & Medicaid Services (CMS) announced its Hospitals Without Walls program, which resulted in broader regulatory flexibility in providing services beyond hospital walls. This program was expanded in November 2020 to include the Acute Hospital Care at Home program, which allows eligible patients to be treated for acute illnesses in the comfort of their homes. CMS has outlined more than 60 acute conditions such as heart failure, asthma, pneumonia, and chronic obstructive pulmonary disease (COPD) that can be safely managed from a patient's home with proper monitoring and treatment protocols. As of June 4, 2021, there were 59 health systems and 133 hospitals in 32 different states participating in the Acute Hospital Care at Home program.

Medication management is a mainstay for most, if not all, of the conditions treated under HAH programs. Pharmacy practice leadership and expertise is therefore needed to ensure patient safety and quality outcomes. Patients treated in HAH programs are entitled to the same level of high-quality, patient-centered pharmacist care as those treated in an

inpatient hospital setting. ASHP supports HAH care models that provide high-quality, patient-centered pharmacist care. Patients receiving HAH care should have access to clinical pharmacy services that are fully integrated with the services provided by rest of the patient's care team. To ensure optimal medication use, the HAH program should use a medication distribution model that is fully integrated with the providing organization's distribution model, and the organization's pharmacy leader should retain authority over the entire HAH medication-use process to promote integration with the organization's pharmacy enterprise. The HAH program should use information technology (IT) systems that are integrated or interoperable with the organization's IT systems to allow patients to access pharmacy services, the pharmacy workforce to optimize medication management, and the organization to promote patient safety. Finally, HAH programs should ensure the safety of the healthcare workers delivering care, including members of the pharmacy workforce.

The pharmacy workforce needs to be included in the planning, implementation, and maintenance of HAH programs. Early in the planning process, pharmacy departments can evaluate and determine (1) the in-person, virtual, and electronic patient assessment role for pharmacists in the HAH program to determine staffing requirements; (2) how medications will be provided and stored for patients, especially controlled substances and medications with strict storage requirements (e.g., temperature-sensitive medications); (3) formulary considerations and payer design; (4) state and federal regulations and licensure interpretations to support the practice and supply chain model requirements necessary for HAH programs; (5) how medication administration will be documented (e.g., through bar-code-enabled medication administration), including waste management; (6) electronic healthcare record platform capabilities required to support the HAH program, including an assessment of ancillary information systems or platforms that will need to be integrated with the organization's IT systems to support medication-use documentation and pharmacist consultations; and (8) differences between HAH and home infusion models, and when to deploy the appropriate model.

Pharmacy departments should proactively assess the pharmacy clinical services needed to care for patients in the HAH program and determine the competencies and training to meet expected demands. Examples would include determining how drug information questions will be channeled and how care transitions will be managed (e.g., follow-up appointments for chronic care management, transitions to palliative care). The pharmacy department will need to develop processes to integrate telehealth services for patients to receive pharmacist care (e.g., education). Other considerations include patient choice and healthcare disparities, which may impact the ability to meet the criteria to receive HAH care.

Changes in law, regulations, and standards will be required to support HAH care models, particularly because some elements of the HAH care model were supported by temporary regulatory flexibilities granted to address the COVID-19 public health emergency. Specifically, the continued adoption and expansion of the HAH model will require the creation of sustainable reimbursement models for pharmacist-provided HAH services. Additionally, regulatory changes, particularly from CMS may be needed to ensure that pharmacists can administer medications in the home setting.

To prepare the pharmacy workforce to meet the needs of patients in HAH programs and the organizations managing them, ASHP will need to provide education, training, and resources to prepare the pharmacy workforce for these new and evolving roles, including the

development of best practices, residency standards, and workforce competencies. To achieve these goals, ASHP will need to collaborate with interprofessional organizations such as the Hospital at Home Users Group (HAHUsersgroup.org), a collaborative of HAH programs around the U.S. and Canada that fosters the development and dissemination of resources and best practices to expand the reach of HAH programs, drive practice advancement, and inform regulatory and reimbursement policies to spread the HAH model of care. To provide a basis for these efforts, ASHP will also need to encourage research on the HAH model of care.

2220
PROMOTING TELEHEALTH PHARMACY SERVICES
Source: Council on Pharmacy Practice

To advocate for innovative telehealth pharmacy practice models that (1) enable the pharmacy workforce to promote clinical patient care delivery, patient counseling and education, and efficient pharmacy operations; (2) improve access to pharmacist comprehensive medication management services; (3) advance patient-centric care and the patient care experience; and (4) facilitate pharmacist-led population and public health services and outreach; further,

To advocate for removal of barriers to access to telehealth services; further,

To advocate for laws, regulations, and payment models for telehealth services that are equitable to similar services provided in person by health systems, with appropriate accountability and oversight; further,

To encourage comparative effectiveness and outcomes research on telehealth pharmacy services.

Rationale
The definitions and terminology used to describe telehealth vary. Many refer to virtual health, telehealth, telemedicine, and/or telepharmacy interchangeably. The Centers for Medicare & Medicaid Services (CMS) describes telemedicine as a means for improving a patient's health by permitting two-way, real-time, interactive communication between a patient and a healthcare provider who are geographically separated. ASHP defines telepharmacy as a method used in pharmacy practice in which a pharmacist utilizes telecommunications technology to oversee aspects of pharmacy operations or provide patient care services.

Telehealth is part of a larger digital transformation in healthcare. Patients are increasingly making decisions about who delivers their care and engaging in the delivery of that care digitally. As a result, hospitals and health systems need a strategy for their own digital transformation and to meet patient demands. In general, telehealth includes a broader scope of remote healthcare services than telemedicine and telepharmacy; therefore, ASHP considers telehealth to be the overarching term for the remote delivery of patient care services.

The availability of telehealth services in rural areas facilitates greater access to care by eliminating the need to travel long distances to see a qualified healthcare provider. It promises to save patients time and money, reduces patient transfers, emergency department and urgent

care center visits, and delivers savings to payers (American Hospital Association [AHA]. Fact Sheet: Telehealth; AHA. Optimizing Pharmacy Services: Managing your hospital pharmacy during the COVID-19 pandemic and beyond). Pharmacists' role in telehealth is instrumental, as telehealth serves are a valuable tool for the profession of pharmacy to extend its reach to patients for the provision of medication management and complex patient care (AHA. Optimizing Pharmacy Services: Managing your hospital pharmacy during the COVID-19 pandemic and beyond; ASHP Statement on Telepharmacy). Telehealth services have grown significantly over recent years, especially during the COVID-19 pandemic. Telehealth services have the potential to improve patient access to care, cost efficiencies, and quality while meeting consumer demand. They also offer patients the convenience of remote drug therapy monitoring, authorization for prescriptions, patient counseling, and monitoring patients' compliance with prescriptions, and they can be offered remotely to patients with diabetes, congestive heart failure, and other chronic diseases. Pharmacists may also use telehealth when suitable to remotely verify sterile compounding, offer pre- and postoperative medication order review, provide interactive postoperative patient medication counseling, or deliver drug information to a facility that is geographically isolated (ASHP Statement on Telepharmacy). To ensure the best patient care outcomes and most efficient use of healthcare resources, additional research will be needed to compare telehealth pharmacy services with those offered in person.

2221

TAMPER-EVIDENT PACKAGING ON MULTIDOSE PRODUCTS

Source: Council on Pharmacy Practice

To support the standardization and requirement of tamper-evident packaging on all multidose prescription and nonprescription products; further,

To encourage proper safety controls be in place to prevent harm and ensure proper disposal of multidose products.

This policy supersedes ASHP policy 9211.

Rationale

Multidose products provide more than one dose of a medication. Medications available in multidose forms include but are not limited to topical creams, gels, and ointments, inhalers, and solutions. Tamper-evident packaging is needed to ensure the viability and safety of medications in multidose containers. The Food and Drug Administration defines a tamper-evident package as "one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering occurred." In addition, when multidose products are disposed of, best practices in medication waste disposal need to be employed to prevent harm or diversion.

2222

PHARMACIST'S ROLE IN MEDICATION PROCUREMENT, DISTRIBUTION, SURVEILLANCE, AND CONTROL

Source: Council on Pharmacy Practice

To affirm the pharmacist's expertise, responsibility, and oversight in the procurement, distribution, surveillance, and control of all medications used within health systems and affiliated services; further,

To assert that the pharmacy leader retains the authority to determine the safe and reliable sourcing of medications; further,

To assert that the pharmacy workforce is responsible for the coordination of medication-related care, including optimizing access, ensuring judicious stewardship of resources, and providing intended high-quality clinical care; further,

To encourage payers, manufacturers, wholesalers, accreditation bodies, and governmental entities to enhance patient safety by supporting the health-system pharmacy workforce's role in medication procurement, distribution, surveillance, and control.

This policy supersedes ASHP policy 0232.

Rationale

Pharmacists are accountable for ensuring that medications will be optimally used in the care setting in which they work. (For the purposes of this policy, "medications" include those used by inpatients and outpatients, large- and small-volume injectables, radiopharmaceuticals, diagnostic agents including radiopaque contrast media, anesthetic gases, blood-fraction drugs, dialysis fluids, respiratory therapy drugs, biotechnologically produced drugs, investigational drugs, drug samples, drugs brought to the setting by patients or family, and other chemicals and biological substances administered to patients to evoke or enhance pharmacologic responses.) The pharmacist and pharmacy workforce, as part of their leadership over all aspects of the medication-use process, are responsible for medication procurement, distribution, surveillance and control. One of the central roles of the pharmacist and pharmacy workforce in hospitals, health systems, and affiliated services is to oversee and assume accountability for these responsibilities while also supporting patient access to medications and engaging in clinical services to optimize medication use. While recognizing the stakeholders that influence medication procurement, distribution, surveillance, and control such as payers, manufacturers, wholesalers, accreditation bodies, and governmental entities, pharmacists require the autonomy to make decisions related to these aspects for their institutions and affiliated service provision.

2223

ASHP STATEMENT ON THE ROLE OF THE PHARMACY WORKFORCE IN EMERGENCY PREPAREDNESS

Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Role of the Pharmacy Workforce in Emergency Preparedness.

This statement supersedes the ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness dated June 2, 2002.

2224

DRUG DESENSITIZATION

Source: Council on Therapeutics

To encourage an allergy reconciliation process to ensure allergy documentation is accurate and complete for drug desensitization; further,

To advocate for pharmacist involvement in the interdisciplinary development of institutional drug desensitization policies and procedures; further,

To support the creation and implementation of drug desensitization order sets and safeguards in the electronic health record to minimize potential error risk; further,

To recommend appropriate allocation of resources needed for the drug desensitization process, including adequate availability of allergic reaction management resources near the desensitization location; further,

To support the education and training of pharmacists regarding allergy reconciliation, drug desensitization processes, and allergic reaction prevention and management; further,

To recommend patient education and appropriate documentation in the electronic health record of the outcomes of the drug desensitization process.

Rationale

Only about 5-10% of all drug-related adverse events are allergic in nature. Patients are often labeled with an allergy on the basis of a side effect or intolerances such as headache or gastrointestinal disturbance. Allergen misidentification and documentation can be detrimental to patient care by preventing the use of optimal drugs or by causing re-exposure to a true allergen. However, when a patient has a true allergy, and the drug is required for treatment, drug desensitization is often the next step in patient care.

Drug desensitization is a procedure that transiently alters a patient's immune response to a drug to permit an allergic patient to receive the sensitizing drug safely. Approaches to desensitization are often drug- and protocol-specific and vary widely (e.g., in the length of sensitization based on patient-specific factors such as immune response, body composition, height, and weight). This approach to patient care is not without risk or controversy, as the

mechanism of drug desensitization is not completely understood but the procedure is often deemed essential to patient care when a specific drug is the only appropriate therapy for a patient. Drug concentrations and dilutions are often not standardized, and depending on the drug, can be a source of significant error, particularly with high-risk medications such as chemotherapeutic agents. Sources of error that have been cited in the literature include compounding errors, order entry into the electronic health record, lack of standardized order sets, variability in concentrations of sensitizing doses, allergic reaction prevention, and documentation of desensitization outcomes.

2225

ASHP STATEMENT ON PHARMACIST PRESCRIBING OF STATINS

Source: Council on Therapeutics

To approve the ASHP Statement on Pharmacist Prescribing of Statins.

This statement supersedes the ASHP Statement on Over-the-Counter Availability of Statins dated June 14, 2005.

2226

ASHP STATEMENT ON THE ROLE OF PHARMACISTS IN PRIMARY CARE

Source: Section of Ambulatory Care Practitioners

To approve the ASHP Statement on the Role of Pharmacists in Primary Care.

This statement supersedes the ASHP Statement on the Pharmacist's Role in Primary Care dated June 7, 1999.

2227

ASHP STATEMENT ON TELEHEALTH PHARMACY PRACTICE

Source: Section of Pharmacy Informatics and Technology

To approve the ASHP Statement on Telehealth Pharmacy Practice.

This statement supersedes the ASHP Statement on Telepharmacy dated November 18, 2016.

2228

ROLE OF THE PHARMACIST IN SERVICE-LINE DEVELOPMENT AND MANAGEMENT

Source: Council on Pharmacy Management

To recognize pharmacists bring unique clinical, operational, and financial expertise to help organizations develop and manage high-value health-system service lines; further,

To support the role of pharmacy leadership in the development and management of high-value health-system service lines.

Rationale

To drive success in the current market, health systems, especially those within integrated delivery networks, must optimize growth by applying strong tactics to acquire and retain patients. Service-line development is structuring patient-centered care in clinically specific areas across the healthcare system. Service-line design groups patients into specific areas of need, improving care coordination and accountability and allowing for a nimble response to changes (e.g., in the allocation of resources).

Pharmacists bring clinical, operational, and financial expertise to help organizations (1) optimize resources, (2) ensure safe medication use and patient-centric system design, (3) drive patient and provider satisfaction, (4) improve patient outcomes, and (5) achieve financial growth when part of critical decision-making for setting an organization's overall service-line growth and management strategy. For example, pharmacists working as part of a specialty pharmacy can leverage their expertise to assess a certain population within a service line, with the goal of improving care and patient safety while promoting use of cost-effective treatments. Most specialty pharmacies allow pharmacists to oversee financial, operational, and clinical services, which has led to growth in patient access and revenue for health systems. Health systems can reap many benefits from expanding service lines, including increased patient volumes, improved health outcomes, boosted market share, and improved patient and provider satisfaction. By focusing on developing high-value service lines, health systems have the opportunity to achieve financial growth and significant return on investment. Growing high-value service lines is one of the most effective ways in which hospitals and health systems can add value to the healthcare system. Growing service lines requires careful strategic planning, and success hinges on an organization's proficiency in (1) understanding and predicting patient needs; (2) acquiring commercial health plans; (3) using an omni-channel approach; (4) focusing on provider referrals; (5) safe medication use and patient-centric system design (e.g., medication stewardship, formulary alignment, medication-use policies); and (6) ensuring the C-suite is fully committed to the service-line development strategy. High-value service lines exemplify exceptional performance in many ways, including attracting the most patients and providers, driving the most revenue, achieving the highest care success rates, and presenting the greatest growth potential. Healthcare organizations identify their high-value service lines by analyzing financial data, external market factors (e.g., value-based contracts), and other relevant economic conditions. Data analytics and effective patient communication are important when healthcare organizations are working to grow service lines. High-value service lines may differ among hospitals, depending on the patients and markets they serve. During times of scarce capital and growing demand for services, service-line analysis becomes a high-priority task for hospital and health-system decision-makers. Leaders must face hard questions when it comes to identifying the areas of operations critical to an institution's long-term financial viability and should ensure those service lines get the investment and management attention they need. Service-line analysis may also mean eliminating low-volume and/or unprofitable service lines that drain resources. Before hospital leaders decide to discontinue a given service line, they should consider whether the line has been properly managed. Many hospitals may have inadvertently harmed service-line management by not investing sufficiently in the resources needed for success.

In today's environment, successful service-line development efforts need input from pharmacy leaders from the outset of discussions through implementation and management. Engagement in every step of service-line development and management assures long-term success as strategic direction is set. Success as a pharmacy leader is predicated on building and maintaining relationships with diverse groups of people in order to be part of setting the overall strategy for an organization. This relationship-building may include partnering with nontraditional healthcare participants to develop new strategies for care. As healthcare markets continue to shift away from volume and toward value, appealing to patients by building high-value service lines designed to meet patients' unique needs will become increasingly important.

2229
PHARMACIST'S ROLE IN RESPIRATORY PATHOGEN TESTING AND TREATMENT

This policy was superseded by ASHP policy 2324.

2230
ADVANCING DIVERSITY, EQUITY, AND INCLUSION IN EDUCATION AND TRAINING
Source: Council on Education and Workforce Development

This policy was discontinued in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

2231
CULTURAL COMPETENCY

This policy was superseded by ASHP policy 2504.

2232
REVENUE CYCLE MANAGEMENT AND REIMBURSEMENT AND PHARMACIST COMPENSATION FOR DRUG PRODUCT DISPENSING
Source: Council on Pharmacy Management

To encourage the pharmacy workforce to serve as leaders in the development and implementation of strategies to optimize medication-related revenue cycle compliance, which includes verification of prior authorization, patient portion of payment, billing, reimbursement, and financial documentation for the healthcare enterprise; further,

To advocate for the development of consistent, transparent billing and reimbursement policies and practices by both government and private payers; further,

To collaborate with payers in developing optimal methods of reimbursing pharmacies and pharmacists for the costs of drug products dispensed, pharmacy and pharmacist services, and associated overhead; further,

To educate the pharmacy workforce and stakeholders about those methods; further,

To advocate that information technology (IT) vendors enhance the capacity and capability of IT systems to support and facilitate medication-related purchasing, billing, and audit functions; further,

To investigate and publish best practices in medication-related revenue cycle compliance and management.

This policy supersedes ASHP policies 1710 and 1807.

Rationale

Pharmacy has an increasingly important role in optimizing revenue capture and avoiding revenue erosion resulting from improper billing or inadequate documentation of medication-related charges. Pharmacy needs to be involved in aspects of medication-related billing, including not just pharmacy drug charges and billing but also contracting and negotiating for carve-outs. Pharmacy leaders need to actively engage senior leadership and collaborate with various departments to ensure organizational success in revenue cycle management.

Recently, organizations have experienced increasing compliance pressures. This pressure comes from many sectors, including Centers for Medicare & Medicaid Services (CMS) programs plus state-specific requirements, third-party payers, and financial intermediaries. These policies impact organizations in two ways: increased requirements before the insurers will pay for a claim, and increased audit pressure to be sure the organizations are billing accurately. The frequency and nature of audits has also been changing. Insurers have increased the use of audits to control costs. Government agencies have also increased the use of audits. CMS has implemented Recovery Audit Contractor (RAC) audits, and the Office of the Inspector General is also auditing organizations. Results of the audits can have significant financial impact on the organization when money needs to be returned based on improper billing or lack of documentation.

Historically, pharmacy departments have great strength in managing supply chain issues. Drug expenditures are typically a significant portion of any hospital's budget, and the pharmacy department is a key leader in managing these expenses. However, pharmacy departments are involved in broader revenue cycle management in variable ways. In some organizations, the billing or patient accounting departments, or in some cases a contracted third-party vendor, handle all billing issues with various degrees of pharmacy department involvement. Accurate billing requires integration of the organization's clinical services, pharmacy, billing, and chargemaster functions. The required elements for proper billing may reside in several systems. As coverage decisions become more complex, pharmacy expertise is increasingly required in the clinical coverage decisions and information integration in order to be successfully reimbursed for services. For the healthcare enterprise to successfully manage compliance and optimize revenue capture there must be effective collaboration among various departments. Pharmacy knowledge and leadership is increasingly required to ensure organizational success in revenue cycle management.

In well-intentioned efforts to reduce healthcare costs, public and private payers often seek to minimize the reimbursement to pharmacies for drug products. Historically, those reimbursements have sometimes exceeded the simple cost of the drug product to reimburse pharmacies for associated costs (e.g., storage, compounding, preparation, dispensing). Each insurer has different requirements for coverage determinations, and coverage decisions have become more complex. More drugs now require prior authorization processes. In some cases, even if the prior authorization process has been used, the charge is denied. Medicare has implemented requirements for self-administered drugs (SADs), and diabetic supplies are now handled under durable medical equipment (DME) requirements, which may require different data elements before a bill is processed. Medicaid requires the National Drug Code (NDC) prior to payment, and billing requirements for Medicare and Medicaid programs are not harmonized. Healthcare Common Procedure Coding System (HCPCS) codes also need to be attached where indicated. It is challenging to keep up with all the changes. International Classification of Disease 10 (ICD-10) codes further complicate required coding.

Current IT solutions are inadequate and do not effectively facilitate effective billing. Current systems are often not designed to capture all necessary information required to properly document and bill. Even when necessary data is captured, it often resides in different departmental computer systems that are not integrated and designed to share data. There is a need for better IT solutions to facilitate both billing and audits. Greater consistency in billing and reimbursement practices would facilitate greater compliance and enable the development of effective technology solutions to improve billing and reimbursement processes.

Since pharmacy leaders have had variable levels of engagement in revenue cycle management, there is a need for education, tools, and resources related to best practices. Because cost-management efforts are likely to continue to reduce pharmacy reimbursement, other means of compensating pharmacies for those expenses will need to be found, and pharmacists and other stakeholders will require education about those reimbursement methods. In addition, pharmacists and pharmacies need to be reimbursed for professional services associated with management of medications and related patient care. Some pharmacy departments have created a business manager position in part to deal with these issues. This position is often not a pharmacist, but a staff member with business training. New roles for pharmacy technicians have also emerged in this area. ASHP and the Section of Pharmacy Practice Leaders are committed to developing and sharing best practices and providing education to support pharmacists in optimizing reimbursement and pharmacist compensation for drug product dispensing and pharmacy's role in revenue cycle compliance.

2233

VALUE-BASED PURCHASING

Source: Council on Pharmacy Management

To support value-based purchasing reimbursement models when they are appropriately structured to improve healthcare quality, patient satisfaction, and clinical outcomes, and encourage medication error reporting and quality improvement; further,

To affirm the role of pharmacists in actively leading the design and interdisciplinary implementation of medication-related value-based purchasing initiatives; further,

To support pharmacy workforce efforts to ensure safe and appropriate medication use by using data and technology for continuous quality improvement in pharmacy-designed, medication-related value-based purchasing initiatives; further,

To advocate that the Centers for Medicare & Medicaid Services and others guide the development of a common portfolio of measures for potential alignment across regulated programs, federal programs and agencies, and the private sector.

This policy supersedes ASHP policies 0708 and 1209.

Rationale

Value-based purchasing is one aspect of a portfolio of healthcare reform incentives based on pay-for-performance principles. The Hospital VBP Program adjusts payments to hospitals under the Inpatient Prospective Payment System (IPPS) based on the quality of care they deliver. In April 2021, the Centers for Medicare & Medicaid Services (CMS) announced efforts to (1) readdress 2020 policies during the duration of COVID-19 public health emergency (PHE) and (2) close healthcare equity gaps and provide greater accessibility to care, requesting comments regarding the modernization of the quality measurement enterprise to digital quality measurement. In response to the pandemic, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) for eligible discharges during the PHE. To enhance the medical workforce in rural and underserved communities, CMS is proposing to distribute 1,000 additional physician residency slots to qualifying hospitals, phasing in 200 slots per year over five years. To address the future of digital quality measurement, CMS is currently reviewing proposals and holding discussions through 2022.

CMS was seeking comment on plans to modernize its quality measurement enterprise by:

- clarifying the definition of digital quality measures;
- using the Fast Healthcare Interoperability Resources (FHIR) Standard for electronic clinical quality measures that are currently in the various quality programs;
- standardizing data required for quality measures for collection via FHIR-based application programming interfaces;
- leveraging technological opportunities to facilitate digital quality measurement;
- better supporting data aggregation; and
- developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector.

ASHP recognizes the pharmacist's leadership role while explicitly acknowledging the interdisciplinary nature of initiatives designed to achieve value-based purchasing measures. Often, however, active membership on the design team does not include pharmacy. Because there needs to be thoughtful consideration of what pharmacy can reasonably control within an organization in terms of achievable tactics to improve a specific goal, pharmacy leaders need to engage their entire departments in these efforts to ensure that there is a concerted approach toward improving patient care. Finally, as value-based purchasing program proliferate, CMS and

other stakeholder organizations need to guide the development of a common portfolio of measures for potential alignment across regulated programs, federal programs and agencies, and the private sector.

2234
FINANCIAL MANAGEMENT SKILLS
Source: Council on Pharmacy Management

To foster the systematic and ongoing development of management skills for the pharmacy workforce in the areas of (1) health-system economics, (2) business plan development, (3) financial analysis, (4) metrics for clinical and distributive services, (5) pharmacoeconomic analysis, (6) diversified pharmacy services, (7) compensation for pharmacists' patient-care services, and (8) revenue cycle compliance and management; further,

To encourage colleges of pharmacy to incorporate these management areas in course work, electives (e.g., financial and managerial accounting), and experiential education; further,

To promote the growth of dual PharmD/MBA degree programs, postgraduate training, and other degree programs focused on financial management, and similar certificates or concentrations; further,

To encourage financial management skills development in pharmacy residency training programs; further,

To provide education for new practitioners and student pharmacists on foundational skills for business administration and personal financial management; further,

To promote education on financial management for other members of the pharmacy workforce (e.g., pharmacy technicians, data scientists, inventory specialists, department business managers).

This policy supersedes ASHP policies 0508 and 1207.

Rationale
Revenue cycle compliance and management represent an increasingly important aspect of the business operations of hospitals and health systems. Pharmacy leaders must exert leadership in managing medication-related revenue cycle compliance in order to ensure financial success of the healthcare enterprise. The development of foundational skills in financial literacy and business management is critical for many members of the pharmacy workforce (e.g., residents, new practitioners, student pharmacists, pharmacy technicians, and support staff such as data scientists, inventory specialists, or department business managers) to gain perspectives on contemporary management techniques and fiscal solvency. Some ways to achieve this are through (1) college of pharmacy curriculum (e.g., dual Pharm.D./M.B.A. degree or similar programs) or experiential program requirements; (2) degree programs with a concentration in financial management; (3) during residency training as incorporated projects; or (4) as a

certificate program for student pharmacists, residents, and new practitioners. Pharmacy leaders must also develop and maintain knowledge in this area to sharpen skills in planning, forecasting, decision-making, and implementation.

2235

USE OF INCLUSIVE VERBAL AND WRITTEN LANGUAGE

Source: Council on Pharmacy Practice

To recognize that stigmatizing and derogatory language can be a barrier to safe and optimal patient care as well as compromise effective communication among healthcare team members; further,

To promote the use of inclusive verbal and written language in patient care delivery and healthcare communication; further,

To urge healthcare leadership to promote use of inclusive language; further,

To provide education, resources, and competencies for the pharmacy workforce to champion the use of inclusive verbal and written language.

Rationale

Inclusive verbal and written language (i.e., language that is free of stigma, bias, and oppression) is essential for the provision of equitable patient care. The use of derogatory and stigmatizing language in the healthcare environment is a risk to patient safety and a threat to optimal health. In addition, when used among care team members, it introduces a culturally insensitive and noninclusive work environment. Stigmatizing language may fuel and trigger implicit or explicit bias in a healthcare clinician or team member and harm patients, worsen health outcomes, and compromise team dynamics. Derogatory and stigmatizing language may occur between patients and the care team, among care team members, and in medical documentation. Commitment to the use of conscious language—the intentional use of words and terms to create empathetic, inclusive, and non-stigmatizing content—is suggested as an alternative to ensure language and communication does not lead to poorer health outcomes, health inequities, and stigma.

The use of stigmatizing and derogatory language in medical chart documentation becomes even more damaging as patients have increased access to their own health records (Davis B. Derogatory language in charting: the domino effect. *Patient Safety*. 2021; 3:74-8.). Patients may not be empowered to take ownership of their care if stigmatizing and derogatory language is used. The same can apply for verbal communications. The use of argot or slang to disguise the meaning to bystanders may be useful to build bonds between colleagues but is unprofessional and creates judgments about patients not based in facts (Goldman B. Derogatory slang in the hospital setting. *AMA J Ethics*. 2015; 17:167-71).

There are multiple strategies for eliminating the use of stigmatizing language in the course of caring for a patient, such as using person-first and technical language and avoiding the use of sensational or fear-based language. Eliminating derogatory and stigmatizing language from healthcare settings requires leadership commitment across the spectrum of care

delivery and an educated and empowered healthcare workforce. Pharmacists, student pharmacists, and pharmacy technicians have a professional duty to provide culturally competent and compassionate patient care and can serve as champions in eliminating the use of stigmatizing language in healthcare.

2236
PHARMACIST PRESCRIBING IN INTERPROFESSIONAL PATIENT CARE

This policy was superseded by ASHP policy 2423.

2237
UNIVERSAL VACCINATION FOR VACCINE-PREVENTABLE DISEASES IN THE HEALTHCARE WORKFORCE
Source: Council on Pharmacy Practice

To support policies and mandates that promote universal vaccination for preventable infectious diseases among healthcare workers, including all members of the pharmacy workforce, as a safeguard to patient and public health; further,

To encourage the use of evidence-based risk assessments to determine inclusions in and exemptions from mandatory vaccine requirements; further,

To support employers in establishing and implementing mandatory vaccine requirements for healthcare workers if evidence-based risk assessments determine they are safe and promote patient and public health; further,

To urge healthcare organizations to have policies that address additional infection prevention practices required for exempted healthcare workers; further,

To develop tools, education, and other resources to promote vaccine confidence, increase vaccination rates, and minimize vaccine-preventable diseases among healthcare workers.

This policy supersedes ASHP policies 2138 and 2140.

Rationale
Vaccine-preventable diseases (VPDs) pose a threat to vulnerable patients, the healthcare workforce, and public health. Vaccines are effective in protecting the healthcare workforce and the patients they care for and with whom they interact.

Voluntary vaccination of healthcare workers (HCWs), supported by employer-offered strategies, increases vaccination rates to some extent. For example, the Centers for Disease Control and Prevention (CDC) estimates that in the 2019-2020 season, approximately 80% of healthcare workers were vaccinated against influenza, with rates over 90% among hospital employees, despite the fact that only approximately 70% of hospitals require an annual

influenza vaccination and the CDC has recommended influenza vaccinations for HCWs since 1981.

Mandatory vaccination requirements, in contrast, carry heavier weight and can result in near-universal vaccination rates. The effectiveness of the mandatory approach has led to HCW vaccination requirements from the Occupational Safety and Health Administration, recommendations from the Centers for Disease Control and Prevention (CDC), policy endorsements from numerous professional organizations, and quality measures for federal and commercial payer reporting programs. For example, the CDC Advisory Committee on Immunization Practices proposes recommendations for the immunization of healthcare workforce based on (1) those diseases for which routine vaccination or documentation of immunity is recommended for healthcare personnel because of risks to them in their work settings and, should healthcare personnel become infected, to the patients they serve; and (2) those diseases for which vaccination of healthcare personnel might be indicated in certain circumstances. The current list of VPDs in which healthcare personnel are considered to be at substantial risk for acquiring or transmitting and in which vaccination is recommended includes hepatitis B, influenza, measles, mumps, rubella, pertussis, and varicella. In the future, this list may include vaccination against SARS-CoV-2.

In its recommendations, the CDC considers HCWs to include (but not be limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCWs and patients.

The vaccination-related policies of various healthcare professional organizations contain similar themes. These policies recognize that mandatory vaccination policies improve vaccination rates, protecting patients and the healthcare workforce; acknowledge the limited circumstances that may preclude an HCW from being vaccinated (e.g., medical contraindications and legally required religious exemptions); express support for following evidence-based practices in determining which vaccines should be mandatory; and support education of the healthcare workforce on the benefits of vaccination.

2238

PATIENT DISABILITY ACCOMMODATIONS

Source: Council on Public Policy

To promote safe, inclusive, and accessible care for patients with disabilities; further,

To advocate for research to enhance capabilities in meeting the needs of patients with disabilities; further,

To advocate for inclusion of caring for patients with disabilities in college of pharmacy and pharmacy technician program curricula and in postgraduate residencies; further,

To support pharmacy workforce training to improve awareness of the barriers patients with disabilities face and ensure equitable care.

Rationale

Current statistics indicate that 20–30% of Americans have some type of disability Many of these patients, regardless of whether their disability is physical or mental, would benefit from the creation and adoption of technology and communication tools that improve how pharmacists and other providers interact with them. Because there is such a broad spectrum of potential patient needs, additional research on appropriate and safe implementation of technology and the creation of new solutions, including solutions to improve health equity, is needed and should be supported by federal, state, and private funding. Further, pharmacy schools and other pharmacy workforce training programs should integrate education on serving patients with disability into their established curricula.

2239

DRUG PRICING PROPOSALS

Source: Council on Public Policy

To advocate for drug pricing and transparency mechanisms that ensure patient access to affordable medications, preserve existing clinical services and patient safety standards, and do not increase the complexity of the medication-use system.

Rationale

As drug prices have continued to climb, policymakers have proposed numerous solutions. While each proposal will need to be evaluated on its merits, it is critical that, at a minimum, policy solutions promote transparency, protect patient access to medications, and limit or reduce patient out-of-pocket costs. However, drug pricing solutions should not threaten programs that support expanded patient services (e.g., the 340B Drug Pricing Program), create patient safety risks (e.g., certain drug importation proposals), or add to the administrative or practice burden of healthcare providers.

2240

POST-INTENSIVE CARE SYNDROME

Source: Council on Therapeutics

To recognize that multidimensional rehabilitation is essential for recovery after intensive care; further,

To support research on and dissemination of best practices in the prevention, identification, and treatment of post-intensive care syndrome (PICS) in patients of all ages; further,

To advocate that health systems support the development and implementation of interdisciplinary clinics, inclusive of pharmacists, to treat patients with PICS, including provisions for telehealth and innovative practice models to meet the needs of patients with PICS; further,

To advocate for the integration of post-ICU patient and ICU caregiver support groups; further,

To provide education on the role of the pharmacist in caring for patients with PICS.

Rationale

Post-intensive care unit (post-ICU) rehabilitation is essential for recovery after critical illness. Post-intensive care syndrome (PICS) is a conglomerate of new or worsening multidimensional impairments in physical, psychological, cognitive, and social status arising from critical illness that continue after hospital discharge. PICS is associated with high morbidity among patients discharged from ICUs, with 30-80% of patients having issues with remembering, paying attention, solving problems, or organizing and working on complex tasks.

The burden of PICS continues to grow. With only up to 50% of patients with PICS able to return to work within the first year, some are unable to return to the jobs they had before their illness and need help with activities after leaving the hospital. While PICS is widely discussed across medical disciplines, it not well defined, nor are ways to prevent and treat this disorder well researched. It is recognized that patients with PICS require a multidimentional, interdisciplinary treatment effort, including cognitive rehabilitation, mental health treatment, and intensive transitions of care interventions, as patients may be discharged on medications that should not be continued and they may need support to resume daily activities. The rapid COVID-19-related increase in patients requiring the use of ICUs has exacerbated the demand for high-quality PICS care, but the simultaneous expansion of telemedicine and other innovative patient care models has shown that rapid changes in team-based care can be achieved with the proper incentives and flexibilities.

2241

HUMAN USE OF VETERINARY PHARMACEUTICALS

Source: Council on Therapeutics

To oppose human use of pharmaceuticals approved only for veterinary use; further,

To support use of veterinary pharmaceuticals only under the supervision of a licensed veterinarian in compliance with the Animal Medicinal Drug Use Clarification Act of 1994; further,

To encourage state and federal regulatory bodies as well as other stakeholders to monitor the misuse of veterinary pharmaceuticals and, when appropriate, limit the public availability of those pharmaceuticals; further,

To educate healthcare professionals and the public about the adverse effects of human consumption of veterinary pharmaceuticals; further,

To encourage research, monitoring, and reporting on the adverse effects of human consumption of veterinary pharmaceuticals to define the public health impact of and to quantify the strain these agents place on the healthcare system.

Rationale

Medications that are formulated for veterinary use are often supplied at higher concentrations, contain compounds not safe for human use, and require specialized knowledge to administer. The prevalence of drug misuse in the veterinary setting is not well documented, but surveys of veterinarians by the Idaho Board of Veterinary Medicine, Colorado Veterinarians, and Veterinary Hospitals in Pennsylvania found that they suspect 23% of animal owners misuse veterinary medicines on themselves, their children, or friends, and that the most-documented misused drugs are opioids, benzodiazepines, and ketamine. These findings are concerning because animals often require a more potent dose of controlled substances, which can be appealing for individuals with substance use disorders, and medications are often dispensed directly to the animal owner, bypassing pharmacists, who are critical players in prescription drug misuse risk mitigation.

In the in United States, licensed veterinarians can prescribe, administer, carry, stock, and dispense medications, including veterinary-only drugs, drug compounds, and FDA-approved over-the-counter veterinary drugs. These drugs are typically veterinary formulations that are not tested for human safety or approved for human use, and the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) permits veterinarians to prescribe those drugs in an "extralabel" manner. Under AMDUCA regulations, "extralabel use" means the actual or intended use of a drug, by or on the order of a veterinarian, in a manner that is not in accordance with approved labeling (similar to off-label use in human medicine). Any deviation from labeled use, by veterinarians or lay persons, is an illegal use unless it meets all the requirements of FDA's extralabel drug-use rules. Deviations from the label include use in a species or production class not on the label and use of a different route of administration.

More recently, the COVID-19 pandemic has exacerbated human consumption of veterinary compounds, as some medications being studied for efficacy against the virus produce promising or equivocal preliminary results that are seized upon by the public and some prescribers, leading to inappropriate prescribing. For example, ASHP, APhA, and AMA have called for an immediate end to the prescribing, dispensing, and use of ivermectin for treatment of COVID-19 outside of a clinical trial. Due to the response of the medical community, many physicians and pharmacies are not writing or filling prescriptions for this medication, driving patients to purchase the animal formulation of ivermectin for human consumption. Earlier in the pandemic, a patient in Arizona consumed chloroquine phosphate meant for fish as a treatment for COVID-19 and died. The FDA, aware of the misuse of chloroquine products, issued a cautionary letter to stakeholders and worked with online marketplaces to remove the products from the market.

Finally, some veterinary compounds produce mild to life-threatening human adverse effects upon accidental or intentional exposure or ingestion. Patients exposed to or ingesting these products present to the emergency department with symptoms that range from bronchospasm, central nervous system stimulation, and miscarriage to sudden death, which

demonstrates the need for timely reporting of abuses, misuses, or accidental exposures of these agents.

2242
USE OF INTRAVENOUS DRUG PRODUCTS FOR INHALATION

This policy was superseded by ASHP policy 2516.

2243
ENROLLMENT OF UNDERREPRESENTED POPULATIONS IN CLINICAL TRIALS
Source: Council on Therapeutics

To support the enrollment of underrepresented populations in clinical trials; further,

To advocate that drug product manufacturers and researchers conduct and report outcomes of pharmacokinetic, pharmacodynamic, and pharmacogenomic research in underrepresented populations to facilitate safe and effective dosing of medications for these patient populations; further,

To advocate that if such research considers age, sex, gender, ethnicity, or race, the reason for such consideration be based on validated ethical or scientific reasons and be specified in the research protocol; further,

To foster the use and development of postmarketing research strategies to support the safe and effective use of drug products for approved and off-label indications for underrepresented patient populations; further,

To advocate that pharmacists should be involved in the design of clinical trials to provide guidance on drug dosing, administration, and monitoring in all patient populations.

This policy supersedes ASHP policy 1723.

Rationale
Pregnant women, fetuses, neonates, children, members of racial or ethnic minority group and the elderly are populations in which the pharmacokinetic, pharmacodynamic, and pharmacogenomic properties of medications may differ from those of people typically enrolled in clinical trials. These differences can dramatically alter the behavior of drugs, producing supra- or subtherapeutic levels, which may result in adverse effects. While there has been legislation that provides incentives for drug manufacturers to study these effects, many drugs already approved by the FDA do not have such information or robust outcomes reporting for these at-risk populations. The need for this guidance is supported by the complexity of dosing for these patients, which varies based on medication- and patient-specific characteristics. There is a paucity of research in these patient populations, which is similar to the lack of preapproval studies in obese patients. ASHP also encourages independent clinical and practice-based

research in which pharmacists are involved in the study design to further define clinical use of medications in the treatment of these patients, as well as clinician reporting of patient experience via published articles and clinical registries.

2244
PEDIATRIC DOSAGE FORMS
Source: Council on Therapeutics

To support research on and development of pediatric-specific drug formulations; further,

To encourage manufacturers to develop formulations suitable for pediatric administration during research that includes pediatric patients; further,

To encourage manufacturers of off-patent medications that are used in pediatric patients to develop formulations suitable for pediatric administration; further,

To advocate that manufacturers comparably price a newly developed pediatric-specific commercial product to that of its extemporaneously prepared formulation; further,

To educate prescribers and caregivers regarding the nuances of pediatric drug administration to ensure the availability of an appropriate dosage form is considered when selecting and administering safe and effective therapies for a pediatric patient.

This policy supersedes ASHP policy 9707.

Rationale

Pediatric patients are at high risk for medication errors because so few formulations are created for them. Challenges to pediatric dosage development include insufficient background information on the drug molecule in the target population, issues with safety and tolerability of excipients, taste-masking issues, technology requirements, the risks involved in clinical trials, small market size and low profitability, and lack of regulatory clarity.

To ensure that the proper dose is administered, different routes of administration, dosage forms, and strengths may be required. Because many existing formulations are not suitable for children, many hospitals and health systems will use components to extemporaneously prepare a formulation that provides a measurable, stable, and consistent delivery of a needed medication. The concentration and availability of these formulations, most often in the form of suspensions and solutions, may also vary in storage requirements, bioavailability, and palatability, all which can affect patient tolerability and adherence.

Furthermore, since many medications are needed for a relatively small patient population, often only a few commercial products are manufactured, resulting in the need for compounding. As a result, research is often stymied in the pediatric patient population as well, since compounding a medication may introduce variables that may affect results in unpredictable ways.

Boards of pharmacy have also recognized the safety issues surrounding variability in stability and concentrations of the same drug, and many have laws in place that prohibit the extemporaneous compounding of drugs in concentrations that are commercially available.

As pediatric patients have different tolerability to excipients, organ development, taste preferences, and swallowing abilities as they age, it is essential that pharmacists are a part of the team that determines a medication regimen. It is also important that caregivers are taught to properly measure, store, and administer pediatric formulations as a part of patient care.

2245
SUBSTANCE USE DISORDER
Source: Council on Therapeutics

To affirm that a patient with a substance use disorder (SUD) has a chronic condition with associated neurodevelopmental, physiologic, and psychosocial changes; further,

To recognize that dehumanizing language and stigmatization regarding SUD and persons who use drugs (PWUD) create barriers to healthcare access and result in poor clinical outcomes; further,

To recognize the disproportionately harmful health impact that criminalization and policing practices related to SUD and PWUD have had on communities; further,

To advocate for destigmatization efforts and elimination of barriers to care for SUD and PWUD; further,

To support risk mitigation and harm reduction strategies, including syringe services programs, recognizing the roles they have in public health efforts to reduce infectious disease burden, improve access to healthcare, improve patient trust, and reduce expenditures; further,

To advocate for expansion of comprehensive medication management services provided by pharmacists for prevention, treatment, and recovery services within the interprofessional care team and throughout the continuum of care; further,

To support pharmacists leading community-based comprehensive preventive health and treatment programs; further,

To encourage longitudinal SUD training in didactic pharmacy curricula, starting with an early initiation of education; use of evidence-based practices, including risk mitigation, harm reduction, and destigmatizing communication strategies; and increasing experiential education pertaining to SUD; further,

To support and foster standardized education and training on SUD, including dispelling common misconceptions to the pharmacy workforce and other healthcare professionals.

This policy supersedes ASHP policy 9711.

This policy was revised in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

Rationale

Substance use disorder (SUD) is a public health crisis that has grown to epidemic levels in the United States over the past 30 years. The Department of Health and Human Services recognized it as a public health emergency in 2017. In 2019, over 70,000 people died from drug overdoses, and between June 2019 and June 2020, overdoses of synthetic opioids caused over 48,000 deaths. Additionally, the Centers for Disease Control and Prevention (CDC) estimates that the economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement. The National Academy of Medicine and the Department of Health and Human Services identify several populations that are at risk for SUD, including justice-involved populations; those living in rural areas; people who inject drugs; pregnant patients; children born to SUD; and those with lower incomes, insecure housing, and lacking access to health insurance. Additionally, researchers have demonstrated links between the increase in opioid overdoses and the rate of opioid prescriptions, particularly in populations in which overdoses had not been seen before. Age-adjusted rates of opioid overdose deaths from 1990 to 2017 have increased sixfold among Whites, climbed from 3.5 to 6.8 overdoses per 100,000 people among Hispanics, and among Blacks has increased from 3.5 to 12.9 per 100,000 people in the U.S. The age-adjusted rate of overdose deaths increased by 31% from 2019 (21.6 per 100,000) to 2020 (28.3 per 100,000). When considering infectious diseases, SUD had also been cited as a cause for a tripling of hepatitis C cases from 2010 to 2017 as well as increases in hepatitis B, human immunodeficiency virus, bacterial, and fungal bloodstream infections, as well as sexually transmitted infections and endocarditis.

SUD is a chronic condition with associated neurological and physiological changes, not a personal choice. Dehumanizing language and stigmatization regarding SUD and people who use drugs (PWUD) create barriers to healthcare access and result in poor clinical outcomes. In addition, criminalization and policing practices related to SUD and PWUD have disproportionately harmful health impact on communities of color.

The best approach to managing SUD is a multifaceted one that requires involvement at the community, hospital and health system, legislative, government, and provider levels. Programs must also include stakeholders from these levels at the planning, implementation, and enduring service stages to optimize uptake, adoption, and sustainability. Pharmacists are an essential team member as part of interprofessional teams and providing comprehensive medication management (CMM) for patients with SUD. Pharmacists are integrated as key team members across the continuum of care from community pharmacies, health systems, and ambulatory care settings. Clear communication and coordination are also crucial so that successes and failures can be assessed, modified, or discontinued to suit the goals of prevention, treatment, harm reduction, and recovery.

Harm reduction strategies including syringe service programs have proven effective, not only in preventing deaths from injectable drug overdoses and infections but also as a site of care for providing such additional services as vaccinations, testing, referral to infectious disease

care and substance use treatment, and access to and disposal of needles, syringes, and other injection equipment. Elimination of barriers to sterile syringe access, including discouraging prescription or logbook requirements and providing methods of syringe disposal, promotes access to healthcare.

Education and tools for the pharmacy workforce that assist in supporting the needs of PWUD and patients with SUD should also incorporate specifics about destigmatization, person-first language, harm reduction strategies, evidence-based practices, and social determinants of health. Education should include efforts to recognize bias and misinformation, as these contribute to the stigma that serves as a major barrier in treating SUD.

2246
AUTOVERIFICATION OF MEDICATION ORDERS
Source: Council on Pharmacy Practice

To recognize the importance of pharmacist verification of medication orders, and the important role pharmacists have in developing and implementing systems for autoverification of select medication orders; further,

To recognize that autoverification of select medication orders under institution-guided criteria can help expand access to pharmacist patient care; further,

To discourage implementation of autoverification as a means to reduce pharmacist hours; further,

To promote and disseminate research, standards, and best practices on the safety and appropriateness of autoverification of medication orders; further,

To encourage healthcare organizations to develop policies, procedures, and guidelines to determine which care settings, medications, and patient populations are appropriate candidates for autoverification of select medication orders in order to support the implementation of autoverification models for those circumstances; further,

To advocate for regulations and accreditation standards that permit autoverification of select medication orders in circumstances in which it has proven safe.

Rationale
The purpose of autoverification of medication orders is to improve medication-use safety and quality and more efficiently and effectively utilize pharmacy personnel. When autoverification functionality is used, medications ordered via computerized provider order entry (CPOE) are evaluated against predetermined parameters in electronic health records (EHRs). Orders that fall within set parameters are autoverified and available to be administered; those that fall outside the parameters require review by a pharmacist. Critical values, patient history, and clinical decision support tools are used to create the algorithm that determines whether a medication order is reviewed. The healthcare community has long recognized the importance of pharmacist verification of medication orders, and that role is no less important when

developing and implementing systems for autoverification of select medication orders. Recent experience has shown that autoverification of medication orders, when done safely and efficiently, can allow more effective use of pharmacist resources by expanding access to pharmacist patient care.

In the 2016 ASHP survey of health systems, 51.6% of hospitals utilized the autoverification functionality in the CPOE system; this rose to 62.2% utilization by the 2019 survey. Of the health systems surveyed in 2019 that utilized autoverification, 52.9% autoverified in selected areas (e.g., all emergency department orders, perioperative orders); 50.2% identified selected medications for autoverification in specific areas (e.g., pain medications in the emergency department); and 17.1% of hospitals had autoverification for select medications (e.g., flushes, influenza vaccine) throughout the hospital. Between 2016 and 2019, overall use of autoverification and autoverification of select medications throughout the hospital and for select medications in certain areas increased. In contrast, the use of autoverification for all medications in a select area of the hospital decreased from 2016 to 2019.

According to the ASHP survey, the most commonly cited reasons for not implementing autoverification were patient safety concerns (40.4%); "our hospital has not discussed this" (23.2%); and requirements by law, regulation, or accreditors (22.9%). Less common reasons were that EHR software does not have the functionality (6.9%) and EHR limitations on criteria used for autoverification (4.6%). Healthcare professionals have also expressed a concern about medication optimization: medication appropriateness may not be the same as medication optimization. Pharmacy directors have also stated that staffing determinations based on pharmacist workload and other measurable metrics must be carefully considered; autoverification should not be a mechanism for reducing pharmacist hours, which would negate the potential to expand patient care services.

2247
PHARMACY WORKFORCE'S ROLE IN VACCINATION

This policy was superseded by ASHP policy 2614.

2248
HEALTH-SYSTEM USE OF DRUG PRODUCTS PROVIDED BY OUTSIDE SOURCES

This policy was superseded by ASHP policy 2309.

2249
SCREENING FOR SOCIAL DETERMINANTS OF HEALTH

This policy was superseded by ASHP policy 2310.

2250
ACCESS TO REPRODUCTIVE HEALTH SERVICES

This policy was superseded by ASHP policy 2426.

2251
QUALIFICATIONS AND COMPETENCIES REQUIRED TO PRESCRIBE MEDICATIONS

This policy was superseded by ASHP policy 2423.

2252
STANDARD DRUG ADMINISTRATION SCHEDULES
Source: Council on Pharmacy Management

To support the principle that standard medication administration times should be based primarily on optimal pharmacotherapeutics and safe medication administration practices, with secondary consideration of workload, caregiver preference, patient preference, and logistical issues; further,

To encourage the development of hospital-specific or health-system-specific standard administration times through an interdisciplinary process coordinated by the pharmacy; further,

To encourage information technology vendors to adopt these principles in system design while allowing flexibility to meet site-specific patient needs.

This policy supersedes ASHP policy 0707.

Rationale
Administering medications at the right time is one of the original "five rights" of medication administration. To achieve the best patient outcomes, standard medication administration times should be based primarily on optimal pharmacotherapeutics and safe medication administration practices. Standard drug administration times help prevent over- or under-dosing of patient medications, improve communication between disciplines, and reduce workload and potential for errors. For example, appropriate timing of laboratory blood draws and other bedside monitoring is critical for obtaining accurate patient data, and standard administration times decrease the chance for miscommunication.

Although considerations such as workload, caregiver and patient preference, and logistical issues cannot be ignored, they should be only secondary considerations in the interprofessional development of hospital- or health-system-specific standard administration times, a process best coordinated by the pharmacy, as medication-use experts. Healthcare systems should establish interdisciplinary policies and procedures related to standard drug administration times for all practitioners responsible for administering medications. Such policies can help concentrate staffing, optimize workflows, and mitigate potential medication safety gaps.

To promote adoption and avoid dangerous work-arounds, standardization of drug administration times and pertinent monitoring times should be built into workflows to the extent possible. Healthcare information technology vendors should design these systems to

optimize the safety and operational aspects of the medication-use process while allowing for necessary site-specific individualization.

2253
UNIT DOSE PACKAGING AVAILABILITY

This policy was superseded by ASHP policy 2407.

2254
PAIN MANAGEMENT
Source: Council on Therapeutics

To advocate for improved access to equitable and patient-centered pain care for all patient populations; further,

To advocate that pharmacists actively participate in the development and implementation of multimodal pain management stewardship programs, policies, protocols, and research; further,

To support pharmacist participation and collaboration in interprofessional healthcare teams for selecting appropriate drug therapy regimens, educating patients and caregivers, monitoring patients, and continually assessing outcomes of pain management therapy; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of medication use that can increase the risk of serious adverse events; further,

To foster the development of educational resources on multimodal pain therapy, substance use disorder, and prevention of adverse effects; further,

To encourage and support the education of the pharmacy workforce and other healthcare providers regarding the principles of multimodal pain management and substance use disorder, including approaches to reduce stigma, improve access to care, and improve general health and well-being.

This policy supersedes ASHP policy 1722.

Rationale
Currently there are over 100 million adults in the United States affected by acute and chronic pain. ASHP emphasizes the importance of individualized patient-centered care in the diagnosis and treatment of acute and chronic pain. A multimodal and interprofessional team approach should be implemented to target outcomes that focus on improvement in function and quality of life. Pain management requires ongoing assessment of the care plan, and pharmacists are well poised to fill a key role in appropriate treatment and optimization of pain with multimodal treatment strategies. Pain therapies, in particular, have the potential for serious adverse

events. ASHP is cognizant of the delicate balance between undertreatment of pain and barriers that can occur with the implementation of strategies that restrict or limit access to treatment.

ASHP advocates increased awareness of the risks of pain therapies, and encourages pharmacists to take a lead role in implementing harm reduction strategies through individual clinician efforts (e.g., prescriber and patient education on medication risk, ensuring access to naloxone when applicable) and system-based approaches (e.g., use of information technology systems to monitor for trends that suggest unsafe prescribing or patient use). ASHP also supports the inclusion of pharmacists as key members of interprofessional care teams that specialize in pain management and stewardship. Finally, ASHP advocates for the inclusion of pharmacists in pain research as pharmacists are well poised to fill a key role in research initiatives across the spectrum of pain management.

2255

THERAPEUTIC INDICATION FOR PRESCRIBED MEDICATIONS

Source: Council on Therapeutics

To advocate that all healthcare professionals involved in a patient's care have immediate access to the intended therapeutic purpose of prescribed medications in order to ensure safe and effective medication use; further,

To encourage all healthcare settings to optimize the use of clinical decision support systems with indications-based prescribing; further,

To advocate for implementation of a universal, interoperable coding system for labeled therapeutic indications that can be integrated throughout the medication-use process, enabling optimum clinical workflows and decision support functionality; further,

To advocate for federal and state laws and regulations to include diagnosis-based indication(s) on medication order(s) and prescription(s), and to allow the withholding of indication on medication prescription labels when patient privacy risks outweigh benefits.

This policy supersedes ASHP policies 0305 and 2123.

Rationale

The Joint Commission (TJC) *Comprehensive Accreditation Manual for Hospitals* includes standards that specify that healthcare professionals involved in the medication-use process should have access to and use patient and medication information important in the prescribing, dispensing, administration, and monitoring of medications. In addition to its accreditation standards, TJC's 2022 national patient safety goals for hospitals include improved staff communication (getting important test results to the right staff person on time) and safe use of medications (recording and passing along correct information about a patient's medications). It is important to recognize that medication indications are used not only by pharmacists, nurses, and physicians but also other important members of the healthcare team, including but not limited to respiratory therapists, social workers, physical therapists, and others who utilize this information to guide patient care.

The Institue for Safe Medication Practices (ISMP) has offered recommendations, including clearly specified dosage form, drug strength, and complete directions on all prescriptions; indication on all outpatient prescriptions and on inpatient PRN orders; with name pairs known to be problematic, reducing the potential for confusion by writing prescriptions using both the brand and generic names; listing both brand and generic names on medication administration records and automated dispensing cabinet computer screens; and, whenever possible, determining the purpose of the medication before dispensing or administering it.

Several well-known studies have demonstrated reductions in wrong-patient errors and adverse events with the inclusion of indication on the prescription order. In 2010, Equale (*Drug Saf*. 2010; 33: 559-67) described the accuracy of indication information in electronic health records (EHRs). Galanter (*J Am Med Inform Assoc.* 2013;20:477–81) focused on preventing wrong-patient medication errors with the use of indication-based prescribing. Indication-based alerts resulted in an interception rate of 0.25 interceptions per 1000 alerts. One team of investigators conducted a trial of inpatient indication-based prescribing using computerized provider order entry with drugs commonly used off-label (*Appl Clin Inf.* 2011;2:94–103). Off-label prescription drug use without strong scientific evidence has also been associated with increased rates of adverse drug events (*JAMA Internal Medicine* 2016; 176:55-63). The authors suggested that use of and proper documentation of therapeutic indication can help improve surveillance and safety and decrease risk. This additional safety check is critical in limiting errors due to wrong and/or look-alike/sound-alike medications. In addition to error prevention, indication-based prescribing can improve patient engagement, patient education, and provide pharmacists with information that may be necessary for prior authorizations or claim processing. To foster successful implementation of indication-based prescribing in EHRs, several authors have documented the success of starting electronic prescriptions with a problem or indication list first before medications can be selected to reduce time and medication errors while maintaining clinician satisfaction.

In several countries, including Canada and Spain, the EHR includes indication as part of comprehensive documentation. ASHP first developed official policy on the importance of pharmacists' access to indications in 1993. In 1996, the National Coordinating Council for Medication Error Reporting and Prevention recommended including the purpose of medication orders because of concerns about safety, unless considered inappropriate by the prescribers. In 1999, the Institute for Safe Medication Practices recommended including the purpose of prescribing on all written orders. In 2004, the National Association of Boards of Pharmacy (NABP) approved a resolution encouraging national and state medical associations to support legislative and regulatory efforts to require prescribers to include indications for all oral, written, and electronically transmitted prescriptions. In 2012, the United States Pharmacopeia made amendments to the standards for prescription container labeling to include "purpose-for-use" language. In 2015, the National Council of Prescription Drug Plans drafted language to recommend diagnosis and SNOMED indication be sent with any prescription. Despite these recommendations, few states have adopted any laws requiring inclusion of indication on all medication orders or prescriptions.

More recently, ISMP has recommended updating the five "rights" of patient, drug, dose, time, and route to include a sixth "right": the right indication. They cite benefits of indication-based prescribing as (1) helping to prevent errors by narrowing medication choices; (2)

empowering and educating patients, which helps increase patient adherence; (3) improving communications among the healthcare team, patients, and families; (4) facilitating medication reconciliation; (5) helping prescribers select the best medications for their patients; and (6) aiding in measuring drug effectiveness and learning from off-label use.

ASHP also has policy on off-label use that encourages the use of the three authoritative drug compendia, peer-reviewed literature, and consultation with experts in research and clinical practice to make specific coverage decisions. ASHP supports informed decision-making that promotes third-party reimbursement for drug products approved by the Food and Drug Administration (FDA) appropriately prescribed for unlabeled uses.

Implementation and use of interoperable clinical decision support systems with indications-based prescribing would be eased by agreement on a universal coding system for labeled therapeutic indications. The FDA, the National Council for Prescription Drug Programs, and other organizations should work collaboratively to select and implement such a system.

Furthermore, ASHP recognizes that there are circumstances in which it would be inappropriate to include diagnosis on a medication order, and encourages such exceptions in federal and state laws and regulations. One clear example of such an exception would be six protected categories of drugs (antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics), as including these may inadvertently result in breaches in patient privacy.

2021 Policy Positions

2101
DIRECT-TO-CONSUMER CLINICAL GENETIC TESTS

This policy was superseded by ASHP policy 2607.

2102
USE OF ANTIMICROBIALS IN SURGICAL WOUNDS AND PROCEDURES
Source: Council on Therapeutics

To oppose the use of antimicrobial agents in surgical wounds and procedures not based on evidence; further,

To encourage further research to assess the efficacy, safety, and risks of resistance development of antimicrobials used in surgical wounds and procedures; further,

To foster evidence-based recommendations on the use of antimicrobial agents in surgical wounds and procedures and on how to prepare those agents according to appropriate sterile practices; further,

To advocate that antimicrobial stewardship programs review and monitor the use of antimicrobial agents in surgical wounds and procedures; further,

To encourage pharmacists to educate prescribers on adverse outcomes and reactions associated with the use of antimicrobials in surgical wounds and procedures; further,

To support clear and consistent documentation of antimicrobial agents used for surgical wounds and procedures in the electronic health record.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
The addition of antimicrobials to irrigation solutions during surgical procedures to prevent surgical site infections has been a long-standing yet controversial surgical practice. Antibiotics are the most common additives to surgical irrigation fluids, but recent data shows no clinical benefit compared with saline irrigation, likely due to the mechanism of antibiotics needing a longer exposure time than is allowed during irrigation to exert their antimicrobial effects. Further, the use of topical antibiotics in the open surgical wound is often not monitored and has not been subject to any evidence-based standardization of care. When mixing practices were surveyed across hospitals and health systems, most respondents from facilities in which the solutions were mixed in the operating room (OR) were unaware of who was doing the

mixing; of those who were aware, surgical scrub technicians or nurses were the individuals most often reported to be doing the mixing.

Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, Surgical Infection Society, American Society of Health-System Pharmacists, World Health Organization, American College of Surgeons, and the International Consensus on Orthopedic Infections all recommend against the use of topical antimicrobial irrigation. Despite these recommendations, this practice is still prevalent throughout hospitals and health systems. The use of topical antimicrobials in surgical wounds remains widespread. Use persists even with a paucity of evidence supporting any added benefit and some evidence suggests they may pose potential risks to patient safety and public health. Neither the Joint Commission nor the Centers for Medicare and Medicaid Services have directly addressed the use of topical antibiotics.

Due to the risks of topical use and the lack of evidence supporting it, this practice should be an essential part of antimicrobial stewardship programs. All antibiotics sent from pharmacy to the OR, including those intended for topical use, should be documented clearly in the electronic health record, including type and amount used, and should be part of comprehensive surveillance for patient outcomes for surgical site infections, allergic reactions, resistance trends, management of shortages, and toxicity adverse events related to topical surgical administration of antibiotics. The Joint Commission Standard MM.09.01.01 requires hospitals to strengthen their Antimicrobial Stewardship Programs (ASP) by prioritizing ASP staffing and following nationally recognized guidelines to monitor and improve the use of antibiotics. This policy supports the reduction of antimicrobial use in irrigation solutions during surgical procedures and the development of standardized protocols for their use.

2103
PROFESSIONAL DEVELOPMENT AS A RETENTION TOOL

This policy was superseded by ASHP policy 2501.

2104
FOSTERING LEADERSHIP DEVELOPMENT

This policy was discontinued in 2026.

2105
INTERPROFESSIONAL EDUCATION AND TRAINING
Source: Council on Education and Workforce Development

To advocate for interprofessional education as a component of didactic and experiential education in pharmacy workforce education and training programs; further,

To support interprofessional education, mentorship, and professional development for healthcare professionals and learners; further,

To urge collaboration with other healthcare professionals and executives in the development of education and training models for interprofessional, team-based, patient-centered care; further,

To foster documentation and dissemination of outcomes achieved as a result of interprofessional education of healthcare professionals.

This policy supersedes ASHP policy 1612.

This policy was reviewed in 2025 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

Pharmacist involvement in team-based patient care improves medication-use safety and quality and reduces healthcare costs. For patient-care teams to be effective, they must possess unique skills that facilitate effective team-based interactions. Some pharmacists are exposed to team-based care models through interprofessional education and interaction with students of other disciplines when they are student pharmacists. Some colleges of pharmacy have very effective interprofessional didactic courses that include medical, pharmacy, nursing, and other healthcare professional students. Additionally, most experiential rotations involve interaction with other members of the healthcare team and help students of all disciplines learn about the expertise of other team members. However, not all colleges and schools are effective in providing interprofessional education that facilitates team-based patient care. The reasons vary, but may include differences in teaching philosophies or a lack of access to other health professional schools at the university or campus.

The Hospital Care Collaborative (HCC) has described common principles for team-based care. The HCC principles recognize the knowledge, talent, and professionalism of all team members and support role delineation, collaboration, communication, and the accountability of individual team members and the entire team. The HCC principles note that collaboration of the healthcare team can lead to improved systems and processes that provide care more efficiently and result in better patient outcomes. The HCC states that current undergraduate and postgraduate professional education of team members is inadequate to promote true team functions.

This policy is aligned with the ACPE Standards 2025, which emphasize the importance of interprofessional team education in preparing practice-ready graduates. The standards call for interprofessional didactic and experiential curricula, thereby fostering collaboration and improving the quality of patient care. Interprofessional education (IPE) activities, whether delivered through direct patient care experiences or simulations, help students develop an understanding of the competencies, abilities, and scope of practice of other healthcare professionals. These activities should be guided by the Interprofessional Education Collaborative (IPEC) Core Competencies for Interprofessional Collaborative Practice, which provides a framework focused on values and ethics, roles and responsibilities, interprofessional

communication, and teamwork. Embedding IPE throughout pharmacy education and training ensures that pharmacists are equipped to thrive in collaborative, team-based care environments that drive better health outcomes.

ASHP believes that interprofessional education is important not only for student pharmacists but also throughout one's professional career. Similarly, it is important for other professionals on the team so that collaboration and synergistic relationships can develop. Failure to establish these collaborative working relationships early in one's career can result in poor interactions in years to come. A positive working relationship, including interprofessional mentorship, with physicians and nurses is productive, while a bad working relationship can be detrimental to all parties, including patients.

2106

PHARMACY EDUCATION AND TRAINING MODELS

Source: Council on Education and Workforce Development

To promote pharmacy education and training models that: (1) provide experiential and residency training in interprofessional patient care; (2) use the knowledge, skills, and abilities of students and residents in providing direct patient care; and (3) promote use of innovative and contemporary learning models; further,

To encourage the collaboration between colleges of pharmacy and residency programs with accreditation agencies on innovative education and training models; further,

To support the assessment and dissemination of the impact of these pharmacy education and training models on the quality of learner experiences and patient care outcomes.

This policy supersedes ASHP policy 1829.

This policy was reviewed in 2025 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

Pharmacy training models are continuously evolving. The ideal training model includes characteristics such as flexibility to be useful in all patient care settings, providing patient care through an interprofessional team, and allowing team members to practice at the top of their licenses. Many healthcare organizations are successfully employing innovative and contemporary training models. One such model is the layered learning approach to residency and student pharmacist training, in which a pharmacist oversees multiple residents, student pharmacists, and sometimes generalist pharmacists. Each member of this pharmacy team is integrated into a patient care team, with specific roles and responsibilities, but each also has accountability to the supervising pharmacist. The layered learning model may be more practical in larger institutions, however, because they have more staff, residents, and student pharmacists than smaller hospitals. ASHP recognizes that it is important to individualize the training program to the practice site and its corresponding practice model and supports the

assessment of the impact of these pharmacy training models on the quality of learner experiences and patient care outcomes. Training models should prioritize instilling a strong sense of accountability to patients and their medication-related outcomes, preparing the next generation of pharmacists for independent practice. It's crucial to account for preceptors' capacity, balancing their ability to fulfill job responsibilities while effectively mentoring learners within a layered learning model. Additionally, identifying pharmacy-specific metrics and indicators is essential to evaluate the impact of education and training programs on improved medication-related outcomes, ensuring that these models directly contribute to enhancing patient care.

2107
PHARMACY INTERNSHIPS
Source: Council on Education and Workforce Development

To encourage state boards of pharmacy to adopt the standardized pharmacy internship hour requirements recommended in the National Association of Board of Pharmacy Model Rules for Pharmacy Interns; further,

To support structured requirements, goals, and objectives for pharmacy internship experiences, in alignment with requirements for introductory and advanced pharmacy practice experiences; further,

To promote new staffing models that offer expanded roles for pharmacy interns, providing work experiences that build upon their knowledge and help them develop as future pharmacists.

This policy supersedes ASHP policy 1110.

This policy was reviewed in 2025 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale
State boards of pharmacy vary with respect to the pharmacy internship requirement. Some state boards of pharmacy allow internship hour requirements to be completed as part of the pharmacy curriculum. Other state boards of pharmacy require students to complete internship hours outside of the pharmacy curriculum.

Inconsistencies in internship requirements among states have had significant implications for pharmacy residents. Pharmacy graduates from a state with minimal internship requirements may relocate to a state post-graduation for employment with stringent internship requirements, sometimes delaying their eligibility for licensure until they can complete internship requirements. Greater standardization would prevent these issues as new graduates relocate to other states.

The National Association of Boards of Pharmacy Model Rules for Pharmacy Interns requirements coincide with the ACPE Accreditation Standards and Guidelines. In the rule,

boards of pharmacy are strongly encouraged to utilize these Accreditation Standards and Guidelines as a basis for the establishment and revision of board standards for pharmacy practice experiences.

2108
PATIENT EXPERIENCE
Source: Council on Pharmacy Management

To encourage the pharmacy workforce to evaluate their practice settings for opportunities to improve the experience patients have with healthcare services and with the outcomes of their drug therapy; further,

To educate the pharmacy workforce about the relationship between patient experience and outcomes; further,

To develop or adopt tools that will (1) provide a system for monitoring trends in the quality of pharmacy services to patients, (2) increase recognition of the value of pharmacy services, and (3) provide a basis for making improvements in the process and outcomes of pharmacy services in efforts to engage patients and improve their experience; further,

To promote use of interactive patient technology (e.g., self-learning teaching resources) to augment patient experience and help prioritize and improve the effectiveness of pharmacy services; further,

To facilitate a dialogue with and encourage education of patient experience database vendors to include the value of pharmacy services in the patient experience.

This policy supersedes ASHP policy 1616.

Rationale

A major component of quality of healthcare is patient satisfaction (often referred to as "the patient experience"), which is critical to how well patients respond and adhere to healthcare. Research has identified a clear link between patient outcomes and a positive patient experience. Additionally, the patient experience is a key determinant of quality of care and an important component of pay-for-performance metrics. Pharmacy leaders need to continually assess how pharmacists and pharmacy services support an improved patient experience with their care across the continuum of practice sites, including how pharmacists contribute to team-based care.

A study detailed in a white paper by The Beryl Institute found that hospitals using interactive technology to communicate with patients saw improvement in patient satisfaction scores. Interactive patient technology gives patients faster access to hospital staff and services, including access to health education information about the care they receive and the steps they need to take after discharge. Hospitals using interactive technology realize tangible benefits, which translate into significant, measurable improvements in patient outcomes, the hospital's

financial performance, and greater patient engagement, making for an exceptional patient experience.

2109
PHARMACY SERVICES FOR UNINSURED AND UNDERINSURED PATIENTS
Source: Council on Pharmacy Management

To support the principle that all patients have the right to receive care from pharmacists; further,

To declare that pharmacists should play a leadership role in ensuring access to pharmacists' services for indigent or low-income patients who lack insurance coverage or are underinsured; further,

To encourage the pharmacy workforce to work with organizational patient assistance, case management, and care coordination teams to ensure seamless patient care transitions for all patients, including uninsured and underinsured patients; further,

To advocate better collaboration among health systems, community health centers, state and county health departments, and the federal Health Resources and Services Administration in identifying and addressing the needs of indigent and low-income patients who lack insurance coverage or are underinsured.

This policy supersedes ASHP policy 0101.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Consistent with ASHP Practice Advancement Initiative 2030 themes for change, patients must have access to: 1) a pharmacist in all settings of care; 2) a collaborative, interprofessional care team that coordinates seamless, convenient, and cost-effective care transitions; and 3) a collaborative, interprofessional care team that identifies, assesses, and resolves barriers to medication access, adherence, and health literacy. These principles apply even for patients who lack insurance coverage or are underinsured. Pharmacists and pharmacy technicians should take leadership roles in ensuring access to pharmacists' services for these patients, working with organizational patient assistance, case management, and care coordination teams to ensure seamless patient care transitions for this vulnerable population. Further, community health centers, state and county health departments, and federal agencies should collaborate in identifying and addressing the needs of these patients.

2110

PATIENT ACCESS TO PHARMACY SERVICES IN SMALL AND RURAL HOSPITALS

Source: Council on Pharmacy Practice

To advocate that critical-access hospitals (CAHs) and small and rural hospitals meet national medication management and patient safety standards, regardless of size or location; further,

To provide resources and tools to assist pharmacists who provide services to CAHs and small and rural hospitals in meeting standards related to safe medication use; further,

To promote allocation policies that address the unique challenges faced by CAHs and small and rural hospital pharmacies in procuring medications and supplies.

This policy supersedes ASHP policy 1022.

Rationale

State legislation has sometimes exempted small or rural hospitals from requirements applied to others. For example, Texas has exempted hospitals with fifty or fewer beds in remote locations from requiring prospective medication order review by a pharmacist. Pharmacist prospective order review is a well-supported safety practice that is required by the Centers for Medicare & Medicaid Services Conditions of Participation, Joint Commission accreditation standards for hospitals, and in state practice acts. ASHP policy supports pharmacist prospective order review as a minimum standard for pharmacies in hospitals and a consistent standard of care for all patients regardless of where that care is provided. Furthermore, ASHP encourages under-resourced facilities, including rural settings, to employ alternative strategies, such as expanded use of telehealth and pharmacy technicians, to meet the challenges they face. In addition, ASHP recognizes that one of the challenges faced by these hospital is industry allocation practices (e.g, allocations based on previous purchases) and restrictive distribution criteria (e.g., requiring specific facilities, equipment, or staff) that reduce access to medications and other resources in times of critical need. ASHP advocates that those allocation practices be made more flexible to meet patient needs, especially in times of crisis.

2111

PHARMACIST INVOLVEMENT IN THE STRATEGIC NATIONAL STOCKPILE

Source: Council on Public Policy

To advocate for the inclusion of pharmacist expertise in the development and maintenance of the Strategic National Stockpile (SNS); further,

To advocate for transparency and improvement of SNS processes, including standardization of the request process and enhanced periodic review of SNS contents; further,

To advocate that pharmacists lead distribution of medications and related supplies requested from the SNS.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The depletion of the Strategic National Stockpile (SNS) during the COVID-19 pandemic presents an opportunity to significantly improve SNS operations. Pharmacists should be engaged in determining which medications and supplies are included in the SNS, as well as how to maintain quality and ensure the stock remains up to date. Further, pharmacists should be engaged to help determine how to address the financial and practical implications of making certain dosage forms available for patient use, including when those forms are not readily usable as-is and need to be modified for use (e.g., atropine dosage forms).

At the outset of the pandemic, hospitals and health systems did not have a clear mechanism to make requests to the SNS for both medications and supplies. For this reason, the process varied among states, where even sharing tips and best practices between providers was not always helpful. The SNS should increase transparency regarding stock and should implement a single consistent process for making requests. Providers should not have to devote inordinate amounts of time to making SNS requests, including in the midst of an emergency, and there should be a mechanism to quickly check the status of SNS requests.

Finally, to streamline processes, the SNS should have a standard distribution logistics process for medications and related supplies centered on pharmacists. Ensuring that pharmacists receive distributions of medications and related supplies will allow them time to prepare storage space (e.g., freezer space for remdesivir) and ensure proper storage and handling of products.

2112

MEDICATION PRICE-GOUGING LAWS

Source: Council on Public Policy

To advocate for price-gouging laws that include medications.

This policy supersedes ASHP policy 1622.

Rationale

Price gouging, whether due to shortages or other causes, can result in trafficking in counterfeit and diverted products through gray-market distributors, which can ultimately result in adverse patient outcomes and increased healthcare costs. Strategies, including specific legislation with stiff penalties for price gouging on medications, are needed to deter these activities. Thirty-one states currently have price-gouging laws that prohibit price markups on life-sustaining products (e.g., food, water, fuel), usually during a time of disaster, natural or otherwise. ASHP advocates for laws that specifically address price gouging on medications on medications at any time, rather than predicating action on a triggering event, such as a disaster or shortage.

2113
PHARMACOGENOMICS

This policy was superseded by ASHP policy 2308.

2114
FDA REQUIREMENT FOR DOSE-RESPONSE INFORMATION
Source: Council on Therapeutics

To advocate that the Food and Drug Administration require drug product manufacturers to (1) identify average dose-response curves for desirable and undesirable effects, and make this information available to healthcare providers; and (2) publish dose-response information, to the extent possible, on factors that lead to differences in pharmacokinetics and pharmacodynamics among individuals; further,

To encourage drug product manufacturers to conduct studies on and publicly report minimum effective dose data.

This policy supersedes ASHP policy 0602.

Rationale
Knowledge of the relationships among dose, drug concentration in blood, and clinical response (effectiveness and undesirable effects) is important for the safe and effective use of drugs. This information can help identify an appropriate starting dose, titration of dosing, and identification of doses that would produce unacceptable side effects or be unlikely to provide added benefit. Important to this understanding is the analysis of the dose–response relationship, particularly with drug levels above the ED50, the dose that provides approximately 50% of the maximum possible drug effect, as efficacy increases only slightly, while adverse effects increase.

Manufacturer dose-finding studies sometimes provide a dose estimate and the range of a drug's population ED50, but this information appears to have little bearing on prescribing. Many are either not aware of this measurement or do not consult the information after the drug is marketed with recommended dosage guidelines. Often overlooked is the variation in individual ED50 depending on body size, pharmacokinetics, and pharmacodynamics. This variation in ED50 may cause the effective dose to be lower in many patients compared with participants in clinical trials. It is important to note that the ED50 also can alert a clinician to the likely useful and safe dose range and should be more widely available. ED50 should be an important variable in drug approval, marketing, and, most importantly, prescribing. Furthermore, numerous observational studies have shown that providers often prescribe increasingly higher levels of treatment, often without clear clinical indication for such high doses. As such, the FDA recommends that dose-response assessment should be an integral part of drug development, including minimum effective doses.

2115
MEDICAL CANNABIS
Source: Council on Therapeutics

To recognize that there is limited evidence to support safe and effective use of medical cannabis; further,

To encourage research that quantifies the therapeutically active components and defines the effectiveness, safety, and clinical uses of medical cannabis; further,

To recognize that there is not a standardized product subject to the same regulations as a prescription drug product, and to advocate for the development of processes that would ensure standardized formulations that would ensure consistent potency and quality of medical cannabis; further,

To advocate for the alignment of federal and state laws to eliminate barriers to research on and therapeutic use of medical cannabis, including review of medical cannabis's status as a Schedule I controlled substance, and its potential for reclassification; further,

To encourage healthcare organizations to develop policies and procedures regarding the handling of medical cannabis consistent with applicable laws, regulations, and accreditation standards; further,

To promote the documentation of medical cannabis use and indication in the electronic health record; further,

To encourage education that prepares pharmacists as part of an interprofessional team to educate patients, caregivers, healthcare providers, and healthcare administrators about therapeutic and legal aspects of medical cannabis use.

This policy supersedes ASHP policy 1101.

Rationale

To date, 33 states and the District of Columbia, Guam, and Puerto Rico have enacted workable medical cannabis laws that provide, or will provide, meaningful access to medical cannabis for qualifying patients. Healthcare providers in those jurisdictions, including pharmacists, are grappling with the challenges presented by medical use of medical cannabis (defined for purposes of this policy as whole or parts of the natural marijuana plant and therapeutic products derived therefrom). ASHP recognizes that there is some evidence supporting the effectiveness of medical cannabis to treat or ameliorate symptoms of disease. The extent and quality of this evidence is limited, however, and even less is known about the safety of medical cannabis, especially related to its long-term use. Well-designed research is necessary to further define the therapeutic uses of medical cannabis, including determination of its therapeutically active components; clinical indications and contraindications; precautions; dosing; routes of

administration; adverse effects; drug-drug, drug-disease, and drug-laboratory interactions; and effectiveness compared to existing therapies.

Current inconsistencies in product formulation, potency, and quality are also a hindrance to developing a strong evidence base. Standardizing these factors, to the extent possible, will help ensure the quality and reliability of research results. ASHP encourages efforts by the United States Pharmacopeia to develop quality standards for medical cannabis. Federal legislation and regulation, including marijuana's classification as a Schedule I substance under the Controlled Substances Act, remains a barrier to the necessary research, and ASHP advocates that federal and state laws and regulations be aligned to remove or minimize these barriers.

Conflicting federal and state laws also create confusion about research on and use of medical cannabis, as federal law precludes procurement, storage, preparation, or distribution of medical cannabis by pharmacies or healthcare facilities registered with the Drug Enforcement Administration. Given the complexity of the issues involved, ASHP encourages healthcare organizations to develop policies and procedures regarding medical cannabis to conduct research and provide patient care that is consistent with applicable laws, regulations, and accreditation standards. Recreational or medical use of cannabis should be documented in the patient medical record. ASHP recognizes the need for pharmacists and other healthcare providers to provide education about the unique therapeutic and legal issues created by research on and use of medical cannabis.

2116
NONPRESCRIPTION AVAILABILITY OF OSELTAMIVIR

This policy was superseded by ASHP policy 2325.

2117
EDUCATION AND TRAINING IN TELEHEALTH
Source: Council on Education and Workforce Development

This policy was discontinued in 2023.

2118
SUPPLY CHAIN RESILIENCE DURING DISASTERS AND PUBLIC HEALTH EMERGENCIES
Source: Council on Pharmacy Management

To support building an enhanced and resilient hospital and health-system supply chain that is lean and economical during normal operations yet nimble enough to support patient care needs during large surges in demand for pharmaceuticals and medical supplies; further,

To advocate for ongoing federal evaluation of a national hazard vulnerability assessment to determine how pandemics and disasters present risks to healthcare and public health critical infrastructure; further,

To advocate for the development of critical pharmaceutical and medical supply requirement listings based on a national hazard vulnerability assessment to guide the composition of government and distributor-managed emergency stockpiles; further,

To urge Congress and state legislatures to direct medical supply and pharmaceutical distributors to manage both "private sector-owned" medical materiel (just-in-time for normal operations) and government-owned/distributor-managed emergency stockpiles (just-in-case for emergencies) that can flow into the private sector supply chain when release of government-owned materiel during public health emergencies, disasters, or contingencies is authorized.

Rationale

Hospitals and health systems experience supply chain challenges for patient care during routine operations, and these challenges can be exacerbated by public health emergencies and disasters. Aspects of the novel coronavirus disease 2019 (COVID-19) pandemic that have required nimbleness in thinking and action are the transformation of organizational governance and the need for speed in decision-making. The COVID-19 pandemic has dramatically changed inventory management and supply chain practices.

Many pre-existing factors contributed to the supply chain crises triggered by COVID-19, including but not limited to overextended supply lines, lean manufacturing, and outsourcing, which have been especially unfavorable for hospitals and health systems running just-in-time (JIT) inventory replenishment. Designed to use capital more efficiently, JIT replenishment relies on highly accurate demand forecasting and tight coordination with suppliers. When there is a sudden increase in demand, from a larger number of buyers trying to purchase the same products at the same time or from the typical number of buyers trying to make larger purchases, the thin supply chains that support JIT inventories can't respond quickly enough, creating long-term backorders at the local, regional, and national levels. An alternative just-in-case (JIC) inventory strategy would maintain extensive inventories to reduce backorder risks in the face of supply and demand uncertainties, but at the cost of forcing organizations to tie up capital in inventory.

During the COVID-19 pandemic, hospital and health-system governance structures had to quickly pivot to accommodate shifts in unexpected operational, clinical, and financial challenges. Organizations quickly embraced the "new normal" of supply chain management conundrums (e.g., shortages of personal protective equipment and critical drug, minimizing drug waste), controversial drug therapy considerations for pharmacy and therapeutics committees, and provisioning planning for alternate care sites (e.g., field hospitals). To prepare the healthcare system to endure the stresses on critical infrastructure caused by future public health emergencies or disasters, a shift toward a hybrid supply chain model needs serious consideration, to reap the benefits of both models and build resiliency into supply chains. Such a system would use information from a national hazard vulnerability assessment to guide the composition of emergency stockpiles of critical pharmaceuticals and medical supplies and require private-sector distributors of those products to manage the supply chains for those stockpiles when they are released during public health emergencies or disasters in addition to

their normal operations.

2119
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN PUBLIC HEALTH
Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Pharmacist's Role in Public Health.

2120
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN CLINICAL PHARMACOGENOMICS
Source: Section of Clinical Specialists and Scientists

To approve the ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics.

This statement supersedes a previous version dated June 7, 2015.

2121
UNIVERSAL INFLUENZA VACCINATION
Source: Council on Therapeutics

To advocate for universal annual administration of influenza vaccinations to the United States population; further,

To advocate that annual influenza vaccination be a national public health priority; further,

To support the development of safe, effective, and affordable universal influenza vaccination, with the goal of long-term immunity.

This policy supersedes ASHP policy 0601.

Rationale
Influenza places a significant health burden on the United States, with estimates of 9–35 million illnesses, 4–16 million outpatient medical visits, and 139,000–708,000 hospitalizations each season. The influenza virus evolves and changes each year, with changes in its genome that require adjustments to vaccine viruses each season. Furthermore, the timing of the onset, peak, and end of each flu season varies annually, typically falling in the fall and winter. Evidence from several observational studies demonstrate that higher influenza vaccination is associated with a lower risk of influenza outbreaks, but Healthy People 2030 estimates that only 49.2% of persons 6 months or older were vaccinated for the 2017-18 season. Influenza vaccination in low-risk individuals has also shown to be effective and can prevent many illnesses, deaths, and losses in productivity.

The *Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza* emphasize that annual vaccination is the best method for preventing or mitigating the impact of influenza, and the 2030 Infectious Disease Goals for Healthy People

2030 have a goal of minimum vaccination rates of 70%. In 2019, an Executive Order created the National Influenza Vaccine Task Force, which identified that collaborative efforts across the federal government, academia, the private sector, and international stakeholders over the past decade have advanced influenza vaccine technologies. The Task Force also noted that influenza is a public health and national security challenge, with significant gaps remaining in vaccine effectiveness, pace of vaccine production, sustainable manufacturing, and vaccine access and coverage across all populations.

2122
VACCINE CONFIDENCE

This policy was superseded by ASHP policy 2247.

2123
THERAPEUTIC INDICATION IN CLINICAL DECISION SUPPORT

This policy was superseded by ASHP policy 2255.

2124
PREVENTING EXPOSURE TO ALLERGENS
Source: Council on Therapeutics

To advocate for pharmacy workforce participation in the collection, assessment, documentation, and reconciliation of a complete list of allergens and intolerances pertinent to medication therapy, including food, excipients, medications, devices, and supplies; further,

To promote the education of the healthcare team and patients on the differences between medication-related allergic reactions and medication intolerances; further,

To encourage vendors of electronic health records to create readily available and distinct data fields with consistent designations for medication allergies and intolerances; further,

To advocate that vendors of medication-related databases incorporate and maintain information about medication-related allergens and cross-reactivity; further,

To encourage the accurate and complete documentation of allergens and intolerances within the electronic medical record, including detailed descriptions of the reactions occurring upon exposure, for the purpose of clinical decision-making; further,

To advocate that pharmacists actively review allergens and intolerances pertinent to medication therapy and minimize patient and healthcare worker exposure to known allergens, as feasible.

This policy supersedes ASHP policy 1619.

Rationale

The common theme of several ASHP policies is that patients may be exposed to potentially life-threatening allergens in items encountered in the medication-use process (e.g., natural rubber latex, drugs, drug product excipients, devices, and supplies). Pharmacy workforce involvement in collection, assessment, and documentation of a complete list of allergens pertinent to the medication-use process, including food, excipients, medications, devices, and supplies, would assist in clinical decision-making. Members of the pharmacy workforce should also minimize patient and healthcare worker exposure to known allergens, for example by limiting or banning the use of latex gloves in pharmacies and striving for latex-safe medication formularies. Although allergy information is becoming more readily accessible though the electronic health record (EHR) and clinical decision support systems, some well-known cross-sensitivities are good candidates to be included in medication-related databases.

Only about 5-10% of all medication-related adverse events are allergic in nature. Patients are often labeled with an allergy to many drugs on the basis of a side effect or intolerances such as headache or GI disturbance. Allergen misidentification and documentation can be detrimental to patient care by preventing the use of optimal drug agents or by causing re-exposure to a true allergen. Pharmacists and pharmacy technicians can help clarify and provide detailed documentation in the EHR regarding patient allergens. Furthermore, there is inconsistent standards on how and where allergies are located in the EHR and as such, there should be a consistent and standardized approach to documentation.

2125

TOBACCO, TOBACCO PRODUCTS, AND ELECTRONIC NICOTINE DELIVERY SYSTEMS

This policy was superseded by ASHP policy 2620.

2126

USE OF RACE CORRECTION IN CLINICAL ALGORITHMS

Source: Council on Therapeutics

To recognize that clinical algorithms that only use race or ethnicity as a variable can contribute to inequities and adverse outcomes; further,

To oppose the use of race or ethnicity correction in clinical algorithms unless there is strong evidence to support its use; further,

To advocate that health systems remove algorithms based on race or ethnicity from all sources of therapy decisions, medication information, and the electronic health record, where strong evidence does not support its use; further,

To support further research on the impact of race or ethnicity on drug therapy and outcomes; further,

To advocate that if research includes considerations based on race or ethnicity, the reason for its use as a variable be specified; further,

To provide education on the limitations and appropriate use of race- or ethnicity-corrected clinical algorithms; further,

To support uniform documentation in the electronic health record of a patient-identified designation of race or ethnicity.

Rationale

Although patient care can and should be informed by a patient's racial or ethnic identity, healthcare providers need to recognize the limited utility of that information

There are currently numerous clinical algorithms and practice guidelines that use a patient's race or ethnicity to determine outcomes. The clinical algorithms are then used by providers to help guide individualized risk assessments and clinical decisions. In return, these algorithms may direct attention and resources away from racial and ethnic minorities. However, the majority of these clinical algorithms do not have data to support a patient's race or ethnicity as a clinical factor. When a rationale is given and traced to its origins, the answer leads to outdated, suspect racial science, or biased data. Additionally, these algorithms do not take into account socioeconomic factors and other social determinants of health that may have a large influence on health outcomes.

Currently, a patient's race or ethnicity plays a role in a clinical algorithms or practice guidelines in almost every therapeutic class, including cardiology, surgery, nephrology, obstetrics, urology, and oncology. For example, the American Heart Association Get with the Guidelines - Heart Failure adds 3 points to the risk score of a patient that is non-Black. The higher scores in this tool predict higher in-hospital mortality. Ultimately, this tool is used to help guide clinical decisions for allocations of healthcare resources and referral to cardiology. The consequences of adding race to this algorithm would mean less direct patient care due to the patient being deemed as lower risk. There are many other clinical algorithms that adds points to their risk score for a patient that is non-Black, such as the STONE Score, Urinary Tract Infection Calculator, and Osteoporosis Risk SCORE. Another example is the estimated glomerular filtration rate (eGRF) MDRD and CKD-EPI equations. Both these equations report higher eGRF for Black patients than for other patients with the same serum creatinine levels. Originally, this disparity was thought to be due to patients that identify as Black having a higher average serum creatinine. However, there have been some concerns that this is not always true, especially when looking at the complexity of patient's racial backgrounds. Overestimating a patient's renal function can delay the time to referral to a kidney specialist or transplantation. In short, the addition of race to the clinical algorithms leads to less patient-specific interventions and ultimately worse patient outcomes.

Healthcare providers using the clinical algorithms and practice guidelines should be educated on how to critically evaluate the addition of race and ethnicity, along with the consequences of adding race when not clinically appropriate. Many providers do not assess the

algorithm prior to implementing the results, which can lead to improper treatment of a patient.

Education on the limitations of the clinical algorithms can help providers and patients overcome the barriers that the addition of race and ethnicity has created. Additionally, the medical community needs to advocate to re-evaluate our current clinical algorithms and evaluate future algorithms to determine if there is an evidence-based reason that race should be included. It is imperative that the medical community, primarily researchers, understand how race and ethnicity affects the outcome before adding it into a clinical algorithm.

Researchers have developed guidelines to follow when trying to rationalize when race and ethnicity should be included or excluded in a study, such as explaining how the category was determined, considering all confounders, and determining whether there is uncertainty in the algorithm. Researchers should then favor the practices that will help close health inequities over practices that might amplify them. Appropriately determining if race should be included in the algorithm will then help decrease the inappropriate clinical implementation of these tools.

Future research is needed to determine the relationship between pharmacogenomics, race, and ethnicity. Most providers and researchers use the standard five races and two ethnicities categories determined by the Office of Management and Budget to categorize people according to race and ethnicity. However, many individuals do not fit into these categories due to their complex racial and ethnic backgrounds, which may ultimately fail to account for genetic differences.

Drug therapy stems from these clinical algorithms and practice guidelines, and pharmacists need to work with other providers to critically evaluate the current tools. Additionally, pharmacists could collaborate with other providers to perform research to help better understand the differences between genomics and race. Therefore, providers could assess when race and ethnicity should be added to future clinical algorithms and practice guidelines.

2127

TESTING AND DOCUMENTATION OF PENICILLIN ALLERGY AS A COMPONENT OF ANTIMICROBIAL STEWARDSHIP

Source: Council on Therapeutics

To advocate that state board of pharmacy regulations include penicillin allergy skin testing under pharmacists' scope of practice; further,

To advocate involvement of pharmacists in the clarification and assessment of penicillin allergy, intolerance, and adverse drug events; further,

To advocate for documentation and de-labeling of penicillin allergies, intolerances, reactions, and severities in the medical record when appropriate to facilitate optimal antimicrobial selection; further,

To recommend the use of penicillin skin testing, graded antibiotic challenges, and oral direct challenges in appropriate candidates when clinically indicated to optimize antimicrobial selection; further,

To support the education and training of pharmacists in the assessment, management, and documentation of penicillin allergies, intolerances, and adverse events; further,

To advocate for reimbursement for pharmacists' patient care services involved in penicillin allergy skin testing; further,

To educate patients, healthcare providers, and the public about the risks of inaccurate penicillin allergy labeling and the role of pharmacists in health-record reconciliation and the value of pharmacist-driven health-record reconciliation, including penicillin skin testing.

This policy supersedes ASHP policy 1921.

Rationale

Approximately 10% of all patients in the United States report having a penicillin allergy; however, only 1 in 10 patients with a labeled penicillin allergy are truly allergic. Furthermore, approximately 80% of patients with an IgE-mediated penicillin allergy lose their sensitivity after 10 years. Specific rates of cross-reactivity between penicillins and cephalosporins vary depending on specific resources, although the likelihood of cross-reactivity is lower than previously described. Historically, it has been estimated that 10% of patients with a true penicillin allergy will experience an allergic reaction if administered a cephalosporin, but this data is from early cross-reactivity studies with potential contamination of early cephalosporin products with penicillin G. More recent data suggest cross-reactivity rates of less than 1%. Cross-reactivity is more closely associated with structurally similar R-1 side chains than with the beta-lactam ring itself.

Penicillin allergies have led to considerable public health risks and unintended consequences, including receipt of more broad-spectrum antibiotics, suboptimal therapy for infectious disease management, more antibiotic-related costs, increased risk of adverse effects, and increased risk of methicillin-resistant *Staphylococcus aureus* and *Clostridioides difficile*. As such, structured and thorough interview assessments with appropriate documentation and de-labeling of penicillin allergies are necessary to combat these potential negative consequences of labeled penicillin allergies. Penicillin skin testing and graded or oral challenges are excellent opportunities to assist in the assessment and de-labeling of penicillin allergies. Although pharmacists are well positioned to be involved in these processes, state boards of pharmacy have different regulations regarding whether penicillin skin testing is within pharmacists' scope of practice. Penicillin allergy assessment, management, and documentation are excellent opportunities to improve pharmacist involvement in patient care and to improve antimicrobial stewardship initiatives for health systems, and offer a potential opportunity for pharmacists to bill for their services.

The American Academy of Allergy, Asthma, and Immunology, as part of the Choosing Wisely campaign, recommends against the overuse of non-beta-lactam antibiotics in patients with a history of penicillin allergy, without appropriate evaluation. In a research abstract from the Canadian Society of Allergy and Clinical Immunology meeting in 2014, researchers found

that only 15% of hospital-discharged patients notified a family physician of a negative penicillin allergy evaluation; at the same time, 30% were still listed as penicillin allergic upon readmission to the hospital. Additionally, the existence of a pharmacist-provided allergy skin test has proven

to positively impact patient care by optimizing antibiotic regimens and accelerate discharges for patients while reducing healthcare costs.

2128

USE OF UNAPPROVED GENE THERAPY PRODUCTS, DRUGS, BIOLOGICS, AND MEDICAL DEVICES (BIOHACKING)

Source: Council on Therapeutics

To advocate for enhanced government oversight and regulation of use of gene therapy, drugs, biologic products, and medical devices created outside of the Food and Drug Administration approval process (i.e., "biohacking"), and aggressive enforcement of those regulations; further,

To oppose the use of biohacking on vulnerable and at-risk populations and those unable to provide consent; further,

To promote education of healthcare professionals regarding use of biohacking and its implications in the medical setting; further,

To encourage the pharmacy workforce to include questions about the use of biohacking when obtaining medication histories; further,

To encourage the pharmacy workforce to ensure that patients using biohacking are educated about the risks and benefits of these treatments, including lack of regulatory oversight; further,

To recommend that health systems use a consistent method for documenting the use of biohacking in the electronic health record.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

Although the term biohacking has been applied to a wide range of potentially beneficial health behaviors and interventions, in its most extreme form, biohacking has been defined as "do-it-yourself biology or "do-it-yourself citizen science merging body modification with technology" (Yetisen AK. *Trends Biotechnol.* 2018; 36:744-7). Biohacking is performed by biology enthusiasts, citizen scientists, and other like-minded individuals and includes neurohacking (focuses on brain stimulation for change); manufacturing of pharmaceutical products;

implantation of modified technology; and the genetic modification of bacteria, yeast, plants, and humans (as a form of self-experimentation) to improve oneself or treat a disease.

Genetic biohacking has proven to be easy and affordable, with individuals using inexpensive, semi-professional and portable labs to carry out their experiments, including Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology, which permits the user to edit the genome by removing, adding, or altering sections of DNA. It is estimated that more than 30,000 people are involved in do-it-yourself biology in the United States alone. Furthermore, many see themselves as serving the greater health interests of the patient community at large with the right to experiment and create treatments such as gene therapy as a form of social justice. However, many of these biohackers have little to no formal training in safety and do not obtain ethical reviews of their work as one would in an institution with an internal review board. Although most biohackers currently experiment only on themselves, concern about the practice may grow as the cost of traditional therapies, particularly biologics, increases, luring sick and desperate patients to biohackers in hopes of cheaper or more accessible treatments.

The other concern about the biohacking movement is bioterrorism. The Federal Bureau of Investigation continues to form relationships with labs where genetic experimentation occurs to police this threat, but the concern remains.

Currently in the United States, there is no ban on genome editing outside of licensed laboratories. Although the Food and Drug Administration (FDA) does have jurisdiction over regular raw biological products, traditional drug products, and do-it-yourself CRISPR kits, they have not taken public enforcement action against those conducting genome editing. This may be due to practicality, however, as many biohackers are individuals or work within a small community and are hard to track. Additionally, many current laws are outdated and apply only to agricultural genetic modification. The FDA has issued draft guidance for the regulation of intentionally altered genomic DNA in animals and stated that “any use of CRISPR/Cas9 gene editing in humans [is] gene therapy” and therefore subject to regulation.

Another facet of biohacking that must be addressed is its potential impact on manufacturing. For example, due to the high cost of biosimilar insulins, a community of biohackers has created the Open Insulin Project to develop an insulin production method for personal use. This and similar projects may lead to intellectual property, regulatory, patent, and legal issues that could impact manufacturing.

Another aspect of do-it-yourself biology is implantation of devices into one’s body for medical purposes. Many of these devices are used to monitor a medical condition or to optimize drug delivery to manage disease, such as implantation of veterinary chips for monitoring vital signs, use of a wearable artificial kidney that performs dialysis via a coated skin port, and homemade insulin pumps. Pharmacists need to be aware of these devices, as they impact how patients receive medications and how they are treated. At some point in their health journey, patients using these devices are likely to be admitted to a hospital, a mechanism for documentation of this information in the electronic health record is necessary. Furthermore, pharmacists will need to understand the impact these devices have on the pharmacokinetics, pharmacodynamics, and other aspects of drug therapy.

An overall approach that should be considered is that of education of those engaged in the biohacking movement regarding the role of the federal agencies in consumer protection, risks and benefits and establish practice standards and norms that minimize harm.

2129

PROFESSIONAL IDENTITY FORMATION

Source: Council on Education and Workforce Development

To encourage the pharmacy workforce and pharmacy education and training programs to foster professional identity formation, described as the process of developing a commitment to: (1) high professional standards of pharmacy practice, (2) high personal standards of integrity and competence, (3) service to humanity, (4) a just and inclusive healthcare system and society, (5) analytical thinking and ethical reasoning, (6) continuing professional development, (7) acquisition of personal leadership skills, (8) development of effective interpersonal skills, (9) maintenance of personal well-being and resiliency, and (10) membership and participation in professional organizations.

This policy supersedes ASHP policy 1113.

This policy was reviewed in 2025 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

The terms “professionalism” and “professional identity” are sometimes mistakenly used interchangeably. Professionalism is defined by behaviors that are often outwardly visible (e.g., credentialing, continuing education, efforts to advance the profession). In contrast, professional identity formation (PIF) is defined as the process of internalizing a profession’s core values and beliefs. PIF incorporates the three domains of thinking, feeling, and acting. PIF in pharmacy may be described as the process of developing a commitment to the 10 listed characteristics.

Pharmacy professionals and educators have a direct or indirect responsibility to support the growth and success of others in the pharmacy workforce through mentorship and modelling. As pharmacy professionals interact with learners, new practitioners, and even seasoned colleagues, they have the ability to model professional behavior, integrity, ethical standards, and service to the community. Pharmacy professionals who serve in formal or informal leadership roles are in a unique position to mentor others in leadership skills. Pharmacy professionals should mentor others in the various career paths they may pursue as well as encourage them to elevate their practice level and education.

Some of the barriers to PIF include mentors and preceptors being pressured into a role rather than being allowed to decide whether they choose to do so voluntarily, increased pharmacy workload, and staff burnout. Developing student professionalism (sometimes referred to as “professional socialization”) has been part of pharmacy education for decades, but a broader focus on PIF more generally will better serve the profession of pharmacy during a time of practice transformation than the current approach to teaching professionalism. Colleges of pharmacy, other providers of education and training programs, and employers could promote PIF by providing mentorship programs and other resources.

2130
CAREER OPPORTUNITIES FOR PHARMACY TECHNICIANS
Source: Council on Education and Workforce Development

To promote pharmacy technicians as valuable contributors to healthcare delivery; further,

To advocate that pharmacy technicians complete an education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE), and maintain Pharmacy Technician Certification Board certification; further,

To advocate that pharmacy technicians complete ACPE-approved certificate programs that provide training for their current or anticipated roles; further,

To develop and disseminate information about career and training opportunities that enhance the recruitment and retention of qualified pharmacy technicians; further,

To encourage employers to offer career advancement opportunities (e.g., career ladders) for pharmacy technicians; further,

To urge compensation for pharmacy technicians commensurate with advanced roles and responsibilities.

This policy supersedes ASHP policy 1610.

This policy was reviewed in 2025 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale
As the responsibilities of pharmacy technicians expand and their role as a vital member of the healthcare team is recognized, it is imperative that pharmacy technicians be well-trained and competent to perform those responsibilities. Pharmacists cannot provide quality patient care without the support of competent pharmacy technicians. To support pharmacists and promote retention, it is important that pharmacy technician positions be viewed as a career and not just a job. Pharmacy technicians should be provided opportunities for life-long advancement and compensated appropriately for advanced roles that they assume. There is current ASHP policy, 1912, Pharmacy Technician Training and Certification and 2424, Additional Education Requirements for Pharmacy Technicians in Advanced Roles, which advocates for the education, training, and certification for new pharmacy technicians. This covers a need for the ongoing professional development and career advancement for pharmacy technicians beyond basic operational activities.

2131

ZERO TOLERANCE OF HARASSMENT, DISCRIMINATION, AND MALICIOUS BEHAVIORS

Source: Council on Education and Workforce Development

To assert that the pharmacy workforce has a right to expect and responsibility to ensure a profession in which all individuals are treated with respect and civility, with zero tolerance for all forms of harassment, discrimination, and malicious behaviors; further,

To commit to a culture of responsibility and accountability within the profession, and promote anti-retaliation policies and timely follow-up; further,

To foster the development of tools, education, and other resources to ensure such a culture.

Rationale

The Code of Ethics for Pharmacists states that "A pharmacist acts with honesty and integrity in professional relationships." The ASHP Statement on Professionalism includes among the elements of professionalism pride in and service to the profession, conscience and trustworthiness, and ethically sound decision-making. All forms of discrimination (e.g., race, color, sex, national origin, religious, sexual orientation/identity, age, disability), harassment (including sexual harassment), and malicious behaviors such as bullying, intimidation, or exploitation go against the core beliefs of the profession. All members of the pharmacy workforce have a professional responsibility to create and sustain a culture of responsibility and accountability within the profession in which all individuals are treated with respect and civility, with zero tolerance of harassment and discrimination.

A culture of responsibility and accountability requires that employers and organizations establish mechanisms for retaliation-free reporting of harassment and discrimination, and that such reports receive timely follow-up. For such a culture to thrive, the pharmacy workforce must recognize its professional obligation to not only follow institutional policies regarding prevention, reporting, and consequences for such behaviors but to seek out ways to improve the effectiveness of those policies and procedures. This culture of responsibility and accountability includes the workplace and learning environments but extends even to such personal but quasi-public conduct as interactions on social media. As stated in the ASHP Statement on the Use of Social Media by Pharmacy Professionals, the "higher standards of conduct expected of professionals, even in personal behavior" imply that "[p]ostings on social media should be subject to the same professional standards and ethical considerations as other personal or public interactions."

As stated in the ASHP Statement on Professionalism, "[o]ne of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession's ideals and mission." Formal and informal mentorship relationships are fundamental to the growth and health of any profession, and abuses of those positions of trust are especially injurious to victims and the profession. These relationships should be subjected to the strictest scrutiny and oversight to ensure they are held to the highest standards of conduct.

To further the goal of creating and sustaining a culture of responsibility and accountability regarding harassment and discrimination, ASHP commits to developing tools, education, and other resources to help members, employers, and other organizations address these important issues.

2132
STANDARDIZING AND MINIMIZING THE USE OF ABBREVIATIONS
Source: Council on Pharmacy Management

To support efforts to standardize and minimize the use of abbreviations in healthcare; further,

To oppose use of abbreviations when communicating with patients to enhance transparency and understanding; further,

To encourage education of healthcare professionals and learners on standardizing and minimizing the use of abbreviations across all patient care settings.

This policy supersedes ASHP policy 0604.

Rationale
Although there are anecdotal examples of medical abbreviations causing harm to patients, there is little good clinical evidence to demonstrate that medical abbreviation use is dangerous or is causing problems in the delivery of care. Nevertheless, minimizing or even eliminating the use of medical abbreviations in healthcare has been encouraged for decades. The Institute of Safe Medication Practices regularly receives reports of errors, some of which have resulted in adverse events, due to misinterpretation of medical abbreviations. The Joint Commission has regularly issued updates and guidance on the safe use of medical abbreviations and has also published a short list of dangerous medical abbreviations and dose expressions that should never be used. However, despite many key organizations discouraging the use of medical abbreviations, they continue to be used at an alarming rate. Such use can place new practitioners at great risk when they have to interpret the abbreviations, as the new practitioner may have limited knowledge about what the abbreviations mean. Use of abbreviations should be minimized, and when abbreviation use cannot be avoided, they should be standardized to ensure accurate interpretation. In addition, use of abbreviations when communicating with patients should be avoided to enhance transparency and patients' understanding of their treatment.

2133
OPTIMAL PHARMACY STAFFING
Source: Council on Pharmacy Management

To encourage pharmacy leaders to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care and employee engagement; further,

To encourage pharmacy leaders to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, telehealth practices, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings; further,

To encourage pharmacy leaders to develop contingency plans for changes in staffing models to accommodate rapid changes in the healthcare environment and the needs of patients and staff; further,

To encourage pharmacy leaders to develop key performance indicators to support safe staffing models.

This policy supersedes ASHP policy 2034.

Rationale

The advancement of the pharmacy profession over the past decade has prepared and positioned pharmacists to care for complex patients and adapt to the dynamic and rapidly progressive field of medicine. Throughout the years, an increased involvement of pharmacists in specialty areas such as transplant, critical care, oncology, and pain and palliative care has been observed. Therefore, it is imperative that such advancement is considered when developing staffing models, in order to ensure the pharmacy workforce is appropriately allocated for the provision of consistent, safe, and high-quality patient care.

The complexity of patient care will continue to increase, and with that, so will the expected responsibilities, opportunities, and skills of the pharmacy workforce. Consequently, pharmacists engaged in direct patient care are encouraged to pursue and maintain their training and credentialing in order to continue to enhance their competency, skills, and participation in innovative practice. The expansion and dynamic nature of the pharmacy profession requires new approaches to explore flexible staffing models to avoid a stagnant practice, encourage continual advancement, and accommodate the evolving priorities of the pharmacy workforce.

The development and implementation of flexible staffing models can enable pharmacists to engage in further professional development and career advancement (e.g., training in areas of specialization, degree programs) and enjoy a more stable work-life integration experience. Recently, more attention has been drawn to burnout, resilience, and job satisfaction among the pharmacy workforce. Research has shown that pharmacists are reporting increased job stress over the previous years and that approximately 53% of pharmacists are reporting a high degree of burnout, which can consequently threaten patient safety. Therefore, there is an imperative to develop staffing models to meet staff members' changing priorities and provide additional flexibility in the workplace. Implementation of flexible staffing models could improve performance and promote employee engagement in the workplace. Pharmacy leaders should be committed to maintaining high-quality and consistent patient care services and to also promote models that balance patient care with staff priorities.

Various options to consider when exploring flexible staffing models include telehealth practices, remote order review and verification (i.e., telecommuting), and productivity measures to ensure patient census is well distributed among pharmacists in charge of providing clinical services. Another concept related to flexible staffing models is leveraging pharmacy technicians' roles to support pharmacist engagement in direct patient care activities. Some institutions have explored data-driven, staffing-to-demand models based on real-time patient-volume metrics. The concept is to allocate staff to tasks based on the current workload, which is evaluated daily. Other institutions are also utilizing metrics such as number of doses dispensed at a certain point in time and volume of order verification throughout the day in order to divide patient care units evenly among pharmacists that perform order verification or provide clinical services. Flexible staffing models should support the following principles:

- Sufficient qualified staff must exist to ensure safe and effective patient care.
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care.
- Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services.
- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

The COVID-19 pandemic and the ensuing reduction in elective procedures, routine visits, and admissions amplified the emphasis on flexing staff to volume. To support fiscal solvency during and in the aftermath of the pandemic, organizations had to quickly pivot and align staff to accommodate shifts in volume, resulting in redesigned staffing models to optimize scheduling. These models have included a mix of onsite and remote offering of services to perform synchronous and asynchronous work in a more efficient manner, as well as staff furloughs. Flexing pharmacy staffing models have been previously described, such as pharmacy staffing-to-demand models; alternative work schedules; and productivity monitoring to guide hiring and staffing decisions.

Other healthcare disciplines (e.g., nursing) have historically utilized flexible staffing models to optimize services, reduce the risk of adverse events, and improve patient outcomes. The different models explored by nursing include patient ratio, key performance indicators, patient acuity, collaborative staffing, and supplemental staffing models. There is limited literature on the use of flexible staffing models, but the concept is being explored by various health-system pharmacy departments.

2134
PATIENT ACCESS TO PHARMACIST CARE WITHIN PROVIDER NETWORKS

This policy was superseded by ASHP policy 2405.

2135
ROLE OF THE PHARMACY WORKFORCE IN PANDEMIC PREPAREDNESS AND RESPONSE
Source: Council on Pharmacy Practice

To advocate that all healthcare organizations include pandemic preparedness in emergency preparedness planning; further,

To encourage all healthcare organizations to be actively engaged with their regional healthcare coalitions and to promote collaboration and communication among healthcare workers, healthcare organizations, government agencies, industry, and other stakeholders in pandemic preparedness and response; further,

To promote pharmacy workforce involvement in networks at the federal, state, local, and institutional levels for emergency response; further,

To advocate that pharmacy personnel be included as leaders on teams responsible for pandemic preparedness planning and response at the federal, state, local, and institutional levels, and that they integrate such planning into emergency preparedness planning for their workplaces; further,

To encourage all healthcare organizations to establish criteria for evidence-based medication-use decisions, even when such evidence is scarce, incomplete, or conflicting, and recognize the unique role that pharmacy personnel have in ensuring the safe and effective use of medications based on best available evidence and resources; further,

To advocate that healthcare organizations recognize the unique and collective stress a pandemic places on healthcare workers and provide suitable resources to maintain workers' well-being and resilience; further,

To support research on and provide resources and education to aid the pharmacy workforce in preparing for and responding to pandemics.

Rationale

ASHP has long advocated "that hospital and health-system pharmacists must assertively exercise their responsibilities in preparing for and responding to disasters, and the leaders of emergency planning at the federal, regional, state, and local levels must call on pharmacists to participate in the full range of issues related to pharmaceuticals." (ASHP Statement on Emergency Preparedness)

The Coronavirus Disease 2019 (COVID-19) global pandemic differs from other types of disasters in significant respects, testing the resiliency of the healthcare system and workforce. Treating patients with a novel viral pathogen has driven rapid evolution in therapies, forcing

healthcare providers to make patient care decisions based on scarce, incomplete, or conflicting information. These decisions have sometimes been complicated by shortages of crucial drugs, equipment, or staff, creating a crisis standard of care in which difficult patient care decisions must be made. The patient surges that healthcare organizations have had to manage have lasted significantly longer than those of other disasters. Healthcare workers have faced stressful patient care situations and extended shifts for a longer period of time than in other disasters. In addition, the fear of infection and of spreading that infection to family members and others has added additional stress. Infection control procedures have shut down some areas of healthcare operations, forcing healthcare workers into unfamiliar roles and care settings.

ASHP advocates that the lessons learned from the COVID-19 pandemic be shared broadly and incorporated into emergency planning at the federal, state, local, institutional, and pharmacy department levels. All healthcare organizations should be actively engaged with their regional healthcare coalitions, and pharmacy leaders, with their unique understanding of medication-use processes, should be relied upon to provide strategic direction on the full range of issues related to medication use, especially when evidence is scarce, incomplete, or conflicting, and drugs or other critical resources are in shortage. The pharmacy workforce should incorporate the lessons learned in its emergency planning efforts, integrating those efforts into the efforts of emergency response networks at the federal, state, local, and institutional levels. ASHP pledges to promote collaboration and communication among the various stakeholders in pandemic preparedness and response, and to provide resources and education to aid the pharmacy workforce and others in preparing for and responding to pandemics, including resources regarding novel therapies, shortages of drugs and other critical supplies, and healthcare worker well-being and resilience.

2136

ROLE OF THE PHARMACY WORKFORCE IN SUPPORTING PATIENT ACCESS TO MEDICAL SUPPLIES

Source: Council on Pharmacy Practice

To support patient access to medical supplies as part of a comprehensive treatment plan; further,

To advocate for policies that empower pharmacy personnel to facilitate patient access to and effective use of medical supplies, including reimbursement policies; further,

To educate pharmacists, other healthcare professionals, payers, and policymakers about the role of pharmacy personnel in helping patients obtain and use medical supplies; further,

To collaborate with other healthcare professional and patient advocacy organizations to advocate for expanded patient access to medical supplies.

(*Note:* For purposes of this policy, “medical supplies” includes durable medical equipment, Food and Drug Administration-approved medical devices, and other nondurable

disposable healthcare materials.)

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

Pharmacists and pharmacy technicians have the knowledge and skills to support patient access to medical supplies and equipment, durable medical equipment (DME), and medical devices. These tools, like medications, are essential components to a patient's personalized care plan. Although many providers combine medical supplies and equipment, DME, and medical devices under the umbrella term "medical supplies," as is done here for purposes of this policy, there are critical differences between them that determine how these items are accessed and reimbursed. Under Centers for Medicare & Medicaid Services (CMS) rules, "medical supplies and equipment" (e.g., bandages and gauzes) are nondurable disposable healthcare materials used to serve a medical purpose that cannot be used in the absence of illness or injury or repeatedly by different individuals. CMS typically does not consider medical supplies and equipment as a covered benefit. DME (e.g., blood sugar monitors, blood sugar test strips, continuous glucose monitors, and infusion pumps and supplies) are durable healthcare materials used at home that can withstand repeated use, provide a medical purpose, and are not used in the absence of an illness or injury. In contrast to medical supplies and equipment, DME is covered under Medicare Part B. Finally, the Food and Drug Administration (FDA) defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory.

Pharmacists are experts in initiating and managing a patient's comprehensive medication management (CMM) plan. Any intervention that supplements medication goals and improves a patient's quality of life and patient outcomes should be considered in the CMM process and plan, including use of medical supplies and equipment, DME, and medical devices, and provide an opportunity for a pharmacist or pharmacy technician to improve patient care. To increase patient access, pharmacists can collaborate with patients and physicians to determine which device to use based on patient indication, preferences, and product specifications. Pharmacists could also collaborate with CMS and other insurance plans to ensure that patients have adequate coverage of DME along with advocating to allow pharmacists to submit claims for reimbursement.

Additionally, the pharmacy workforce can advocate for broader pharmacy management of medical supplies and equipment, DME, and medical devices along with medications as a part of the patient's CMM plan. The pharmacy workforce can support patient access through documentation required for coverage, provide education on how to use the device, monitor the device for safety and efficacy, and interpret results if applicable. Collaborative practice agreements and credentialing and privileging are two ways pharmacists can use data provided from the devices to help make necessary changes to the patient's medication plan.

Lastly, ASHP could collaborate with patient advocacy organizations and disease specific organizations (e.g., American Diabetes Association) to advocate for increased patient access to specific medical supplies and equipment. This includes advocacy encouraging regulatory and

accreditation agencies to acknowledge community pharmacies as accessible, ideal sites for providing medical supplies and to establish streamlined and fair requirements for accreditation, thus enabling them to be recognized as providers of comprehensive patient care.

2137
DOCUMENTATION OF PHARMACIST PATIENT CARE
Source: Council on Pharmacy Practice

To promote the use of standardized, integrated documentation of pharmacist care provision in a patient's health record; further,

To advocate that documentation by pharmacists in the medical record be used for billing and attribution of value without requiring additional documentation from other clinicians; further,

To advocate for standardized measurement of pharmacist care provision and the attribution of those activities to patient-centered outcomes.

Rationale

ASHP has advocated for the importance of documentation of pharmacist care in patient medical records to ensure accurate and complete documentation of the care and services provided to the patient. However, differences in pharmacy practice within and across health systems make it hard to standardize such documentation in the electronic health record (EHR). The differences are caused by diverse clinical practices, EHR permissions, and documentation elements of the care provided by pharmacists. Documentation by the pharmacist may change depending on care settings, the level of care provided, or in respect to reimbursement. As a result, it is hard to validate and evaluate pharmacists' impact on patient outcomes due to the incomplete measurement and attribution of such care and lack of standardized documentation.

Other healthcare providers have released similar statements on documentation within their fields. The American College of Physicians states that physicians should define professional standards regarding clinical documentation and use macros and templates appropriately (Kuhn T, Basch P, Barr M et al. Clinical documentation in the 21st century: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med.* 2015; 162:301-3). The American Nurses Association (ANA) Principles for Nursing Documentation states that if patient documentation is not timely, accurate, accessible, complete, legible, readable, and standardized, it will interfere with the ability of those who were not involved in and are not familiar with the patient's care to use the documentation (ANA's Principles for Nursing Documentation: Guidance for Registered Nurses. 2010. www.nursingworld.org/~4af4f2/globalassets/docs/ana/ethics/principles-of-nursing-documentation.pdf). The American Speech-Language-Hearing Association (ASHA) states that speech-language pathologists should participate in the development of the templates that they will use for billing and clinical documents so that the information that is necessary is provided (ASHA. Documentation in health care. www.asha.org/PRPSpecificTopic.aspx?folderid=8589935365&section=References).

Other healthcare providers have recognized the benefits of requiring their documentation to be recorded in a standardized form that allows other healthcare stakeholders to quickly access the information. Employing accessible, standardized documentation improves communication and knowledge sharing between providers. Pharmacists are valuable members of the healthcare team that contribute significantly to patient care. More consistency and standardization of a pharmacist's documentation can provide essential information on a patient's care, such as therapeutic drug monitoring, appropriateness and effectiveness of patient's medications, or pain and antibiotic management, for example. Standardized notes enable healthcare team members to review the pharmacist note and become aware of the medication plan. Implementing standardized and integrated documentation across all healthcare providers, especially pharmacists, will allow for increased interactions and information to be shared between healthcare providers to improve overall patient care. In addition, such standardized and integrated documentation by pharmacists should be used for billing and attribution of value without additional documentation requirements from other clinicians.

Implementing a standardized clinical pharmacy documentation system will also inform and enable a measurement approach for evaluation of the impact of pharmacist services. Many institutions use different tools for operational internal and external benchmarking to meet these measures; however, the tools are limited in their use for clinical benchmarking (Rough SS, McDaniel M, Rinehart JR. Effective use of workload and productivity monitoring tools in health-system pharmacy, pt 1. *Am J Health Syst Pharm.* 2010; 67:300–11). Institutions have tried to implement their own clinical pharmacy productivity measures tools to help demonstrate the value of de-centralized pharmacists on patient care teams. However, no current measure or measure set accurately identifies the impact pharmacists have on patient care outcomes or allows comparison and benchmarking across institutions. In response to this need, the ASHP Pharmacy Accountability Measures (PAM) Work Group seeks to identify pharmacy-related clinical quality measures that institutions could use for benchmarking (Andrawis MA, Carmichael J. A suite of inpatient and outpatient clinical measures for pharmacy accountability: recommendations from the Pharmacy Accountability Measures Work Group. *Am J Health Syst Pharm.* 2014; 71:669-78).

The PAM Workgroup evaluated quality measures endorsed by the National Quality Forum (NQF) and curated those selected into six therapeutic areas, which include antithrombotic safety, cardiovascular control, glycemic control, pain management, behavioral health, and antimicrobial stewardship (Andrawis M, Ellison C, Riddle S et al. Recommended quality measures for health-system pharmacy: 2019 update from the Pharmacy Accountability Measures Work Group. *Am J Health Syst Pharm.* 2019; 76:874–87). Using the NQF-endorsed measures along with appropriate documentation of the care may allow institutions to more readily benchmark performance.

After determining the most appropriate pharmacy quality measures, the documentation of the care provided should be standardized and efficient. Implementing standardized templates and more retrievable data fields in the documentation process has been shown to improve workflow for pharmacists. One study demonstrated that by implementing EHR note templates that allowed retrievable data to be incorporated, pharmacists increased the amount

of time providing value-added services from 47% to 72% and in providing direct patient care from 27% to 53% (Ekstrand MJ, Kobany JM, Pestka DL. Leveraging quality improvement principles in comprehensive medication management pharmacy practice: a case example. *J Am Pharm Assoc.* 2020; 60:509-15.e1.).

Finally, pharmacists must also be properly educated on how to use a standardized pharmacy documentation system. In one study, a health system that implemented an improved pharmacist documentation process found that a focused education initiative increased the number of pharmacist-delivered services by 120% while also imrpoving cost avoidance (Rector KB, Veverka A, Evans SK. *Am J Health-Syst Pharm.* 2014; 71:1303–10). Overall, research has shown that focused education has helped improve the standardized documentation of pharmacist care, leading ultimately to better care for patients and demonstrating the value of pharmacy services.

2138
INFLUENZA VACCINATION REQUIREMENTS TO ADVANCE PATIENT SAFETY AND PUBLIC HEALTH

This policy was superseded by ASHP policy 2237.

2139
SAFE AND EFFECTIVE EXTEMPORANEOUS COMPOUNDING

This policy was superseded by ASHP policy 2616.

2140
UNIVERSAL IMMUNIZATION FOR VACCINE-PREVENTABLE DISEASES IN THE HEALTHCARE WORKFORCE

This policy was superseded by ASHP policy 2237.

2141
PHARMACIST ENGAGEMENT IN AND PAYMENT FOR TELEHEALTH

This policy was discontinued in 2026.

2142
PHARMACY SERVICES IN A STATE OF EMERGENCY
Source: Council on Public Policy

To advocate that states grant temporary licensure, registration, or any other necessary state-mandated credentials to eligible pharmacies and members of the pharmacy workforce during states of emergency; further,

To encourage expedient licensure or registration for eligible members of the pharmacy workforce during states of emergency; further,

To advocate that state and federal regulatory agencies allow for flexibilities necessary to provide patient care during a declared state of emergency.

Rationale

During the COVID-19 pandemic, both state and federal policymakers scrambled to provide the regulatory flexibility necessary to allow patients to access pharmacist services. Although states are generally willing to be flexible about dispensing during a public health emergency, pharmacy services themselves are not subject to the same degree of flexibility. Specifically, pharmacists, more so than other clinicians, struggled to get temporary licensure across state lines, and pharmacy technicians experienced similar challenges in states that require registration. The lack of access to temporary licensure and registration impeded the ability of pharmacists and pharmacy technicians to move to areas of great need or to volunteer in states with patient surges. Further, pharmacy services require flexibility, particularly around inventory control and the ability to reallocate product and the ability to quickly establish alternate sites of care. During the COVID-19 public health emergency, remdesivir was allocated to the states, and then the state retained full control over distribution, which resulted in situations in which hospitals could not transfer product across state lines to other hospitals, even to related entities, that needed the product more.

2143

ASHP STATEMENT ON THE ROLES AND RESPONSIBILITIES OF THE PHARMACY EXECUTIVE

Source: Council on Pharmacy Management

To approve the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive.

Originally published in 2021, this statement has been republished to incorporate non-substantive edits approved by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

2144

AGRICULTURAL USE OF HORMONE AND PROHORMONE THERAPY

Source: Council on Therapeutics

To advocate that the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) re-evaluate the agricultural use of hormone and prohormone therapies for purposes of animal growth promotion based on evidence demonstrating potential adverse effects on human health; further,

To advocate that the FDA and USDA eliminate approval for nontherapeutic uses in agricultural animals of hormone and prohormone therapies that are known to cause adverse effects on human health; further,

To encourage efforts to eliminate the nontherapeutic agricultural uses of hormone and prohormone therapies previously approved by the FDA and USDA; further,

To support the therapeutic use of hormone and prohormone therapies in animals only under the supervision of a veterinarian; further,

To encourage additional research on hormone and prohormone therapies to better define the public health impact of these therapies for agricultural purposes.

This policy supersedes ASHP policy 1102.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

Natural (e.g., estradiol, progesterone, testosterone) and synthetic (trenbolone, zeranol, melengestrol) hormones are commonly used for growth promotion in beef cattle raised in the United States. While the European Union has banned the use of these substances for growth promotion based on safety concerns, the USDA and FDA have long supported use of these substances based on studies conducted in the 1970s. Of note, a 2002 statement from the FDA stated that the use of hormones for agricultural purposes was safe. However, more recent research has raised new concerns about potential harm to human health, including epidemiological studies demonstrating increased rates of breast cancer in women, testicular cancer and decreased fertility in men, and hormone-related developmental issues in infants and children, including premature sexual development.

Although all approved hormone and prohormone therapies are evaluated by the FDA to ensure that the drug levels within meat have no harmful effects after human consumption, unapproved extralabel uses of hormonal products for growth-promoting purposes may result in abnormally high concentrations and an increased risk for adverse health outcomes. Additionally, use of hormone growth promoters in beef cattle may indirectly contribute to human exposures following consumption of contaminated groundwater or inhalation of hormone-laden dust particles near animal production facilities.

Hormone therapies for agricultural growth promotion should be re-examined based on this new evidence and because technology for measuring exposure to hormone substances has improved since the initial decision by the USDA and FDA. In addition, research to examine the public health impact of agricultural uses of hormone and prohormone therapies that is inclusive of both foodborne and environmental sources of exposure should be encouraged.

2145

REDUCTION OF UNUSED PRESCRIPTION DRUG PRODUCTS

Source: Council on Pharmacy Practice

To recognize that unused prescription drug products contribute to drug misuse, abuse, and diversion; further,

To advocate for staffing, research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, reconciled, and dispensed; further,

To advocate that the pharmacy workforce take a leadership role in reducing excess quantities of unused prescription drug products, including the provision of patient and caregiver education, raising public awareness, and supporting and integrating medication take-back programs.

This policy supersedes ASHP policy 1702.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

Approximately 30 to 50% of prescribed medications remain unused and in patient homes, leading to medication oversupply caused by prescribing practices, automatic refills, mail-order pharmacy delivery, and patient nonadherence or discontinuation of therapy. Reports from the most recent National Prescription Drug Take Back Day, facilitated by the Drug Enforcement Administration, indicate that the total weight of unwanted medication collected since 2010 has reached over 19.2 million pounds. Frequently unused medication classes include opioids, antibiotics, and medications for chronic conditions such as diabetes and hypertension. There continues to be a need for concentrated effort to minimize medication waste from unused prescription drug products beyond disposal efforts.

ASHP recognizes the need for research on best practices to ensure appropriate quantities of drug products are prescribed, reconciled, and dispensed, which include a study of the effectiveness of partial fills or refills of prescription drug products, among other solutions. Imposing quantity and duration limits are not recommended a solution, because this may lead to unintended consequences such as treatment failure or partially treated infections (in the case of antibiotics).

Appropriate community return and disposal of excess prescription drug products reduce diversion, accidental poisoning risk, and environmental harm. ASHP advocates for pharmacist pharmacy workforce leadership in reducing excess quantities of unused prescription drug products and development and implementation of prescription drug product return and disposal programs.

2146

EXPIRATION DATING OF PHARMACEUTICAL PRODUCTS

Source: Council on Pharmacy Practice

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs, such as medications in shortage or used for medical countermeasures, and reducing healthcare costs; further,

To advocate that the Food and Drug Administration implement procedures for pharmaceutical manufacturers to readily update expiration dates to reflect current evidence regarding the maximum length of drug potency and safety, using technology solutions when available; further,

To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.

This policy supersedes ASHP policy 1712.

Rationale

Extending the expiration date of commercially available pharmaceutical products for as long as possible, while maintaining drug potency and safety, reduces healthcare costs and increases access. This is especially important with medications in short supply or those used as medical countermeasures (i.e., FDA-regulated products [biologics, drugs, devices] that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease). ASHP encourages pre- and post-marketing research on expiration dates and the use of the most current authoritative data on expiration dates in drug product management. However, the current process for updating expiration dates in drug product labeling presents barriers to timely revision and should be streamlined to allow for timely updates. Technology solutions should be leveraged when possible to determine and communicate about expiration date extensions. Until such a process is implemented, regulators and accreditation agencies should permit healthcare organizations to rely on authoritative data when determining appropriate extended expiration dates for commercially available pharmaceutical products.

2147

PHARMACIST'S ROLE IN HEALTHCARE INFORMATION SYSTEMS

Source: Council on Pharmacy Management

To strongly advocate key decision-making roles for pharmacists in the planning, selection, design, implementation, and maintenance of medication-use information systems, electronic health records, computerized provider order entry systems, and e-prescribing systems to balance the security and integrity of data with the ability to facilitate clinical decision support, data analysis, and education of users for the purpose of ensuring the safe and effective use of medications; further,

To advocate for incentives to hospitals and health systems for the adoption of patient-care technologies; further,

To recognize that design, maintenance, and cyber-security of medication-use information systems is an interdisciplinary process that requires ongoing collaboration among many disciplines; further,

To advocate that pharmacists must have accountability for strategic planning and direct operational aspects of the medication-use process, including the successful deployment of medication-use information systems and continuity plans when the systems are unavailable.

This policy supersedes ASHP policies 1211 and 1701.

Rationale

ASHP recognizes that design, maintenance, and cyber-security of healthcare information systems (e.g., medication-use information systems, electronic health records, computerized provider order entry systems, e-prescribing systems) is an interdisciplinary process that requires ongoing collaboration across many disciplines. Maintaining the privacy of health information, in compliance with the Health Insurance Portability and Affordability Act (HIPAA), and ensuring patient safety in the face of cyber-attacks are essential concerns for every healthcare organization. Given the ever-evolving nature of pharmacist patient care, medication use, and health information technology, it is essential pharmacists have key decision-making roles in the planning, selection, design, implementation, and maintenance of such systems in order to help prevent and respond to cyber-attacks. To ensure the safe and effective use of medications, pharmacists must have accountability for strategic planning and direct operational aspects of the medication-use process, including the successful deployment of medication-use-related information systems by assessing vulnerabilities and vendor systems to validate the security and integrity of the data. Increased connectivity with vendor systems creates a mutual need to share access to patient information and other vital data, so risk mitigation must be considered at all points of access. This includes, for example, facilitating clinical decision support by assessing the minimum amount of patient health information vendors require to provide services, data analysis, education of users, and developing and implementing business continuity plans, to include fail-over testing of these plans, for when the systems are unavailable.

2020 Policy Positions

2001

SAFETY AND EFFECTIVENESS OF ETHANOL FOR PREVENTION OR TREATMENT OF ALCOHOL WITHDRAWAL SYNDROME

Source: Council on Therapeutics

To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,

To support hospital and health-system efforts that prohibit the use of oral or intravenous ethanol therapies to prevent or treat AWS; further,

To support the removal of oral or intravenous ethanol from hospital and health systems for the prevention and treatment of AWS; further,

To educate clinicians about evidence-based therapies for AWS.

This policy supersedes ASHP policy 1514.

This policy was reviewed in 2024 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

AWS can delay patient recovery and interfere with response to therapy. Based on a review of the available evidence, including treatment guidelines from the American Society of Addiction Medicine (ASAM), ASHP opposes the use of oral or intravenous ethanol to prevent or treat AWS. Limited and conflicting evidence of effectiveness, inability to achieve accurate and consistent dosing and blood levels, and the availability of safer and more effective therapies are among the reasons to oppose use of ethanol to prevent or treat AWS symptoms. Benzodiazepines are the preferred drugs for the treatment of AWS, along with other supportive and adjunctive therapies as clinically appropriate. Guidelines from the American Association of Family Physicians recommend benzodiazepines on a fixed schedule for AWS, outpatient detoxification, and enrollment in an alcohol treatment program. The use of pharmacological agents exclusive of ethanol is also an established part of UK clinical guidelines for alcohol treatment: core elements of alcohol treatment as well as the American Society of Addiction Medicine Clinical Practice Guidelines, both of which recommend that “oral or intravenous alcohol should not be used for the prevention or treatment of alcohol withdrawal.” ASHP supports efforts to prohibit the use of ethanol for AWS and advocates education to a variety of healthcare practitioner audiences to increase awareness of appropriate evidence-based therapies.

2002

EXCIPIENTS IN DRUG PRODUCTS

Source: Council on Therapeutics

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To encourage manufacturers to publicly disclose all excipients in drug products; further,

To advocate that the Food and Drug Administration require manufacturers to declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate, expand, and maintain interoperable information about excipients; further,

To promote research that evaluates the safety of excipients to guide clinical practice and to support the reporting and dissemination of this information via published literature, registries, and other mechanisms; further,

To foster education on the potential adverse events that may be caused by excipients; further,

To encourage documentation of allergic reactions or intolerances to or restrictions on specific excipients in the health record.

This policy supersedes ASHP policy 1528.

This policy was reviewed in 2024 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

Excipients are intended to be inactive ingredients that assist in delivering a pharmaceutically elegant medication. Ideally, excipients should have a specific purpose, including serving as a binder, disintegrant, solubilizer, preservative, or for pH adjustment for the proper performance of the dosage form. The properties of the final dosage form (e.g., stability) are, for the most part, highly dependent on the excipients chosen, their concentrations, and interaction with both the active compound and each other. Poor aqueous solubility and rate of dissolution are often the two critical factors that affect the formulation and development process and as a result, some formulations of medications may include high percentages of excipients to ensure the active ingredients are able to be delivered. However, some excipients are added to formulations to enhance color or texture and are not necessary for a stable and soluble product.

In some patients, however, excipients may cause adverse events or aggravate medical conditions. Examples include patients with a red-dye allergy reacting to a suspension containing red dye, fillers that have a high carbohydrate content breaking ketosis in patients who are on a

ketogenic diet for seizure management, exacerbation of kidney dysfunction in patients receiving a parenteral solution containing cyclodextrins, or metabolic ketoacidosis requiring dialysis in patients who are receiving high amounts of propylene glycol. Additionally, these adverse effects are not always well known or studied.

Inclusion of excipients and changes in excipients in drug product labeling, including their derivative source would allow substitution of a nonallergenic alternative, modification of therapy (such as giving a tablet instead of a dextrose containing suspension), closer monitoring of organ function, or ordering pertinent lab values that may alert practitioners to toxicities associated with excipients as opposed to the active drug.

Additionally, many patients and providers are unaware of the potential impact that excipients may have when selecting therapies and monitoring for adverse events. Currently, the FDA only provides guidance on excipient safety for new products but does not require it unless specific regulatory or statutory requirements are cited. These guidance documents do not establish legally enforceable responsibilities, nor do they require the manufacturer to disclose these excipients unless specifically requested by the FDA. Conversely, the European Union requires manufacturers to declare excipients on labelling if the medicinal product is an injectable, topical, or an eye preparation, as well as requiring excipients known to have a recognized action or effect to be declared on the labelling of all other medicinal products.

Education of manufacturers, pharmacists and other healthcare professionals, and patients regarding the use and potential adverse effects of excipients will be required. Interoperable medication-related databases will need to be configured and continuously updated to include information about drug product excipients, and electronic health record systems will need to permit documentation of allergies and medical conditions related to excipients as well as alert health care professionals to these allergies and intolerances.

2003

ANTICANCER TREATMENT PARITY

Source: Council on Therapeutics

To support anticancer treatment parity legislation at both the state and federal level that ensures equality of access and insurance coverage for all anticancer drug products approved by the Food and Drug Administration (FDA); further,

To advocate all insurers and manufacturers design plans containing limits on out-of-pocket expenditure so that patient cost sharing for anticancer treatment is equivalent, regardless of treatment modality or route of administration; further,

To encourage the development of policies and endorse practices that contribute to a decrease in anticancer treatment costs to the consumer; further,

To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of anticancer agents, regardless of route of administration.

This policy supersedes ASHP policy 1516.

This policy was reviewed in 2025 by the Council Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

An estimated $200 billion will be spent on cancer care by 2020, and a recent survey showed if faced with a cancer diagnosis, 57% of Americans say they would be most concerned about either the financial impact on their families or about paying for treatment. Additionally, there is an increase in insurance premiums, co-pays, co-insurance, and deductibles. Most insured cancer patients in the U.S. are responsible for a portion of the cost of their anticancer agents, which can be significant. The average out-of-pocket expense for Medicare patients with cancer is 23.7% of household income. Cancer survivors are 2.7 times more likely to file for bankruptcy.

Traditionally, intravenous (IV) and injected treatments were the primary methods of chemotherapy delivery. Patient-administered anticancer agents have become more prevalent and are now the standard of care for many types of cancer. Oral anticancer agents account for approximately 35% of the oncology development pipeline. Many oral anticancer agents do not have infusible or injectable alternatives and are the only treatment option for some cancer diagnoses. Oral agents have been embraced because of convenience, efficacy, and safety, but because insurers cover them differently than intravenous drugs, prescribing oral anticancer agents can impose burdensome levels of cost-sharing on patients.

While IV anticancer treatments are covered under a health plan's medical benefit, often requiring patients to pay a minimal co-pay or no cost at all for the medication, oral anticancer agents are usually covered under the pharmacy benefits. This results in increased out-of-pocket costs. Cost sharing of oral specialty drugs has increased from 3% in 2004 to 25% in 2013 and continues to rise.

The impact of rising out-of-pocket prescription costs for cancer patients can negatively affect adherence and subsequently treatment outcomes. Co-pays can be hundreds or thousands of dollars per month and, as a result, almost 10% of patients choose not to fill their initial prescriptions for oral anticancer agents. A study of claims data from more than 38,000 people who received a new prescription for one of 38 oral anticancer agents from 2014 to 2015 found that, as out-of-pocket costs rose, fewer patients filled their prescriptions. When the required co-pay was less than $10, only 10% of patients failed to pick up their prescriptions. This increased to 32% for patients whose out-of-pocket costs were between $100 and $500, and to 41% when costs were between $500 and $2000. When the out-of-pocket costs exceeded $2000, nearly half of patients (49%) never filled their prescriptions. Delayed initiation of treatment was also significantly higher for those with higher cost-sharing burdens.

Oral parity is a proposed legislative solution to alleviate coverage discrepancies between oral and intravenous anticancer agents. Parity laws are designed to ensure that orally administered agents for treating cancer are not more costly for patients than anticancer agents given via infusion at a clinic or hospital. At this point, 43 states and Washington, DC, have enacted parity laws that require patients to pay no more for an oral cancer treatment than they would for an infusion. Studies conducted in states with parity laws have generally showed an increase in treatment utilization, which have been found to reduce mortality rates in some instances.

However, state parity laws only apply to certain commercial health insurance plans, including those purchased by small groups and individuals. Self-funded patients, patients covered by health plans that fall under federal law (large, multi-state health plans), or those covered by Medicare and other federally funded insurance plans are not eligible. An estimated fifty percent of cancer patients are currently not protected under state parity laws.

The Cancer Drug Parity Act of 2019 (H.R. 1730, introduced on March 13th, 2019; formerly introduced in 2017 as H.R. 1409) would require any health plan that currently provides coverage for cancer treatment to provide coverage for self-administered anticancer agents at a cost no less favorable than the cost of IV, port-administered, or injected anticancer agents. The Cancer Drug Parity Act of 2023 (S. 2039) was recently introduced to the senate on June 15, 2023. It is proposed as a bill to amend the Employee Retirement Income Security Act (ERISA) and group health plans it supports. Medicare patients are not currently covered by this legislation, though Medicare is undergoing significant changes to combat the same problem of exorbitant out-of-pocket spending on oral medications.

There may be false patient perception that oral anticancer agents are less dangerous than IV chemotherapy, further supporting the important role of the pharmacist in educating the patients about the agent, its adverse effects, how to manage toxicities, and when to contact their healthcare team. Pharmacists monitor oral chemotherapy treatments to prevent medication and food interactions, adverse drug reactions, and medication errors. Pharmacists are also positioned to play an integral role in shared decision-making and assisting with procurement.

Treatment of cancer also continues to evolve, and many agents may not fall under the category of traditional chemotherapy (e.g., biologic agents, antimicrobials, and others). As a result, practitioners and legislatures have moved away from the singular term *chemotherapy* and use *chemotherapy*, *anticancer* and *cancer drug* interchangeably, with *anticancer* being the preferred term.

2004

EVALUATION OF ABUSE-DETERRENT DRUG MECHANISMS

Source: Council on Therapeutics

To encourage manufacturers to develop safe and efficacious abuse-deterrent formulations for drugs known to be abused and misused; further,

To promote research on the efficacy of abuse-deterrent mechanisms in preventing prescription drug abuse, and to support the reporting and dissemination of this information; further,

To advocate for legislation that would limit out-of-pocket expenditures for such formulations.

This policy supersedes ASHP policy 1512.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate

Rationale

The abuse of certain classes of prescription drugs, including narcotics and stimulants, has had a large impact on public health. One way the Food and Drug Administration (FDA) has sought to curb this activity is through the use of abuse-deterrent formulations (ADFs). ADFs are formulations that permit treatment of a patient's medical condition but reduce the likelihood of diversion, misuse, and abuse, and related adverse outcomes through various mechanisms, such as hindering the extraction of active ingredients, limiting their bioavailability, preventing administration through alternative routes, or making abuse of the manipulated product less attractive or rewarding.

The FDA has been taking steps to incentivize and support the development of opioid formulations with progressively better abuse-deterrent properties. These steps include working with individual sponsors on promising abuse-deterrent technologies, developing appropriate testing methodologies for both innovator and generic products, and publishing guidance on the development and labeling of abuse-deterrent opioids.

Despite these efforts, prescription stimulants used to treat attention deficit hyperactivity disorder have become drugs of choice for young adults, with as many as 20% of college students using such drugs for nonmedical purposes. According to a 2011 study, benzodiazepines were involved in 30.6% of prescription drug-related overdose deaths. However, to date, the FDA has not provided guidance on ADFs for any controlled substance other than opioids.

Despite the groundswell of support for abuse-deterrent opioid formulations, there is not strong evidence that such formulations deter abuse. One study of 232,874 patients across 437 facilities found an increase in abuse prevalence of all opioids after introduction of an abuse-deterrent formulation. That study showed little success in deterring abuse, finding instead that patients had switched to alternative drugs. There may also be unintended consequences of preferring abuse-deterrent formulations to regular formulations, such as increased costs borne by patients who legitimately need the drugs.

There also is a need to demonstrate that these formulations are truly abuse deterrent as well. In April 2015, the FDA published an industry guidance document on Abuse-Deterrent Opioids – Evaluation and Labeling. The document explains the FDA's "current thinking about the studies that should be conducted to demonstrate a given formulation has abuse-deterrent properties."

Addressing the growing rate of prescription drug abuse will require a multifaceted strategy; no one tactic will solve the problem. While ASHP supports measures such as abuse-deterrent formulations and rescheduling to prevent abuse, more research is necessary to determine which tactics are the most effective at deterring abuse.

2005

QUALITY CONSUMER MEDICATION INFORMATION

This policy was superseded by ASHP policy 2518.

2006
PHARMACIST'S LEADERSHIP ROLE IN ANTICOAGULATION THERAPY MANAGEMENT

This policy was discontinued in 2024.

2007
USE OF SURROGATE ENDPOINTS FOR FDA APPROVAL OF DRUG USES
Source: Council on Therapeutics

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to qualify the appropriateness of surrogate endpoints; further,

To support the continued use of qualified surrogate endpoints by the FDA as a mechanism to evaluate the effectiveness and safety of new drugs and new indications for existing therapies, when measurement of definitive clinical outcomes is not feasible; further,

To advocate that the FDA consistently enforce existing requirements that drug product manufacturers complete postmarketing studies for drugs approved based on qualified surrogate endpoints in order to confirm that the expected improvement in outcomes occurs, and to require that these studies be completed in a timely manner.

This policy supersedes ASHP policy 1011.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
Expedited approval programs provided by the FDA have resulted in substantial public health benefits, as illustrated by the use of surrogate endpoints to approve therapies for HIV and AIDS in the 1990s. More recently, these programs facilitated the approval of COVID-19 vaccines and treatments. During the pandemic, surrogate endpoints played a crucial role by providing early indications of effectiveness, allowing faster implementation during the global health emergency. The FDA provides four mechanisms to expedite the development and review process for drugs: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The structure and requirements for each of these mechanisms differs as described in a 2013 draft guidance for industry. However, to qualify for any of these programs, a drug must (1) address an unmet medical need, (2) provide benefit over available drug treatments, and (3) be used in the treatment of a serious or life-threatening condition. Further, the FDA guidance states that these programs are "intended to help ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks." Processes used to ensure a favorable risk–benefit profile include, but are not limited to, requirements for postmarketing studies to evaluate safety and effectiveness of the drug in real-world scenarios. However, the accelerated approval program is the only program that includes postmarketing studies as a requirement. The FDA has discretion to require additional studies on a case-by-case basis for drug products

approved via the other expedited mechanisms. Despite these safeguards, some features of these programs (e.g., smaller clinical trials, alternate trial designs, or limited-duration trials) can result in increased patient risk because less is known about a drug's side effect profile and efficacy due to limited patient exposure. In addition, as with all drugs, safety assessments benefit from use of the drug in post-approval patient populations, which better reflect real-world use than the controlled environment of a clinical trial.

A significant concern with the use of surrogate endpoints is the potential lack of transparency in how these endpoints are communicated to the medical community and general public. While surrogate endpoints are essential for facilitating drug approvals, their limitations and rationale for use are not always clearly conveyed. Without comprehensive clinical outcomes data, this lack of transparency can lead to misunderstandings about the benefits and risks of a drug. To address these issues, two new guidelines, SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)-Surrogate and CONSORT (Consolidated Standards of Reporting Trials)-Surrogate, have been specifically developed to enhance the reporting of trials that rely on surrogate endpoints.

Given that these drugs represent medical advances, their post-approval use can be extensive and, like all therapies, off-label use of these drug products is common. Unfortunately, prescribers and other clinicians are frequently unaware that an expedited pathway was utilized and that evidence limitations exist. This scenario raises significant concerns about whether there is sufficient clinician awareness to ensure appropriate and informed use of drugs approved via these pathways. Therefore, ASHP proposes unique labeling requirements, such as use of a logo or other visual mechanism, to temporarily inform clinicians about data limitations and provide guidance on appropriate use. This labeling would describe appropriate patient populations and monitoring parameters. Similar labeling requirements have been proposed for a new pathway under consideration for the development of antibiotics used to treat life-threatening infections. ASHP supports the approach but recommends that the increased labeling requirements be discontinued once the drug product manufacturer and FDA agree that sufficient data is available to support safe and effective use, or after the drug manufacturer completes any required postmarketing study commitments.

Given data limitations associated with approval of these therapies, ASHP advocates that the FDA be extremely diligent in ensuring that postmarketing commitments are met. Further, the FDA should use its existing authority as described under 21 CFR 314 subpart H and 21 CFR 601 subpart E if timelines or expectations for these commitments are not satisfactory. This authority allows the FDA to take legal action through penalties that include requiring labeling changes or rescinding marketing approval.

Finally, ASHP believes that research is needed to determine whether these expedited pathways are achieving the desired benefits, which include reducing the time and costs associated with drug product development, lowering overall healthcare costs, and increasing patient access to safe and effective drug therapies.

2008

HEALTH-SYSTEM FACILITY DESIGN

Source: Council on Pharmacy Management

To advocate the development and the inclusion of contemporary pharmacy and medication-use specifications in national and state healthcare design standards to ensure adequate space for safe provision of pharmacy products and patient care services; further,

To promote pharmacist involvement in the design-planning and space-allocation decisions of healthcare facilities.

This policy supersedes ASHP policy 0505.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate

Rationale

Often the design and location of health-system pharmacy departments are less than ideal. Many pharmacy departments do not have adequate square footage, and too often the pharmacy is located in the basement of the hospital, far removed from the patients. The impact of physical space on staff satisfaction may also contribute to staff turnover. Pharmacy design often occurs before pharmacy leadership has an opportunity for input on the design, location, or size.

Healthcare architects and facility engineers need to be knowledgeable in the contemporary and future needs of pharmacy design and the facility requirements for medication use (e.g., medication preparation rooms, temperature monitoring, automated dispensing cabinets). This includes, for instance, the inclusion of technical specifications (including those in applicable compendial standards of the United States Pharmacopeia) for pharmacies in national healthcare design standards.

Regarding facility design, pharmacist collaboration with the Association of Healthcare Engineers and the American Institute of Architects is paramount to design success. The Guidelines for Design and Construction of Hospital and Health Care Facilities is the primary document driving design decisions by architects and healthcare engineers. Research results on optimal, evidenced-based facility design to support safe medication use should be incorporated in new or renovation construction plans.

2009

ROLE OF THE PHARMACY WORKFORCE IN IDENTIFYING AND CARING FOR VICTIMS OF HUMAN TRAFFICKING

Source: Council on Pharmacy Practice

To recognize that human trafficking is a significant public health problem in the U.S.; further,

To affirm that the pharmacy workforce has important roles in identifying and caring for victims of human trafficking; further,

To foster education, training, and the development of resources to prepare the pharmacy workforce for their roles in identifying and caring for victims of human trafficking.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

The U.S. Department of Health and Human Services Office on Trafficking in Persons (OTIP) describes human trafficking as a form of modern slavery that "occurs when a trafficker exploits an individual with force, fraud, or coercion to make them perform commercial sex or work." OTIP outlines two types of trafficking: labor trafficking, in which individuals are compelled to work or provide services; and sex trafficking, in which "adults are compelled to engage in commercial sex by force, fraud, or coercion or minors are compelled to perform a commercial sex act regardless of the presence of force, fraud, or coercion."

Combating human trafficking is one of the central goals of the American Hospital Association Hospitals Against Violence Initiative. All healthcare providers have a role in identifying and caring for victims of human trafficking. These roles include recognizing indicators of human trafficking; being aware of common healthcare issues faced by human trafficking victims; providing for a patient's medical and nonmedical needs while providing a safe and comfortable environment; complying with applicable laws regarding reporting of suspected human trafficking, including child abuse; and providing care and resources for survivors of human trafficking.

2010

USE OF TWO PATIENT IDENTIFIERS IN THE OUTPATIENT SETTING

This policy was superseded by ASHP policy 2427.

Rationale

Errors caused by dispensing medications to the wrong patient are largely preventable. Although two patient identifiers are routinely used when medications are administered in inpatient settings, similar practices are not employed when dispensing medications for outpatient use. ASHP supports consistent use of two patient identifiers and believes that this safety strategy should be used to confirm patient identity at the time patients or their agents pick up filled prescriptions for outpatient use.

2011

CREDENTIALING AND PRIVILEGING BY REGULATORS, PAYERS, AND PROVIDERS OF COLLABORATIVE PRACTICE

Source: Council on Public Policy

To recommend the use of credentialing and privileging in a manner consistent with other healthcare professionals to assess a pharmacist's competence to engage in patient care services.

This policy supersedes ASHP policy 1907.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Credentialing and privileging processes are key to ensuring clinician competence to provide safe and effective patient care. They are also critical elements to securing reimbursement for healthcare services. ASHP opposes the development of credentialing or privileging processes by government agencies or payers without significant pharmacist input. We recognize that state laws, state boards of pharmacy, and payers will each approach credentialing and privileging differently, making a consistent process extremely beneficial.

2012

IMPORTATION OF DRUG PRODUCTS

Source: Council on Public Policy

To oppose wholesale importation of drug products as a method to lower drug costs.

This policy supersedes ASHP policy 0413.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Recent efforts to rein in drug pricing have centered on proposals to allow the wholesale importation of drugs (meaning importation of drugs by healthcare providers and distributors on a larger scale, rather than by individuals on a small scale) from foreign countries (e.g., Canada) as a means to reduce patient costs. Although states (e.g., Florida and Colorado) have passed wholesale importation laws, those laws cannot take effect until the state has crafted an importation plan, the Food and Drug Administration (FDA) has signed off on it, and the Department of Health & Human Services (HHS) Secretary has made the required certification to Congress.

Current law allows wholesale importation only in very limited circumstances (i.e., shortages) and requires the HHS Secretary to certify to Congress that allowing importation of drugs will not put public health and safety at risk and that it will result in significant savings. No Secretary has ever been able to make such a certification.

ASHP believes that wholesale importation of drugs cannot be accomplished while: (1) maintaining the integrity of the pharmaceutical supply chain and avoiding the introduction of counterfeit products into the U.S.; (2) providing for continued patient access to pharmacist review of all medications and preserving the patient-pharmacist-prescriber relationship; and (3) providing adequate patient counseling and education, particularly to patients taking multiple high-risk medications. Further, wholesale importation is unlikely to result in significant cost savings and reduces focus on drug pricing solutions that can reduce prices over the long term.

Nothing in this policy should be construed to oppose personal importation of drugs, meaning when a person travels over international borders (e.g., to Canada, Mexico, etc.) to access medications. The policy also does not oppose importation of drugs and related medical devices to alleviate a drug shortage when such importation is overseen by the FDA.

2013

PUBLIC QUALITY STANDARDS FOR BIOLOGIC PRODUCTS

Source: Council on Public Policy

To oppose federal or state legislation that would remove the requirement for biologic products to adhere to public quality standards; further,

To review and evaluate current public standards to ensure that they are relevant and appropriate to biologic products.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

ASHP has long recognized that application of quality standards (e.g., United States Pharmacopeia monographs or other applicable guidance) helps guarantee safe use of drugs. ASHP joined virtually all national pharmacy groups, including more than 30 state pharmacy associations, in opposing Congressional efforts to eliminate monographs for biologic medications in the 115th and 116th Congresses. The FDA advocates for voluntary standards for biologic products on the basis of reduced costs and improved access, but the agency does not provide data to justify that stance. The arguments against requiring monographs center on their potential use as a barrier to competition, because manufacturers could incorporate patentable characteristics relevant to the product's safety and efficacy. However, removing monographs for one class of drugs could open the door to removal of standards for other drug classes and to laxer safety standards generally. There is evidence that the monographs do not dampen innovation, as new products continue to enter the market.

2014

NALOXONE AVAILABILITY

This policy was superseded by ASHP policy 2211.

2015

NETWORK CONNECTIVITY AND INTEROPERABILITY FOR CONTINUITY OF CARE

Source: Council on Pharmacy Management

To advocate the use of electronic information systems, with appropriate security controls, that enable the integration of patient-specific data that is accessible in all components of a health system; further,

To support the use of technology that allows the transfer of patient information needed for appropriate medication management across the continuum of care; further,

To urge computer software vendors and pharmaceutical suppliers to provide standards for definition, collection, coding, and exchange of clinical data used in the medication-use process; further,

To pursue formal and informal liaisons with appropriate healthcare associations to ensure that the interests of patient care and safety in the medication-use process are fully represented in the standardization, integration, and implementation of electronic information systems; further,

To strongly encourage health-system administrators, regulatory bodies, and other appropriate groups to provide health-system pharmacists with full access to patient-specific clinical data; further,

To advocate that client-vendor agreements include timelines for data destruction; further,

To oppose the selling of data for unauthorized uses; further,

To educate health-system leaders about potential use and misuse of shared data.

This policy supersedes ASHP policy 0507.

This policy was reviewed in 2025 by the Council on Pharmacy Management and was found to still be appropriate.

Rationale

For the past two decades, the U.S. health system, through the Assistant Secretary for Technology Policy, Office of the National Coordinator for Health Information Technology (ASTP), has supported the adoption of health information technology and the promotion of nationwide, standards-based health information exchange to improve patient care. The 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act provided the Department of Health and Human Services with additional authority to promote health information technology, including the secure exchange of electronic health information.

Institutions and practice sites have invested in information systems that work for its specific situation. These systems were developed by multiple vendors, each with their own proprietary structures and labels. Information was and continues to be found in silos, within health systems, within institutions, and even within departments.

As defined by the Healthcare Information and Management Systems Society (HIMSS), interoperability is “the ability of different information systems, devices, or applications to connect, in a coordinated manner, within and across organizational boundaries to access, exchange and cooperatively use data amongst stakeholders, with the goal of optimizing the

health of individuals and populations." ASTP has developed a roadmap for interoperability and created calls to action for entities with specific roles in our healthcare system (e.g., the Calls to Action and Commitments for People and Organizations That Deliver Care and Services). As government agencies, standards-setting organizations, and professional associations work toward interoperability of health information technology, it is important to ensure this includes the ability of healthcare providers and patients to securely access and use health information from different sources and settings relevant to medication use to ensure patient-centered continuity of care.

Along with secure access and health information sharing, providers and health systems must be cognizant of how a vendor will handle data, how it plans to safeguard data, and whether and how data will be used for secondary purposes (e.g., research, advertising). ASHP recognizes that continuity of care is a vital requirement in the appropriate use of medications. Pharmacy personnel with full access to necessary patient specific clinical data have the responsibility for ensuring continuity of care as patients move from one setting to another (e.g., ambulatory care, inpatient care, community pharmacy, home care). Achieving information systems that share relevant patient care data securely across care settings is critical in optimizing medication use across care settings.

2016

MEDICATION FORMULARY SYSTEM MANAGEMENT

Source: Council on Pharmacy Management

To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; and (3) should not be based solely on economic factors; further,

To support the concept of a standardized medication formulary system among components of integrated health systems when standardization leads to improved patient outcomes; further,

To oppose independent payer-directed formulary decisions that would increase the complexity of the medication-use system.

This policy supersedes ASHP policies 9601 and 1805.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale

A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health. A formulary includes, but is not limited to, a list

of medications, standardized medication concentrations, and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for healthcare organizations to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and cost-effective medication therapy. The formulary system is the ongoing process through which a healthcare organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

As described in more detail in the ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System, a fundamental characteristic of the formulary system is that all decisions are made based on factors that result in optimal patient care, include the involvement of appropriate healthcare professionals, and are not based solely on economic factors.

Formulary management techniques may differ under an integrated or network system versus an individual healthcare entity. Standardized drug formularies within integrated health systems increase coordination complexity but help drive standardized medication use processes across sites of care.

Ensuring consistency within a formulary system is crucial, and the development of adherence tools and metrics for compliance plays a significant role in achieving this. By utilizing these tools, healthcare professionals are more likely to follow formulary guidelines, leading to better patient outcomes and more efficient use of resources. Additionally, monitoring and evaluating compliance through these metrics allows for the identification of areas needing improvement, ensuring that the formulary system is used as intended. This approach also supports quality assurance programs by providing a basis for tracking adherence over time, identifying trends, and implementing corrective actions when necessary. Furthermore, the data obtained from these metrics can inform future formulary decisions, helping committees make more informed choices about which medications to include or exclude based on patterns of adherence and non-adherence.

Additionally, insurance coverage of medications should not interfere with the safe and effective provision of care. For example, some hospitals are currently being forced to administer a specific payer-preferred biosimilar drug to a covered patient, which requires hospitals to stock a different product for each payer and then ensure the correct one is dispensed. This costly and resource-intensive practice also has medication safety implications and negatively affects supply chain efficiency. Biosimilar drugs are considered to be therapeutically equivalent, but the current Food and Drug Administration (FDA) approval process does not include a determination of interchangeability between reference and biosimilar products. Because the substitution of a biosimilar for a reference product is a decision outside the FDA regulatory process, it is therefore a matter of state pharmacy law. The obligation to have a specific payer-preferred biosimilar results in hospitals and health systems devoting significant resources to procure, store, label, and dispense payer-preferred biosimilars. This duplication adds complexity to the medication-use process, and as more biosimilars become available, the potential for harmful medication errors will increase. The use

of biosimilars was a key cost-reduction concept in the Affordable Care Act. However, in May 2018, the price linkage cost-reduction concept within Medicare Part B was rescinded. Going forward, reimbursement will be based on the specific biosimilar product pricing. The full impact of this change for individual healthcare organizations will depend on patient and payer mix. Biosimilars that are priced at a lower acquisition cost compared to the innovator product are likely to stagnate or lose market share due to a low reimbursement margin. As a result, pricing of biosimilars may increase to make the reimbursement margin competitive with the innovator product, leaving healthcare organizations in search of other cost reduction opportunities.

2017

ROLE OF THE PHARMACY WORKFORCE IN PREVENTING ACCIDENTAL AND INTENTIONAL FIREARM INJURY AND DEATH

Source: Council on Pharmacy Practice

To recognize that accidental and intentional firearm injury and death in the U.S. is a public health crisis; further,

To affirm that the pharmacy workforce has important roles in the comprehensive public health and medical approach to reducing death and disability from firearm injury.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

Firearm-related injury is a leading cause of death in the U.S. The Centers for Disease Control and Prevention reported over 48,000 deaths were caused by firearm-related injuries in 2022 (56.1% from death by suicide, 40.8% by homicide, 3.1% by legal intervention, unintentional injuries, or unknown intent). Mass shootings represent approximately 1% of firearm-related deaths.

Studies estimate that the incidence of nonfatal firearm-related injuries is double that of fatal firearm-related injuries. Firearm-related injury is a medical and public health problem that hospitals and health systems play an important role in preventing and treating. Evidence-based public health strategies can be employed when violence and firearm-related injury are framed as a complex disease. This approach enables identification of primary, secondary, and tertiary levels of prevention and intervention strategies. Primary prevention, measures taken before the onset of injury (i.e., before the gun is fired), seek to interrupt the transmission of violence and improve the safety of communities. Examples of primary prevention include surveillance to gain insight into causes and determine the impact of interventions of firearm-related injury and violence; identification of risk factors associated with violence from firearms; and development, dissemination, and implementation of prevention strategies. Secondary prevention begins when the firearm causes injury and includes strategies for early response to triage care and minimize morbidity and mortality through emergency and inpatient medical care. Lastly, tertiary prevention provides long-term strategies aimed at caring for the victim following injury. It offers opportunities to not only provide acute care for the injured but to deploy services such as hospital-based violence intervention programs screening and treatment for post-traumatic

stress disorder, and case management aimed at preventing firearm-related violence and injury recidivism.

In 2024, U.S. Surgeon General Dr. Vivek Murthy released a first-ever Surgeon General's Advisory on Firearm Violence, declaring it to be a public health crisis. Among other recommendations, the advisory calls for the following community risk reduction and education prevention strategies:

- Implement community violence interventions to support populations with increased risk of firearm violence involvement.
- Incorporate organizational violence prevention and emergency preparedness elements into safety programs.
- Encourage health systems to facilitate education on safe and secure firearm storage.
- Address structural determinants that increase the risk of firearm violence.

ASHP recognizes that a comprehensive public health and medical approach to reducing death and disability from firearm injury is needed. The pharmacy workforce has important roles in implementing the interventions needed to reduce death and disability from firearms.

2018

SAFE USE OF TRANSDERMAL SYSTEM PATCHES

Source: Council on Pharmacy Practice

To encourage hospitals and health systems to implement policies and procedures to ensure safe use of transdermal system patches; further,

To advocate for enhanced patient and consumer education and product safety requirements for transdermal system patches; further,

To encourage manufacturers of transdermal system patches to collaborate with pharmacists and other stakeholders to identify and implement packaging, labeling, and formulation changes that prevent accidental exposure and facilitate safe disposal.

This policy supersedes ASHP policy 1404.

Rationale

There have been many reports of errors associated with and abuse or misuse of transdermal system patches. Pharmacists are in a unique position to improve the safe use of these products by encouraging implementation of best practices such as electronic health record builds; regular nursing checks for transdermal patches; and policies for ordering, handling, and disposal of these products. Better patient and consumer education specific to this unique dosage form, especially for outpatient use, is also an important component of safe use. Manufacturers could also take additional steps to prevent misuse of these products by collaborating with pharmacists and other stakeholders to identify and implement packaging, labeling, and formulation changes that would facilitate safe disposal and prevent accidental exposure.

2019
ACCESS TO AFFORDABLE HEALTHCARE
Source: Council on Public Policy

To advocate for access to affordable healthcare for all, including coverage of medications and related pharmacist patient care services; further,

To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective healthcare services; (2) optimize treatment outcomes; (3) minimize overall costs without compromising quality; and (4) ensure patient choice of healthcare providers, including pharmacy services; further,

To advocate that healthcare payers seek to optimize continuity of care in their design of benefit plans.

This policy supersedes ASHP policy 1001.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
This policy expresses ASHP's stance on access to healthcare in the United States. The policy emanated from ASHP policies dealing with affordability and accessibility of pharmaceuticals. ASHP believes that it is important to address the larger issue of healthcare access, particularly due to the impact of the cost of medications on the nation's overall healthcare budget as well as pharmacy budgets in hospitals and health systems. The cost of healthcare is high throughout the United States, for people across all income groups and backgrounds, but even more so for vulnerable and underserved populations. Healthcare should be affordable, but also sufficient to ensure patient access to services.

2020
CARE-COMMENSURATE REIMBURSEMENT
Source: Council on Public Policy

This policy was discontinued in 2025.

2021
FUNDING, EXPERTISE, AND OVERSIGHT OF STATE BOARDS OF PHARMACY

This policy was superseded by ASHP policy 2505.

2022

DISPENSING BY NONPHARMACISTS AND NONPRESCRIBERS

Source: Council on Public Policy

To reaffirm the position that to ensure optimal patient outcomes all medication dispensing functions must be performed by, or under the supervision of, a pharmacist; further,

To reaffirm the position that any relationships that are established between a pharmacist and other individuals in order to carry out the dispensing function should preserve the role of the pharmacist in (a) maintaining appropriate patient safety, (b) complying with regulatory and legal requirements, and (c) providing individualized patient care; further,

To advocate that all medication dispensing, regardless of setting, be held to the same regulatory standards that apply to dispensing by a pharmacist; further,

To urge pharmacists to assume a leadership role in medication dispensing in all settings to ensure adherence to best practices.

This policy supersedes ASHP policy 0010.

This policy was reviewed in 2025 by the Council Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The Council recognizes the reality of limited pharmacist availability and lack of comprehensive pharmacy services in many settings, including public health clinics, rural and urban outreach clinics, and hospital emergency departments. However, the Council believes that responsibility and services of pharmacists are critical to safe medication use and that all dispensing, regardless of setting, should meet the same standards that apply to pharmacies and pharmacists. The Council believes that the current ASHP Minimum Standard for Pharmaceutical Services in Ambulatory Care is explicit and pertinent to the practice of dispensing by nonpharmacists and nonprescribers. The Council also noted that this type of drug delivery and dispensing arrangement does not constitute collaborative drug therapy management as defined in ASHP policy, Dispensing by Nonpharmacists and Nonprescribers.

2023

NEW CATEGORIES OF LICENSED PHARMACY PERSONNEL

Source: Council on Public Policy

To oppose the creation of new categories of licensed pharmacy personnel.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

State efforts to introduce a "pharmacist assistant" category conflict with longstanding ASHP efforts to support the professional growth of licensed or registered pharmacy technicians. Pursuant to these state proposals, pharmacists could delegate a number of activities that fall under the purview of their practice to the pharmacist assistant, such as receiving telephone calls, prescriptions, tech-check-tech, etc. Not only would this create confusion regarding terminology and job roles, it would undermine ASHP's work to professionalize the technician role. It also conflicts with efforts within Veterans Affairs and Department of Defense to fully utilize the pharmacy workforce. The policy should not be read as impeding the use of current licensed personnel, including technicians and students.

2024

SAFETY AND EFFICACY OF COMPOUNDED TOPICAL FORMULATIONS

Source: Council on Therapeutics

To encourage pharmacists to take a leadership role in developing processes that would ensure quality, safety, and effectiveness of compounded topical formulations; further,

To advocate that ASHP expand its repository of evidence-based formulations that could serve as a resource for compounding topical formulations; further,

To advocate that public and private payers and healthcare providers collaborate to create standardized and efficient methods for authorizing payment for medically necessary compounded topical formulations; further,

To encourage hospitals and health systems to develop policies and procedures to guide clinicians in making informed decisions regarding the prescribing and use of compounded topical formulations; further,

To encourage pharmacists to take a leadership role in developing and providing education on the safety and efficacy of compounded topical formulations to providers and consumers.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

Compounded topical formulations are meant to be customized for individuals whose needs cannot be met by commercially available drugs. Unlike the drugs made by conventional manufacturers that require Food and Drug Administration (FDA) approval, compounded drugs such as various topical formulations are not evaluated by the FDA for safety, effectiveness, or quality, and many are exempt from the new-drug approval process, current good manufacturing practice, and other FDA requirements. In addition, quality standards for compounded drugs are generally lower than those for FDA-approved drugs; therefore,

compounded drugs can pose increased safety risks (e.g., being contaminated or having the wrong potency) or lack efficacy.

Because some drugs do have FDA approval for topical application, clinicians and patients may not be aware of potential safety risks or potential lack of effectiveness associated with certain ingredients and combinations of ingredients in compounded topical pain creams. When these agents are compounded, at least one of the ingredients is an active ingredient in an FDA-approved topical pain cream (e.g., lidocaine), while the remaining ingredients may be active ingredients in drugs approved by the FDA for non-topical administration to treat non-pain-related indications (e.g., antidepressants, anticonvulsants, antivirals, narcotics). In addition, the literature supporting the use of the additional agents outside their normal vehicle of administration is often not well designed or sufficiently powered to demonstrate efficacy. A study published by the U.S. Department of Defense found that these combination-compounded pain creams were no better than placebo creams and, given their higher costs, which had escalated to cost of $6 million per day, should no longer be used.

Issues of fraud are also well known with compounded topical formulations. In August 2018, the Department of Health and Human Services Office of Inspector General (OIG) found that from 2006 to 2015, spending for these drugs increased 625%, and spending for compounded topical drugs—such as creams, gels, and ointments—grew at an even faster pace. Medicare Part D sponsors cover these drugs under certain circumstances. The OIG also found that Part D spending for compounded topical drugs increased 2353% from 2010 to 2016, rising from $13.2 million to $323.5 million. Much of this growth occurred from 2014 to 2016, when spending increased by more than $200 million and raised concerns that the drugs that were billed to Part D were not always dispensed or medically necessary. Upon investigation, the OIG found that many of the parties charging Part D were in a handful of cities, with thousands of prescriptions written by a single provider and filled by a limited number of pharmacies. This led HHS to conclude that the prescribers may not have had legitimate doctor-patient relationships with the beneficiaries.

Given these challenges, pharmacists will need to assume a leadership role in developing processes to ensure the quality, safety, and effectiveness of compounded topical formulations, including developing and providing education on compounded topical formulations for providers and consumers, and expanding the ASHP repository of evidence-based formulations. Public and private payers and healthcare providers will need to collaborate to create standardized and efficient methods for authorizing payment for medically necessary compounded topical formulations, and hospitals and health systems will need to develop policies and procedures to guide clinicians in making informed decisions regarding prescribing and use of compounded topical formulations.

Finally, with the updates to USP 795, which outlines provisions on non-sterile topical compounding, issues with training, competence, and compounding topicals during times of drug shortages, ASHP should continue to be a leader in this area for its members.

2025

POSTMARKETING STUDIES

Source: Council on Therapeutics

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest and to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA and other agencies to fulfill this expanded mission related to postmarketing surveillance and studies; further,

To advocate that such studies compare a particular approved drug product or licensed biologic product with (as appropriate) other approved drug products, licensed biologic products, medical devices, or procedures used to treat specific diseases; further,

To advocate expansion of studies of approved drug products or licensed biologic products to improve safety and therapeutic outcomes and promote cost-effective use; further,

To encourage impartial public-private partnerships or private-sector entities to also conduct such studies.

This policy supersedes ASHP policies 1004 and 0515.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

Pharmacists, other members of the healthcare team, patients, and private and public payers need objective, authoritative, and reliable evidence to make the best treatment decisions. Since the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Agency for Healthcare Research and Quality (AHRQ) has been tasked with studying the outcomes, comparative clinical effectiveness, and appropriateness of healthcare items and services. For such research to contribute to the practice of evidence-based patient care, good clinical decision-making, and rational drug use, AHRQ must evaluate devices, invasive procedures, and prescription and nonprescription medications, including both labeled and unlabeled uses of prescription drugs. Since prescription drugs represent a significant and growing portion of healthcare costs, the need for such research is increasingly important. Although impartial private sector entities can supplement the research efforts of government agencies such as AHRQ, only the federal government has the ability to support such independent research, provide oversight to safeguard the integrity of the research process, and disseminate the findings.

Furthermore, to ensure safety, the Food and Drug Administration (FDA) has several requirements for manufacturers and programs in place to monitor postmarket adverse events.

These requirements and programs include the Division of Medication Error Prevention and Analysis, which is responsible for monitoring and preventing medication errors related to the naming, labeling, packaging, and design for CDER-regulated drugs and therapeutic biological products; the Risk Evaluation and Mitigation Strategy (REMS) program, which is designed to help reduce the occurrence and severity of certain serious risks; by informing and supporting the execution of the safe use conditions described in the medication's FDA-approved prescribing information; the Safe Use Initiative, a program that aims reduce preventable harm by identifying specific, preventable medication risks and developing, implementing, and evaluating cross-sector interventions with partners who are committed to safe medication use. Other programs include the FDA Adverse Event Reporting System (FAERS), which is a database that contains adverse event reports, medication error reports, and product quality complaints resulting in adverse events that were submitted to FDA, and MedWatch, the FDA Safety Information and Adverse Event Reporting Program, which permits voluntary reporting by consumers and healthcare professionals and mandatory reporting for regulated industry and user facilities. Additionally, the FDA requires that adverse drug events (ADEs) must be reported in accordance with the requirements of 21 CFR 310.305 and 314.80, which require three types of ADE reports: (1) 15-day reports of serious, unlabeled events; (2) 15-day narrative increased frequency reports of serious, labeled events; and (3) periodic reports.

2026

GABAPENTIN AS A CONTROLLED SUBSTANCE

Source: Council on Therapeutics

To advocate that the Drug Enforcement Administration classify gabapentin as a Schedule V substance due to its potential for abuse and patient harm.

This policy was reviewed in 2024 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

Gabapentin is a structural analog of gamma-aminobutyric acid that is approved by the Food and Drug Administration (FDA) for post-herpetic neuralgia and as an adjunctive therapy for partial seizures. Gabapentin has been identified as an opportunistic drug of abuse which, when used in conjunction with other medications, particularly opioids, may result in serious adverse events such as respiratory depression and even death. Gabapentin is used due to its low cost, classification as a noncontrolled substance, and increasing rates of on- and off-label prescribing attributable to clinicians' desire for an alternative to opioids for pain management. In the U.S., gabapentin is and remains a noncontrolled substance at the federal level despite evidence suggestive of diversion and abuse with opioids. Most recently, several states have made an effort to combat the diversion and abuse of gabapentin by examining various regulatory approaches, such as reclassification of gabapentin as controlled substance or mandating the reporting of the prescribing and/or dispensing of gabapentin to a state-level prescription drug monitoring program (PDMPs). This fragmented geographic approach yields only a modest benefit in combating abuse and the national opioid epidemic. Hence, federal-level reclassification of gabapentin as controlled substance and implementation of national

pharmacovigilance is warranted. As recently as April 2019, the United Kingdom reclassified gabapentin as a Class C controlled substance, which required similar dispensing and monitoring as controlled substances in the U.S., due to the increase in abuse they have seen in this drug.

As defined by the Drug Enforcement Administration (DEA), Schedule V controlled substances "are defined as drugs with lower potential for abuse than Schedule IV" substances. Schedule IV substances "are defined as drugs with a low potential for abuse and low risk of dependence." Recent data from multiple sources have shown a significant increase in gabapentin misuse, abuse, and diversion over the past 10 years, and one study found that 22% of a sample of 162 opioid-dependent patients had a prescription for gabapentin, of which 40% indicated they used more than prescribed to augment and enhance their opioid experiences. Illicit use of gabapentin has increased drug diversion and fatality rates, as indicated by data from the Researched Abuse, Diversion and Addiction Related Surveillance (RADARS) system and American Association of Poison Control Centers (AAPCC), respectively.

The criteria used by DEA to determine whether to control or reschedule a drug include (a) the drug's actual or relative potential for abuse; (b) scientific evidence of its pharmacological effect, if known; (c) the state of current scientific knowledge regarding the abuse of the drug or other substance; (d) its history or current pattern of abuse; (e) the scope, duration, and significance of abuse; (f) what, if any, risk there is to public health; (g) its psychic or physiological dependence liability; and (e) whether the substance is a precursor of a substance already controlled under the law. Based on an assessment using these criteria, gabapentin is similar to other controlled substances found in Schedule V and should therefore be assigned to Schedule V. Additionally, gabapentin closely resembles pregabalin, a schedule V drug under the Controlled Substances Act in its chemical structure and pharmacological activity. Because some states have already taken steps to reschedule gabapentin as Schedule V or have added it to their PDMPs, the DEA should take steps to change the schedule status of gabapentin to ensure continuity of care and monitoring.

While it is difficult to predict the impact rescheduling may have on abuse, the current extent of abuse is likely exacerbated by easy access to and excessive supply of these therapies. However, the potential public health benefit of rescheduling must be weighed against concerns about restricting patients' access to treatment and increasing administrative and other burdens on pharmacists and other clinicians. The proposed change to a more restrictive schedule would require stricter recordkeeping and security processes, which could in turn make providers reluctant to prescribe these therapies for patients who need pain management. In balancing these concerns, it should be noted that increased control of drugs with abuse potential is in the best interests of patients and public health. DEA and other stakeholders should monitor the impact of this scheduling change on patient access and practice, as well as monitor the impact of other strategies that have been implemented to minimize the abuse and diversion of these therapies.

2027

RESIDENCY TRAINING FOR PHARMACISTS WHO PROVIDE DIRECT PATIENT CARE

Source: Council on Education and Workforce Development

To recognize that optimal direct patient care by a pharmacist requires the development of clinical judgment, which can be acquired only through experience and reflection on that

experience; further,

Pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience; further,

To support the position that the completion of an ASHP-accredited postgraduate-year-one residency be required for all new college or school of pharmacy graduates who will be providing direct patient care.

This policy supersedes ASHP policies 0701 and 0005.

This policy was reviewed in 2025 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

Pharmacists who engage in direct patient care can improve patient outcomes and significantly decrease the overall costs of the healthcare system. Completion of a postgraduate pharmacy residency enables a pharmacist to maximize the provision of these direct patient care services. The use of well-trained pharmacy technicians and technological advances will minimize pharmacists' dispensing roles. Based on the assumption that in the next 20-30 years most pharmacists will be providing direct patient care, it is incumbent upon the pharmacy profession to ensure that pharmacists are in a position to most effectively optimize medication outcomes.

Pharmacy students who graduate meet the minimum competency requirements based on pharmacy licensing examinations; however, pharmacists who have completed a residency are better equipped to provide direct patient care due to advanced training based on repetitive practice, preceptor guidance, and the additional interdisciplinary training they receive. This direction is consistent with ASHP's Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems.

Similar to the medical model in which medical school graduates complete a residency that allows for the standardization of physician training and the attainment of an appropriate level of competency, the profession of pharmacy would benefit from a similar standardization of training. The value of pharmacy residency programs has been demonstrated over time and has stimulated a significant increase in accredited residency programs as well as employer demand for residency-trained pharmacists. Residency training bolsters clinical skills and further develops clinical judgement through experience and reflection on that experience.

2028

PHARMACIST'S ROLE IN HEALTH INSURANCE BENEFIT DESIGN

Source: Council on Pharmacy Management

To advocate that pharmacy practice leaders collaborate with internal and external partners who design, negotiate, and select their own organization's health plans and pharmacy benefit management contracts to preserve patient continuity of care and the integrity of the health-system pharmacy enterprise; further,

To provide education and resources for all partners on the health plan development process, analysis of pharmacy benefit design, contemporary formulary review processes, and application of medication safety principles on formulary decision-making.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale

Pharmacy leadership should be directly involved in the selection of the health system's pharmacy benefit manager (PBM) servicing their employees' health plan, and the terms of that contract with that PBM. Employers typically look to balance value for the employee while attempting to control costs. As health systems evaluate and select plans, there may not always be due consideration given to the potential impacts on patient continuity of care and on that health system's pharmacy enterprise and financial solvency in servicing employees' prescriptions through the selected PBM. Aside from the safety and continuity of care implications to the patient if the health system's pharmacy is excluded from the employees' network, organizations may unknowingly undermine utilization of their outpatient cancer and infusion programs. Three PBMs control the majority of the PBM market, exerting heavy influence in costs, pharmacy participation, formulary, and prior authorization criteria. By including pharmacy leadership to help make a well-informed decision about selecting a servicing PBM for a health system, and the contract terms associated with that PBM (i.e., clinical and financial aspects), some of these unintended consequences could be avoided.

2029

PRESERVING PATIENT ACCESS TO PHARMACY SERVICES FOR MEDICALLY UNDERSERVED POPULATIONS

Source: Council on Pharmacy Management

To advocate for funding and innovative payment models to preserve patient access to acute and ambulatory care pharmacy services by rural or medically underserved populations; further,

To support the use of telehealth to maintain pharmacy operations and pharmacist-led comprehensive medication management that extend patient care services to and enhance continuity of care for rural or medically underserved populations; further,

To advocate that the advanced communication technologies required for telehealth be available to rural or medically underserved populations; further,

To advocate for funding of loan forgiveness or incentive programs that recruit pharmacists and pharmacy technicians to practice in rural or medically underserved populations.

This policy was reviewed in 2025 by the Council on Pharmacy Management and was found to still be appropriate.

Rationale

Medically Underserved Areas (MUAs) and Medically Underserved Populations (MUPs) are areas or populations designated by the Health Resources and Services Administration as having too few primary care providers, high infant mortality, high poverty, or a high elderly population. Whereas MUAs are a geographic designation, MUPs have a shortage of primary care health services for a specific population within an established geographic area. MUPs may face economic, cultural, or linguistic barriers to healthcare; examples include low-income, Medicaid-eligible, unhoused, migrant or seasonal worker, or Native American populations. Many federal programs use different types of shortage designations to determine eligibility. Trends within the healthcare industry are also increasing the number of MUPs. Closure of hospitals, waning interest in primary care practice among medical graduates, and the fiscal challenges of providing care in areas with declining populations or fewer insured patients contribute to this problem. Nationally, hospitals in rural areas and MUAs are at high financial risk due to low reimbursement rates and decreasing local populations. These factors make it difficult for hospitals to cover fixed costs, let alone remain up-to-date with technological advances and emerging healthcare practices. The impact of these closures on access to and continuity of care is substantial, such as loss of access to emergency care in the community and acute mental health or substance abuse disorder treatment services.

Regardless of hospital closures, MUAs commonly struggle to recruit and retain healthcare providers, especially when hospitals close due to provider relocation. As a result, MUAs and MUPs are often left without access to vital care sites, which further exacerbates gaps in access to specialty care (i.e., impacted population missing regular specialists visits and losing their access point for referrals after local hospital closures). Once hospitals close, other healthcare resources dwindle, leading to hospital deserts and dramatic decreases in access to and continuity of care. As the number of hospital deserts increase, residents are forced to seek care elsewhere, if at all. In a 2018 Government Accountability Office report, elderly and low-income populations were more likely to be negatively impacted by rural hospital closures, and these populations were also found to be more likely to delay or forgo care after a hospital closure if the patient had to travel longer distances. Not all rural hospital closures lead to complete loss of healthcare access, which is often due to successful transitions of services to community-based primary care. Here, residents still have access to primary care services but not necessarily critical services, such as those necessary for cardiac arrest or stroke. There is no systematic approach to determine which services are critical to provide locally or virtually (e.g., telehealth), and not every hospital closure smoothly transitions residents or their healthcare needs to a primary care facility.

2030
INTERSTATE PHARMACIST LICENSURE

This policy was discontinued in 2025.

2031
CONTINUITY OF CARE IN INSURANCE PAYER NETWORKS

This policy was superseded by ASHP policy 2502.

2033
PATIENT SUPPLIED DEVICE FOR USE IN HEALTH SYSTEM
Source: Council on Pharmacy Management

To recommend that hospitals and health systems have a system in place for determining the risk versus benefit of permitting a patient to use his or her own medication administration devices; further,

To advocate that hospitals and health systems have policies and procedures, including the training of staff, on the use and management of medication administration devices and devices that augment medication administration (e.g., continuous glucose monitors); further,

To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team; further,

To advocate for adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices.

This policy supersedes ASHP policy 0806.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
The potential exists for serious patient safety and liability issues for healthcare staff when the use of patients' own devices is allowed. Devices unfamiliar to staff are particularly risky and may result in patient harm. There are, however, occasions when the benefits of using patients' own devices may outweigh the risks. Organizational policies and procedures should exist for handling such situations, outline expedient methods to gain familiarity and competency demonstration with a device (e.g., insulin pump, surgically implanted pain management pump), and delineate the process for documenting use of a device in the electronic health record. A pharmacist should be available to verify the medication and the associated device and use a technique (e.g., Situation, Background, Assessment and Recommendation [SBAR], team huddle) for communicating critical information to the interprofessional care team.

2034
STAFFING FOR SAFE AND EFFECTIVE PATIENT CARE

This policy was superseded by ASHP policy 2133.

2035
ROLE OF THE PHARMACY WORKFORCE IN VIOLENCE PREVENTION
Source: Council on Pharmacy Practice

To recognize that violence in the U.S. is a public health crisis; further,

To affirm that the pharmacy workforce has important roles in a comprehensive public health and medical approach to violence prevention, including leadership roles in their communities and workplaces; further,

To encourage members of the pharmacy workforce to seek out opportunities to engage in violence prevention efforts in their communities and workplaces; further,

To promote collaboration between the pharmacy workforce and community and healthcare organizations in violence prevention efforts; further,

To foster education, training, and the development of resources to prepare the pharmacy workforce for their roles in violence prevention; further,

To support research and dissemination of information on the effectiveness of pharmacy-focused violence-prevention strategies.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
The World Health Organization defines violence as "the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation." The Centers for Disease Control and Prevention (CDC) reports that in the U.S. 7 people die a violent death each hour -- 47,000 from suicide and 19,500 from homicide annually -- and a 2015 report found more than 2.5 million violence-related injuries annually. The CDC estimates that violence costs the U.S. $9 billion annually in medical costs and lost work, and a separate estimate places the cost of violence as a whole to U.S. hospitals and health systems at $2.7 billion dollars in 2016. The staggering human loss and soaring costs have led numerous organizations of healthcare and public health professionals to label violence a public health crisis and take action to address violence as a public health problem. One prominent example is the American Hospital Association Hospitals Against Violence Initiative, which provides examples and best practices to address its three central topics: workforce and workplace violence, combating human trafficking, and preventing youth violence.

ASHP believes that members of the pharmacy workforce have "a responsibility to participate in global, national, state, regional, and institutional efforts to promote public health" and that the pharmacy workforce has important roles in primary, secondary, and tertiary interventions to prevent violence. The CDC National Center for Injury Prevention and Control, Division of Violence Prevention states that the different forms of violence they identify—child abuse and neglect, youth violence, intimate partner violence, sexual violence, elder abuse, and suicidal behavior—are strongly connected and share common risk and protective factors. Interventions the pharmacy workforce could be involved in include but are not limited to

- improving access to mental health services, including treatment for substance use disorder;
- screening to identify victims of or individuals at risk of violence;
- providing trauma informed care;
- providing lethal means counseling;
- supporting hotlines and community support systems for people in crisis;
- providing or promoting Stop-the-Bleed bystander training; and
- participating in or promoting community- or hospital-based violence prevention organizations.

To fill these important roles, members of the pharmacy workforce will need appropriate education, training, and resources. Although some education, training, and resources are appropriate for different healthcare providers, ASHP is committed to the development of resources to prepare the pharmacy workforce for pharmacy-specific roles in violence prevention and to supporting research and dissemination of information on the effectiveness of pharmacy-focused violence-prevention strategies. In addition, institutional and community leaders need to be aware of the pharmacy workforce's commitment to preventing violence. ASHP is committed to raising awareness with other stakeholders of the profession's commitment to collaborate to end the cycle of violence in their institutions and communities.

2036
RACIAL AND DISCRIMINATORY INEQUITIES
Source: House of Delegates

This policy was discontinued in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

2037
SUPPORT OF THE WORLD HEALTH ORGANIZATION

This policy was superseded by ASHP policy 2503.

2038
ASHP STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE IN PHARMACY

This statement was superseded by ASHP policy 2428.

2039
COMPLEMENTARY, ALTERNATIVE, AND INTEGRATIVE MEDICINE PRODUCTS
Source: Council on Therapeutics

To promote awareness of the impact of complementary, alternative, and integrative medicine (CAM) products on patient care, particularly drug interactions, medication safety concerns, and the risk of contamination and variability in active ingredient content; further,

To advocate for the documentation of CAM products in the health record to improve transparency and optimize patient safety; further,

To advocate for the inclusion of up-to-date and readily available information about CAM products and their characteristics in medication-related databases; further,

To provide education on the impact of CAM product administration on patient care within healthcare organizations.

This policy supersedes ASHP policy 1511.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
The terms *complementary, alternative,* and *integrative* are sometimes used interchangeably to describe healthcare approaches that are not part of conventional medical care. When non-mainstream practice is used with conventional medicine, it is considered *complementary*. When a non-mainstream practice is used in place of conventional medicine, it is considered *alternative*. *Integrative* healthcare often brings conventional and complementary approaches together in a coordinated way and emphasizes a holistic, patient-focused approach to healthcare and wellness. CAM includes the use of natural products such as herbs, vitamins, and minerals sold as dietary supplements. According to the National Center for Complementary and Alternative Medicine (NCCAM), an estimated 38% of adults and 12% of children use some form of CAM.

In the ASHP Statement on the Use of Dietary Supplements, ASHP expresses concern that the widespread, indiscriminate use of dietary supplements presents substantial risks to public health and details the basis of those concerns. Some dietary supplements are inherently unsafe. Product content (both active ingredient and excipients) is not standardized, therapeutic goals are vague, and evidence of efficacy and safety is absent or ambiguous. Lax regulation of dietary supplement manufacturing presents the risk of contamination or adulteration with

harmful substances. Numerous dietary supplements interact with medications and may therefore compromise, complicate, or delay effective treatment. Some patients, particularly those who cannot afford expensive medication regimens, may substitute ineffective alternatives for proven medical therapies.

Healthcare organizations take varying approaches to addressing CAM use. Some actively counsel patients against CAM use, others take a more integrative approach and accept the practice, and some even have clinics for referrals. ASHP has long encouraged healthcare organizations to develop an institutional policy regarding the use of dietary supplements that allows pharmacists and other healthcare practitioners to exercise their professional judgment while balancing patient autonomy and institutional concerns. Such policies should include promoting healthcare practitioner awareness of the potential impacts of CAM use and should encourage documentation of CAM use in the patient's health record and expansion of CAM related data for documentation in the electronic health record (EHR), so pharmacists and other healthcare practitioners have the knowledge and information they need to safely treat and advise patients and the provider with clinical decision support tools already integrated to the EHR. Expansion of documentation CAM data will support medication reconciliation efforts to promote accurate documentation of CAM, CAM-drug related interactions, and CAM-disease state related interactions. ASHP recommends that all healthcare trainees, providers, and staff actively ask patients about their CAM use during the process of medication reconciliation.

2040

PREMARKETING COMPARATIVE CLINICAL STUDIES

Source: Council on Therapeutics

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require premarketing comparative clinical trials when appropriate alternative agent(s) exist on the market, to elucidate the new agent's role and place in therapy for the proposed indication; further,

To recommend that drug manufacturers include a summary of premarketing comparative study results in official product labeling, when available; further,

To advocate that Congress provide adequate funding to FDA and other agencies to support the additional tasks required by such premarketing comparative studies.

This policy supersedes ASHP policy 1506.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

In the past, new drugs were approved in the United States without a requirement to demonstrate efficacy or safety. Today, the FDA reviews new drug applications focusing on 3 major categories: the safety and efficacy of the drug for the proposed indication(s), appropriateness of the manufacturing process to ensure drug identity, potency, and purity, and

proposed drug label information. Randomized controlled trials are the study design of choice to demonstrate the efficacy and safety of a new drug. Today, there is no requirement by the FDA that drug manufacturers conduct premarketing comparative studies due to a lack of legislation providing this express authority. A drug may be approved based on comparison to placebo alone, even if there are comparable treatment options available on the market. Demonstrated efficacy in placebo-controlled trials may overestimate the benefit of the drug and inadvertently lead prescribers to utilize a less effective drug, increases the risk for safety events and delayed time to care goals, and increased cost of care. Comparative clinical studies, when done in advance of approval consideration, may provide clinicians with critical information to stratify which patient populations are most appropriate candidates for a new drug in relation to therapeutic options already on the market.

Recently, the FDA has approved more drugs via expedited approval pathways, creating reliance on postmarketing studies to provide clarity on the role of the therapy in care, as well as for identification of undesirable treatment related effects. While postmarketing data is valuable, it is critical that potential efficacy and safety concerns be identified prior to drug approval where reasonable and applicable. Premarketing trials may not reveal all risks related to a drug, especially for those with adverse events that may take multiple years to emerge, adverse events that are relatively rare, or when used postmarket in more diverse or off-label populations. Postmarketing studies provide the best opportunity to identify such events. Currently, FDA industry guidance on the clinical studies section of product labeling notes that "active control clinical studies that imply comparative effectiveness" are among the study types to not include. The FDA should be granted the authority to require premarketing comparative clinical studies when appropriate, taking into account the potential impact of such therapies on patient care and timing to avoid approval delay when necessary, in order to ensure expedited availability for indications of unmet need. To ensure that the information in premarketing studies is of high integrity, consensus-driven, evidenced-based, and improves healthcare delivery and outcomes, the FDA could include the input of organizations such as the Pharmacy Quality Alliance, the Patient-Centered Outcomes Research Institute, and the Agency for Healthcare Research and Quality. Funding to allow for this expanded scope should be provided to support timely review and consideration of premarketing studies.

2041
SAFETY OF INTRANASAL ROUTE AS AN ALTERNATIVE ROUTE OF ADMINISTRATION
Source: Council on Therapeutics

This policy was superseded by ASHP policy 2516.

2042
CONTROLLED SUBSTANCES DIVERSION PREVENTION
Source: Council on Pharmacy Management

To enhance awareness by the pharmacy workforce, other healthcare workers, and the public of the potential threats to the public and patient care and safety presented by diversion of controlled substances; further,

To encourage healthcare organizations to develop controlled substances diversion prevention programs (CSDPPs) and supporting policies that delineate the core administrative elements and system- and provider-level controls needed to deter diversion of controlled substances at all stages of medication use; further,

To encourage healthcare organizations to address in their CSDPPs the roles, responsibilities, and oversight of all workers who may have access to controlled substances to ensure compliance with applicable laws and scopes of practice; further,

To encourage healthcare organizations to ensure that all healthcare workers are appropriately screened for substance abuse prior to initial employment and that surveillance, auditing, and monitoring are conducted on an ongoing basis to support a safe patient-care environment, protect co-workers, and discourage controlled substances diversion; further,

To advocate that pharmacists take principal roles in collaborative, interdisciplinary efforts by organizations of healthcare professionals, patient advocacy organizations, and regulatory authorities to develop and promote best practices for preventing drug diversion and appropriately using controlled substances to optimize and ensure patient access and therapeutic outcomes; further,

To advocate that the Drug Enforcement Administration and other regulatory authorities interpret and enforce laws, rules, and regulations to support patient access to appropriate therapies, minimize burdens on pharmacy practice, and provide reasonable safeguards against fraud, misuse, abuse, and diversion of controlled substances.

This policy supersedes ASHP policies 1614 and 1709.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale

Pharmacy managers and pharmacists-in-charge have increasing responsibility for ensuring controlled substance management and storage across large healthcare organizations. This responsibility has increased as acquisition of physician office practices, clinics, and other non-hospital business units continue. According to the Drug Enforcement Administration (DEA) 2024 National Drug Threat Assessment Summary, the DEA Theft and Loss Reporting Database reveals that the number of unaccounted-for narcotic prescription drugs (opioids) in 2022 was at its lowest in 12 years and continued decline into 2023. Controlled substances are lost through employee theft (or suspected), disaster (e.g., fire, weather, etc.), hijacking of transport vehicles, accidental breakage and spillage, robberies, break-ins and burglaries, as well as other causes. Traffickers continue to manufacture and distribute counterfeit controlled substances and illicit drugs in attempts to expand their customer base and increase profits. Fentanyl and other synthetic drugs, like methamphetamine, are responsible for nearly all of the fatal drug overdoses and poisonings in the United States.

All pharmacies and healthcare organizations that handle controlled substances are required to have storage and distribution systems in place that prevent diversion. Due to the numerous medication access points embedded within hospital distribution systems, diversion can be difficult to detect. Overall, diversion incidents continue to decline; however, controlled substances lost in transit or diverted by medical professionals remain a prevalent threat across the U.S. that can lead to patient harm. Drug addiction among healthcare workers is well documented. One survey suggested that nurses who reported a perception of easier availability of controlled substances were almost twice as likely as others to divert and use a controlled substance. In another survey published in *AJHP*, 19% of pharmacists reported use of a controlled substance without a prescription during the preceding 12 months. Even the most conservative estimates are that 8–12% of physicians will develop a substance abuse problem at some point during their career, although the exact rate of substance abuse among physicians is uncertain. To ensure compliance with applicable laws and scopes of practice, ASHP advocates that healthcare organizations develop controlled substances diversion prevention programs and policies to describe the roles, responsibilities, and oversight of all personnel who have access to controlled substances throughout the organization. The ASHP Guidelines on Preventing Diversion of Controlled Substances offer detailed suggestions on implementation guidance for pharmacists to employ proactive measures and mitigate diversion in their institutions and communities. ASHP also supports pre-employment screening and ongoing surveillance, auditing, and monitoring of all healthcare workers to reduce the risk of controlled substances diversion.

Healthcare institutions face many challenges in managing controlled substances. New laws and regulations, including DEA quotas and controlled substances monitoring requirements at community outpatient dispensing facilities, are meant to decrease diversion and illegal activity but are also impacting patients and pharmacists. In addition, the DEA has allowed hospitals and clinics with an onsite pharmacy and status as an authorized collector to maintain collection receptacles onsite and administer mail-back programs for controlled substances, adding another layer of complexity to controlled substance disposal. Pharmacists in healthcare organizations are required to meet standards and comply with laws and regulations from a variety of sources, including the DEA, The Joint Commission, Det Norske Veritas, other accreditation organizations, and state and federal governments. The ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance offers detailed suggestions for pharmacists in addressing substance abuse in their institutions and communities and pending ASHP policy, Recovery and Assistance Programs for Healthcare Workers with Substance Use Disorder, supports non-punitive monitoring programs that allow healthcare workers to return to work after receiving treatment for a substance use disorder.

2043

DRUG PRODUCT SUPPLY CHAIN INTEGRITY

Source: Council on Pharmacy Management

To encourage the Food and Drug Administration (FDA) and relevant state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thoroughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated,

outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,

To advocate for improved transparency so that drug product labeling includes a readily available means to retrieve the name and location of the facility that manufactured the specific lot of the product and the country of origin of the active pharmaceutical ingredient; further,

To advocate that this readily retrievable manufacturing information be available prospectively to aid purchasers in determining the quality of a drug product and its raw materials; further,

To foster increased pharmacist and public awareness of drug product supply chain integrity; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

This policy supersedes ASHP policy 1602.

This policy was reviewed in 2025 by the Council on Management and by the Board of Directors and was found to still be appropriate.

Rationale

The aspect of drug product selection that is not transparent from the labeling is its quality. This information needs to be readily available so those who make the purchasing decision on behalf of hospitals and health systems can factor quality into the decision. Aspects of manufacture that affect quality include the production and compliance history of a manufacturer, the specific name and location of the manufacturing plant, and the source of raw materials, including active pharmaceutical ingredients. This information has been useful in responding to a recall, but it is also important as part of the procurement process. The FDA's Strategic Plan for Preventing and Mitigating Drug Shortages recommends that purchasers of medications consider quality as a component of the purchasing decision. FDA publishes some quality information about manufacturers; however, in subcontracting and licensing situations, it is not always known who the actual manufacturer is, which specific plant location produced the product, and the country of origin of the active pharmaceutical ingredient.

Hospitals and health-system pharmacy leaders have years of experience in managing the demands and challenges of ensuring that drug supply chain safety and integrity is at the highest level possible. Unfortunately, there are many forces in the marketplace that seek to divert and introduce illicit products into the supply chain.

ASHP has supported efforts to improve the integrity of the drug product supply chain, which has included advocacy on track-and-trace legislation, collaboration with the United States Pharmacopeia (USP) in its efforts on supply chain integrity, leadership in dealing with the various issues arising from drug shortages, and a voice for patients and pharmacists on needed change (regulatory and practice-based) with pharmacy's trading partners to enable pharmacists to secure legitimate drug products.

On November 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law. Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA) set forth new definitions and requirements related to drug product tracing. The DSCSA outlines critical steps to build an electronic, interoperable system which will identify and trace certain prescription drug products as they are distributed in the United States. Implementation of this new electronic, interoperable system will enhance FDA's ability to help protect U.S. consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain. Full implementation of the enhanced drug distribution security requirements was initially slated for November 27, 2023. However, the FDA has issued exemptions to eligible trading partners from drug distribution security requirements in the DSCSA. These exemptions beyond the stabilization period include a phased compliance timeline and vary depending on the eligible trading partners.

2044

DRUG NAMES, LABELING, AND PACKAGING ASSOCIATED WITH MEDICATION ERRORS

Source: Council on Pharmacy Practice

To urge drug manufacturers, drug packagers and repackagers, outsourcing pharmacies, and the Food and Drug Administration to involve patients, practicing pharmacists, nurses, and physicians in decisions about drug names, labeling, and packaging to help eliminate (a) look-alike and sound-alike drug names, and (b) labeling and packaging characteristics that contribute to medication errors; further,

To inform pharmacists and others, as appropriate, about specific drug names, labeling, and packaging that have documented association with medication errors.

This policy supersedes ASHP policy 0020.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

Confusion caused by drug product names, labeling, and packaging has been associated with medication errors. Despite laws, regulations, and standards that seek to address these areas, safety concerns still exist. For example, the Institute for Safe Medication Practices lists errors

and hazards due to look-alike labeling of manufacturer's products third and unsafe labeling of prefilled syringes and infusions by 503B compounders eighth among the top ten medication errors and hazards. ASHP advocates involving representatives of those who use the products—patients, practicing pharmacists and pharmacy technicians, nurses, and physicians—in the decision-making process regarding drug names, labeling, and packaging to provide advice on how to avoid confusion and prevent medication errors. In furtherance of our mission to support pharmacists in helping people achieve optimal health outcomes, ASHP will continue to inform the pharmacy workforce, other healthcare providers, government agencies, and the public about specific drug names, labeling, and packaging associated with medication errors.

2019 Policy Positions

1901
SUICIDE AWARENESS AND PREVENTION

This policy was superseded by ASHP policy 2402.

1902
SAFE ADMINISTRATION OF HAZARDOUS DRUGS

This policy was superseded by ASHP policy 2415.

1903
VERIFYING COMPOUNDED STERILE PREPARATIONS
Source: Council on Pharmacy Practice

To advocate that health systems adopt automation and information technology to facilitate in-process and final verification of compounded sterile preparations (CSPs) to ensure CSP quality; further,

To advocate that, until such time as automation or technology can be implemented, independent in-process and final verification of CSPs be performed; further,

To oppose the use of the syringe pull-back method or other proxy methods of CSP verification.

This policy supersedes ASHP policy 1617.

This policy was reviewed in 2024 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Adoption of automation and information technology for preparing and dispensing compounded sterile preparations (CSPs) is increasing but not evenly distributed among healthcare organizations. A 2020 ASHP survey showed that 53% of hospitals did not use any technology for sterile product preparation activities. Only 33.8% of health systems surveyed employed barcode verification in their IV medication preparation and verification process. The survey found that 21.3% of all health systems surveyed used drug workflow software to manage IV drug preparation, verification, and dispensing. There are many reasons for these disparate rates of adoption. Each institution has a different break-even point of investment versus return, and challenges of implementation can be daunting. Some organizations have implemented automated compounding technology only to withdraw it later. These technologies may slow the preparation and verification process; however, the enhanced safety outweighs losses in operational efficiency.

Information technology and automation, including robotics, can be used to improve the safety of CSP compounding. Although IV workflow technologies continue to be developed and improved, the majority of pharmacy departments continue to compound manually without the assistance of barcode or other technologies. Health systems have been slow to adopt IV workflow technology. If automated procedures are not employed, there are only two methods of in-process or final verification: real-time, direct, and independent visualization, or retroactive, proxy verification (e.g., the syringe pull-back method). The dangers of the syringe pull-back method have been well demonstrated, and the 2016 Institute for Safe Medication Practices (ISMP) Guidelines for Safe Preparation of Compounded Sterile Preparations discourage its use.

1904

NOTIFICATION OF DRUG PRODUCT PRICE INCREASES

Source: Council on Public Policy

To advocate for manufacturers to provide notice and justification to the public and healthcare providers in advance of drug price increases; further,

To advocate for transparency in drug product pricing decisions.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Many factors contribute to high drug product costs, and addressing the problem is made difficult by lack of knowledge about the marketplace for those products. For example, rebates negotiated by pharmacy benefit managers (PBMs) and discounts to other buyers make it difficult to determine the actual price of a drug product. ASHP advocates for more publicly accessible information on drug product pricing, such as an annual report on increases in drug product prices. Such information would provide patients and their healthcare providers with the information needed to make drug product purchasing choices. The purpose of this policy is to advocate for laws and regulations that would require drug product manufacturers to publicly report price increases in advance and provide justification for those increases, as well as to advocate for transparency regarding drug product pricing decisions. The policy is intended to increase public knowledge concerning pricing decisions made by different parties in the drug product supply chain (e.g., manufacturers, distributors, PBMs, group purchasing organizations) who may influence drug product prices.

1905

MITIGATING DRUG PRODUCT SHORTAGES

Source: Council on Public Policy

To advocate for ongoing federal evaluation of how drug product shortages present risks to national security and public health; further,

To advocate that drug product manufacturers be required to disclose manufacturing sites and sources of active pharmaceutical ingredients (APIs) to facilitate such a risk assessment; further,

To recommend that the Food and Drug Administration (FDA) require drug product manufacturers to have contingency plans for maintaining drug supplies; further,

To advocate that drug product manufacturers be required to provide a specific reason for a shortage and an estimated timeline for resolution in their Food and Drug Administration Safety and Innovation Act notifications to FDA; further,

To advocate that FDA be required to publicly provide quality ratings for 503B outsourcing facilities preparing copies of drug products under the exemption for products on FDA's shortage list; further,

To advocate that the Federal Trade Commission be required to evaluate the potential for drug product supply chain interruptions when considering manufacturer consolidations.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

In November 2017, ASHP convened a meeting of healthcare professional organizations to review and identify new opportunities to address the ongoing supply chain and patient care challenges associated with drug product shortages. Participants at the meeting examined how the 2012 FDA Safety and Innovation Act (FDASIA) has impacted drug product shortages and made recommendations to prevent and mitigate future shortages. One of those recommendations was that the federal government undertake an evaluation of the risks drug product shortages could present to national security. Such an evaluation would need to consider the risks posed by sourcing of APIs and excipients, as well as by the location of manufacturing sites.

FDA's Strategic Plan for Preventing and Mitigating Drug Shortages recommends that drug product purchasers consider quality in making purchasing decisions. Information that purchasers would find helpful in prospectively assessing drug product quality includes the production and compliance history of a manufacturer, the specific name and location of the manufacturing plant, and the source of raw materials. Because approximately 80 percent of APIs used in U.S. drug product manufacturing comes from foreign sources, FDA has limited ability to inspect and certify that those APIs are unadulterated. In addition, although FDA publishes some quality information about manufacturers, it is sometimes difficult to know who the actual manufacturer is and which specific plant location produced the product, because drug companies may rely on contract manufacturers to produce drug products through licensing agreements. Requiring manufacturers to disclose that information publicly would allow for improved evaluation of a manufacturer's integrity and alignment with current good manufacturing processes. Detailed knowledge of manufacturing sites would also allow the

government and healthcare systems to plan for or avoid disruptions to the supply chain like those that followed Hurricanes Irma and Maria in 2017, when supplies of 40 critical pharmaceutical products went into shortage, in part because of disruption to the large number of pharmaceutical manufacturing facilities in Puerto Rico. Lack of information about such disruptions can also lead to hoarding, which exacerbates an existing shortage. To avoid similar disruptions, FDA should require manufacturers to have contingency plans for maintaining drug product supplies during events that could disrupt production, such as natural and manmade disasters (e.g., hurricanes, cyber-attacks, electricity failures, shipping disruptions).

Manufacturers are currently required by law to notify FDA of production disruptions, as well as specific reasons for the shortage and an estimated timeline for resolution. However, despite these requirements, manufacturers still fail to report in a timely fashion, likely because the FDA has limited enforcement authority to force compliance. Healthcare providers addressing drug product shortages also need information to evaluate the quality of copies of drug products produced by 503B outsourcing facilities under the exemption for products on FDA's shortage list. Congress should require FDA to publicly provide quality ratings for 503B facilities, but should update findings to reflect remediation and improvements.

Finally, to avoid future drug product shortages, the Federal Trade Commission should be required to evaluate the potential for drug product supply chain interruptions when considering manufacturer consolidations.

1906
EMERGENCY SUPPLIES OF DRUG PRODUCTS

This policy was discontinued in 2024.

1907
CREDENTIALING AND PRIVILEGING BY REGULATORS, PAYERS, AND PROVIDERS FOR COLLABORATIVE PRACTICE

This policy was superseded by ASHP policy 2011.

1908
340B DRUG PRICING PROGRAM SUSTAINABILITY
Source: Council on Public Policy

To affirm the intent of the federal drug pricing program (the “340B program”) to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate for continued access to the 340B program in accordance with the intent of the program; further,

To advocate that reimbursement and contracting policies promote 340B program stability and to oppose reimbursement and savings reductions to covered entities; further,

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage 340B participants to provide appropriate stewardship of the 340B program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators, risk managers, and pharmacists about the resources required to support 340B program compliance and documentation; further,

To encourage communication and education concerning the value of the 340B program; further,

To advocate that the Health Resources & Services Administration Office of Pharmacy Affairs have sufficient regulatory authority to enforce compliance for all stakeholders with the 340B program.

This policy supersedes ASHP policy 1817.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Statutory and other policy changes to the federal drug pricing ("340B") program over the years have spurred an increase in the number of hospitals and other eligible entities that participate. Since the program's inception, the number of 340B-eligible and participating hospitals has continued to grow. In response, policymakers and other stakeholders have raised questions over how the discounts are used by covered entities and what value the program brings to their respective communities. Congress has held hearings, and bills have been introduced to reform the program. Among the items Congress is considering are transparency, increasing authority of the Health Resources & Services Administration (HRSA) to oversee the program, reimbursement cuts imposed under Medicare Part B on 340B drugs, and examining policy that passes the discount along to the patient.

Expansion of Medicaid eligibility in 2014 (through provisions in the Affordable Care Act) allowed additional hospitals to participate in the program, further driving scrutiny and questions from policymakers and stakeholders. In response to policymaker and stakeholder concerns, ASHP recognizes the important intent and role of the 340B program and stresses the need for its continued sustainability. These developments demonstrate the need for pharmacy leaders to engage in a strategic response to this compliance environment.

The original intent of the 340B program was to "to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rept. 102-384, pt. 2, at 12 [1992]). ASHP emphasizes the need for clarification and simplification (to the extent possible) of the program in order to enable compliance and maintain program integrity. Further, there is a need for communication and collaboration with public and private payers to ensure optimization of benefits from the 340B program and related contract and reimbursement policies.

1909

PHARMACIST AUTHORITY TO PROVIDE MEDICATION-ASSISTED TREATMENT AND MEDICATIONS FOR OPIOID USE DISORDER

Source: Council on Public Policy

To advocate for the role of the pharmacist in medication-assisted treatment (MAT) for opioid use disorder and medications for opioid use disorder (MOUD), including patient assessment, education, prescribing, and monitoring of pharmacologic therapies; further,

To pursue the development of federal and state laws and regulations that recognize pharmacists as providers of MAT and MOUD for opioid use disorder; further,

To foster additional research on clinical outcomes of pharmacist-driven MAT and MOUD; further,

To advocate for the removal of barriers for all providers to be able to provide MAT and MOUD to patients.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

An estimated 2.5 million Americans suffer from opioid use disorder. In 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended that the U.S. increase screenings and treatment for opioid use disorder. Many pharmacists have the skills to provide direct care to patients with opioid addiction or assist other healthcare providers in caring for these patients. Although Congress removed the waiver requirement for clinicians under the Drug Addiction Treatment Act of 2000 to prescribe buprenorphine or other drugs for opioid use disorder, a number of states still limit the ability of pharmacists to prescribe controlled substances, artificially limiting patient access to treatment. Prescribing authority would allow pharmacists to fully exercise their expertise and expand the pool of medications for opioid use disorder (MOUD) providers. ASHP advocates the removal of barriers for all providers to be able to provide MOUD treatment to patients (including ancillary services, such as provision of fentanyl test strips), and encourages additional research on the clinical outcomes of pharmacist-driven MOUD treatment.

1910
THERAPEUTIC USE OF CANNABIDIOL
Source: Council on Therapeutics

To support continued research and to provide education on the therapeutic uses, adverse effects, and drug interactions of cannabidiol (CBD); further,

To oppose use of CBD-containing products not regulated by the Food and Drug Administration; further,

To advocate for enhanced public education regarding safe use of CBD-containing products.

This policy was reviewed in 2024 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

In June 2018, the Food and Drug Administration (FDA) first approved Epidiolex, an oral solution containing cannabidiol (CBD), currently indicated for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, and tuberous sclerosis complex in patients one year of age and older. Epidiolex is the first prescription formulation of a highly purified component of the Cannabis sativa plant. Because it does not contain a significant amount of tetrahydrocannabinol, the intoxicating substance in Cannabis sativa, in September 2018 the Drug Enforcement Administration (DEA) placed Epidiolex in schedule V of the Controlled Substances Act, the least restrictive schedule of the Act. In 2020, after reviewing additional data provided by the manufacturer, the DEA removed Epidiolex from Schedule V and descheduled it entirely.

Given the patchwork of state legislation regarding recreational and medical cannabis, there is a robust but largely unregulated industry in cannabis derivatives, including products promoted as containing CBD. These formulations range from lotions for topical application to oils for enteral consumption, and their components and CBD concentrations vary, leading to questions about their safety. FDA has issued over 40 warning letters to firms marketing products that allegedly contain CBD. As part of these actions, FDA has tested the chemical content of cannabinoid compounds in some of the products, finding that many do not contain the levels of CBD claimed.

With CBD's easy availability came spurious claims regarding its efficacy in treating a number of maladies. Faced with the unique challenge of regulating an approved drug and widely available formulations of a similar product, the FDA released a statement in 2023 addressing their plan for moving forward. They denied requests to allow CBD products to be marketed as dietary supplements due to safety concerns based on current evidence. It was also stated that the FDA will work with Congress on a new regulatory pathway for CBD, as the current pathways for foods and supplements are not sufficient. The new regulatory pathway would provide safeguards, such as CBD content limits, product labeling requirements, and minimum purchase age to help minimize risks associated with CBD products.

ASHP opposes use of CBD-containing products not regulated by FDA in research and patient

care. Further, due to concerns that patients may substitute unapproved cannabis-derivative products for the FDA-approved drug or confuse the two, ASHP advocates for enhanced patient and public education regarding safe use of CBD-containing products, and encourages pharmacists take a leadership role in those efforts. ASHP encourages research on the potential therapeutic uses, adverse effects, and drug interactions of CBD, and is committed to providing education to pharmacists and other healthcare providers on those topics.

1911

PHARMACY EXPERTISE IN STERILE COMPOUNDING

Source: Council on Education and Workforce Development

To support colleges of pharmacy in providing sterile compounding and aseptic technique instruction in didactic and experiential curricula that reflect the needs of the workforce; further,

To promote the use of sterile compounding training programs to foster an increase in the number of pharmacists and pharmacy technicians with sterile compounding expertise; further,

To advocate that pharmacists and pharmacy technicians who work in sterile compounding attain compounded sterile preparations advanced certifications.

This policy supersedes ASHP policy 0915.

This policy was reviewed in 2024 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

ASHP distinguishes between two needs related to pharmacy expertise in sterile compounding: a need for new pharmacy graduates to possess baseline training and knowledge of sterile compounding, and the need for pharmacists with an advanced body of knowledge on sterile compounding, especially in pharmacy departments where complex compounded sterile preparations (CSPs) are compounded.

Although there is a clear need for students to have a basic understanding of sterile compounding upon graduation, education in colleges of pharmacy on sterile compounding varies. Sterile compounding and aseptic technique instruction are important areas of pharmacy practice to incorporate in the didactic curriculum and during experiential education.

The complexity of intravenous therapy, the risk of errors or patient harm, and new biologic therapies all demand a higher level of expertise in sterile compounding in the pharmacy, however. United States Pharmacopeia Chapter 797 and other efforts have increased the focus on the quality of CSP compounding and have prompted organizations to improve staff training, facilities, and procedures. In such an environment, there is a clear need for pharmacists whose education, training, and experience in sterile compounding provide expertise rather than baseline knowledge. To demonstrate competency, pharmacy technicians should attain PTCB's advanced Compounded Sterile Preparation Technician (CSPT) certification,

and pharmacists, the Board of Pharmacy Specialties (BPS) Compounded Sterile Preparations Pharmacy (BCSCP) certification.

1912
PHARMACY TECHNICIAN TRAINING AND CERTIFICATION
Source: Council on Education and Workforce Development

To advocate for adoption of a national standard for accreditation of pharmacy technician education and training programs; further,

To advocate that a pharmacy technician education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required for all new pharmacy technicians; further,

To advocate that all pharmacy technicians be required to obtain and maintain Pharmacy Technician Certification Board certification; further,

To foster expansion of ASHP/ACPE-accredited pharmacy technician education and training programs.

This policy supersedes ASHP policy 1609.

This policy was reviewed in 2024 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale
In January 2017, the Pharmacy Technician Certification Board (PTCB) suspended the condition that by 2020 the completion of an accredited technician education and training program would be required to be eligible for the PTCB certification exam. There is no indication that PTCB will reinstate that requirement; however, ASHP supports completion of an education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) as well as PTCB certification for all pharmacy technicians. Although education requirements have been added by PTCB to take the certification exam starting in 2020, completion of an accredited education and training program is only one pathway for eligibility for the exam; PTCB also recognizes equivalent work experience. If an applicant has completed an unaccredited program, there is a required attestation for the content of that program.

In 2018, ASHP and ACPE developed revised national standards that serve as a guide for the development of ASHP/ACPE-accredited pharmacy technician education and training programs. These standards serve as the criteria for the evaluation of new and established pharmacy technician training programs and will help ensure that pharmacy technicians possess the knowledge, skills, and abilities necessary for their critical role on the healthcare team. A number of environmental factors, including changes in state laws allowing for expanded roles, responsibilities, and authority for pharmacy technicians, prompted the reassessment of the standards, which were last revised in 2015. ASHP supports more uniform state statutes and regulations regarding pharmacy technicians. The anticipated increase in demand for enrollment

in ASHP/ACPE-accredited training programs will require an expansion of the number and distribution of such programs, including innovative education and training formats.

This policy is also aligned with the work of the Pharmacy Technician Stakeholder Consensus Conference, the national consensus conference that engaged all sectors of pharmacy to define basic knowledge, skills, and abilities of pharmacy technicians, to promote and define advanced competencies, and to promote national definitions and regulation of pharmacy technicians. Furthermore, the August 2022 *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* states, "It is contemplated that Boards will approve those Certified Pharmacy Technician Candidate training programs whose standards are at least equivalent to the minimum standards developed by an accrediting organization recognized by state Boards, such as ACPE, ASHP, and ABHES."

1913
PHARMACEUTICAL DISTRIBUTION SYSTEMS

This policy was superseded by ASHP policy 2335.

1914
SAFE MEDICATION PREPARATION, COMPOUNDING, AND ADMINISTRATION IN ALL SITES OF CARE

This policy was superseded by ASHP policy 2422.

1915
PHARMACY DEPARTMENT BUSINESS PARTNERSHIPS
Source: Council on Pharmacy Management

To recognize that a key objective of pharmacy departments is to provide medication management services across the continuum of patient care, and that pharmacy leaders should proactively evaluate potential business partnerships against this objective; further,

To recognize that hospitals and health-system pharmacy leaders must ensure that business partners meet all applicable patient safety and accountability standards; further,

To provide education and tools for pharmacy leaders to aid in the evaluation of and development of business partnerships; further,

To educate health-system administrators on the importance of pharmacy leadership in evaluating and developing pharmacy-related business partnerships; further,

To encourage health-system pharmacy leaders to consider evolving healthcare financing systems when evaluating and developing business partnerships.

This policy supersedes ASHP policy 1416.

This policy was reviewed in 2024 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale

Hospital and health-system pharmacy leaders have to increasingly assess and engage with external business partners in order to facilitate continuity of care for their patients and optimize outcomes. Hospitals and health-system leaders must be positioned to provide the most comprehensive care for their patient populations. As these external entities expand their market share and become more engaged across the healthcare continuum, a significant number of hospitals and health systems are dealing with how to best evaluate potential business partnerships. In some cases, hospital or health-system pharmacy leaders are seeking to create a network of pharmacy locations and services for their patients that the health system cannot build itself. In other cases, hospital and health-system pharmacy leaders need to engage with external business partners to provide services they cannot provide or to improve the efficiency of services provided by the hospital or health system. Additionally, a number of business entities see changes in value-based purchasing and readmission payment as an opportunity to contract with health systems. Finally, there are also business partners (e.g., data management, automation, compounding, and consulting organizations) that pharmacy leaders need to engage with in order to manage their pharmacy enterprise. These changes have posed a political, logistical, and professional challenge for pharmacy leaders.

1916

INTIMIDATING OR DISRUPTIVE BEHAVIOR

Source: Council on Pharmacy Management

To affirm the professional responsibility of the pharmacist to ensure patient and workplace safety by communicating with other healthcare personnel to clarify and improve medication management; further,

To advocate that hospitals and health systems adopt zero-tolerance policies for intimidating or disruptive behaviors in their institutions; further,

To encourage hospitals and health systems to develop and implement education and training programs for all healthcare personnel to encourage effective communication, set expectations for standards of conduct, promote use of de-escalation techniques, and discourage intimidating or disruptive behaviors; further,

To encourage colleges of pharmacy and residency training programs to incorporate training in communications and managing intimidating or disruptive behaviors; further,

To collaborate with other organizations to advocate codes of conduct that do not allow intimidating or disruptive behavior in hospitals and health systems; further,

To encourage hospitals and health systems to adopt processes for identification and reporting of intimidating or disruptive behaviors to evaluate and mitigate unacceptable behaviors in a timely and effective manner.

This policy supersedes ASHP policy 0919.

This policy was reviewed in 2024 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale

Intimidating or disruptive behaviors can lead to medical errors, contribute to poor patient satisfaction, increase costs, and cause staff turnover. Such behaviors range from passive behaviors such as providers refusing to answer questions or return pages to use of condescending language to overt actions such as verbal outbursts or physical threats. The Institute for Safe Medication Practices conducted a national survey regarding intimidation in the workplace in 2003 and conducted a follow-up survey in 2013 for comparison. Based on recent events involving healthcare practitioners along with the results of this survey, disrespectful behaviors continue to erode professional communication, which is essential to employee and patient safety.

In addition, healthcare workers face an increased risk of work-related assaults resulting primarily from intimidating or disruptive behavior of patients and their caregivers or family members. Disruptive behavior, including interference with treatment plans, vulgar language, and threatening statements, can impede a healthcare worker's ability to provide safe and effective care. Another common form of unprofessional behavior may be inappropriate judgement of peers and breaching confidentiality behind peers. While such behavior is often overlooked, underreported, or considered to be part of the job, it can also lead to more serious confrontations. Unfortunately, there is no clear way to identify patients or family members who will be disruptive to healthcare personnel, so every patient and family member must be treated with the same level of caution.

According to the U.S. Bureau of Labor Statistics (BLS), healthcare workers accounted for 73% of all nonfatal workplace injuries and illnesses due to violence in 2018. BLS data also show that the highest rates of injuries caused by workplace violence occur in the healthcare and social service industries, and that healthcare workers are five times as likely to suffer a workplace violence injury as workers overall. Further, it has been demonstrated that workplace violence can harm a person's intrinsic sense of self-worth and confidence, which can result in physical symptoms, such as headaches, anxiety, and depression. The American Nurses Association and the American Medical Association have taken positions concerning violence against healthcare workers and actively promote solutions to address the issue.

ASHP believes organizations should develop training programs to discourage disruptive behaviors and to train employees in handling disruptive situations, including de-escalation techniques, and colleges of pharmacy and residency training programs should also provide such training. Organizations should outline a proposed risk management plan in addition to informing the workforce of the legal ramifications that come with workplace bullying. Education of all team members on appropriate professional behavior, including reporting workplace

concerns (as defined by the organization's code of conduct), instruction in basic business etiquette (e.g., phone, email, and social media interactions), and training in interpersonal skills are a leadership responsibility. These organizational efforts will help with compliance with The Joint Commission workplace violence standards to guide organizations in developing workplace violence prevention systems and post-incident strategies to decrease workplace violence.

1917
PHARMACY TECHNICIAN STUDENT DRUG TESTING
Source: Pharmacy Technician Forum

To advocate for the use of pre-enrollment, random, and for-cause drug testing as a mandatory component throughout any accredited or unaccredited pharmacy technician training program and practice experience, based on defined criteria with appropriate testing validation procedures; further,

To encourage pharmacy technician training programs to develop policies and processes to identify impaired individuals; further,

To encourage pharmacy technician training programs to facilitate access to and promote programs for treatment and to support recovery; further,

To encourage pharmacy technician training programs to use validated testing panels that have demonstrated effectiveness detecting commonly misused, abused, or illegally used substances.

Rationale
Pharmacy technicians are essential members of the healthcare team and help ensure the health, safety, and welfare of patients. They have access to controlled substances and confidential information, and operate in settings that require the exercise of good judgment and ethical behavior. In addition, some state boards of pharmacy have reported that drug-abusing and -diverting persons are enrolling in pharmacy technician training programs to access drugs during experiential training and employment. Thus, an assessment of a pharmacy technician student's possible impairment, which could diminish his or her capacity to function in such a setting, is imperative to promote the highest level of integrity in healthcare services.

ASHP recognizes that drug testing pharmacy technician students, whose responsibilities may bring them into contact with controlled substances, is an essential element of diversion prevention programs. Pre-enrollment, random, and for-cause drug testing should be performed based on defined criteria, with appropriate testing validation procedures, and have demonstrated effectiveness detecting commonly abused or illegally used substances.

1918
MINIMUM EDUCATIONAL QUALIFICATION STANDARDS FOR PHARMACISTS
Source: House of Delegates Resolution

To support minimum educational qualification standards for pharmacists to practice pharmacy that are consistent with the licensing standards of state boards of pharmacy; further,

To oppose the basic education requirement within the Office of Personnel Management Classification & Qualifications - General Schedule Qualification Standards - Pharmacy Series, 0660, requiring a Doctor of Pharmacy or Doctor of Philosophy degree as the minimum qualification to practice pharmacy.

This policy was reviewed in 2024 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

In September 2017, the U.S. Office of Personnel Management (OPM) issued a new qualification standard for pharmacists, GS-0660. The new standard lists the basic educational requirement for pharmacists as a Doctor of Pharmacy (PharmD) or Doctor of Philosophy (PhD) degree. To set this requirement, OPM must have determined that pharmacy cannot be performed by persons without one of these degrees, because Title 5 U.S.C. 3308 permits the establishment of minimum educational requirements only when OPM has determined that the work cannot be performed by persons who do not possess the prescribed minimum education.

All 50 states currently allow pharmacists with a bachelor's degree in pharmacy (BSPharm) to obtain licensure and practice pharmacy, which indicates that all state legislatures or regulators have concluded that pharmacists with a BSPharm degree can practice pharmacy safely and effectively. In the U.S., the BSPharm degree was awarded until 2005; in 2006, the PharmD degree became the only entry-level degree awarded. A 2019 survey of the pharmacy workforce found that 53.5% of pharmacists had earned a PharmD. The minimum educational requirements set by OPM would automatically disqualify approximately 50% of pharmacists from entering the federal government workforce, an inequitable practice not seen outside the federal sector. The OPM minimum educational requirement also creates a monumental challenge to building and maintaining the pharmacist workforce the Department of Defense needs to support U.S. warfighting efforts and take care of veterans. ASHP recognizes that pharmacists must possess the education, training, and experience required to fulfill their roles effectively, efficiently, and responsibly. Further, ASHP supports licensure by a state board of pharmacy as the minimum requirement for pharmacy practice in its Minimum Standard for Pharmacies in Hospitals.

1919

ASHP STATEMENT ON THE ROLE OF THE MEDICATION SAFETY LEADER

Source: Section of Inpatient Care Practitioners

To approve the ASHP Statement on the Role of the Medication Safety Leader.

This statement supersedes a previous version dated April 13, 2012.

1920

RESEARCH ON DRUG USE IN OBESE PATIENTS

This policy was discontinued in 2024.

1921
TESTING AND DOCUMENTATION OF PENICILLIN ALLERGY AS A COMPONENT OF ANTIMICROBIAL STEWARDSHIP

This policy was superseded by ASHP policy 2127.

1922
ANTIMICROBIAL USE IN AGRICULTURE
Source: Council on Therapeutics

To advocate that the Food and Drug Administration (FDA) eliminate future approval of antimicrobials for nontherapeutic uses in agricultural animals that represent a safety risk by contributing to antimicrobial resistance; further,

To encourage efforts to phase out and eliminate the nontherapeutic uses of antimicrobials previously approved by the FDA; further,

To support the therapeutic use of antimicrobials in animals only under the supervision of a veterinarian; further,

To encourage the agricultural industry to report to the appropriate regulatory bodies the specific antimicrobials used, the purpose or indication for their use, and the settings in which they are used; further,

To encourage the FDA, Centers for Disease Control and Prevention, and other stakeholders to monitor and limit, when effective alternatives are available, the therapeutic use of antimicrobials that are essential to the treatment of critically ill human patients; further,

To advocate for the inclusion of pharmacists in antimicrobial surveillance and related public health efforts based on pharmacists' knowledge of antimicrobial drug products and antimicrobial resistance.

This policy supersedes ASHP policy 1009.

This policy was reviewed in 2024 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

The use of antibiotics in animal agriculture represents the majority of antibiotic use worldwide and poses significant public health risks. Approximately 80% of antibiotic consumption in the U.S. is dedicated to agricultural purposes. Despite warnings and risks, antibiotics are still excessively used for growth promotion, feed efficiency, and disease prevention in animal agriculture.

ASHP supports the public health approach to antimicrobial use in agricultural animals outlined in the July 2010 FDA testimony to Congress. The goal of this approach is to minimize the development of antimicrobial resistance, preserving the effectiveness of antimicrobial therapies that are critical in human medicine. According to the FDA, an enhanced action plan would seek to phase out the use of antimicrobials for nontherapeutic purposes (e.g., animal

growth promotion, food efficiency) by eliminating future approvals for new nontherapeutic indications.

ASHP also supports the FDA's request for increased statutory authority that would facilitate removal of previously approved nontherapeutic uses of antimicrobials. This two-pronged approach is critical to preserving the effectiveness of existing antimicrobials as well as those in development. ASHP opposes nontherapeutic uses but supports animal use of antimicrobials for therapeutic purposes (e.g., treatment of disease or prevention of disease in animals within a population that has documented disease) when this use occurs under the supervision of a veterinarian. This policy also aligns ASHP with organizations such as the Infectious Diseases Society of America, which supports the Preservation of Antibiotics for Medical Treatment Act (H.R. 1549 and S. 619) and the FDA's "public health approach" to antimicrobial use in animals. ASHP recognizes that the intent of this legislation and approach may end the over-the-counter sale and nonjudicious use of tons of antimicrobials as they support a valid veterinarian-client-patient relationship. Reporting of the specific antimicrobials used, the purpose or indication for their use, and the settings in which they are used would support achievement of the FDA's action plan. "Encouraging work with stakeholders to support government agency efforts to prevent antimicrobial-resistant infections in humans and animals allows engaged organizations to have a more comprehensive and robust approach to antimicrobial stewardship.". This support includes protection against legal liability for persons who report conditions that predispose agricultural animals to infection. In addition, ASHP advocates that FDA approval and subsequent use of antimicrobials should take into consideration the public health impact of the drugs' use. Pharmacists' knowledge of antimicrobial drugs and antimicrobial resistance will be critical to these efforts, including the identification of antimicrobial classes for which animal treatment use should be minimized in order to retain the effectiveness of these drugs for the treatment of critically ill human patients.

2018 Policy Positions

1802
GENE THERAPY

This policy was superseded by ASHP policy 2510.

1803
CONFIDENCE IN THE U.S. DRUG APPROVAL AND REGULATORY PROCESS
Source: Council on Public Policy

To support and foster legislative and regulatory initiatives designed to improve public and professional confidence in the drug approval and regulatory process in which all relevant data are subject to public scrutiny.

This policy supersedes ASHP policy 9010.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
Patients, healthcare providers, and private and public payers need objective, authoritative, and reliable evidence about drugs in order to make the best treatment decisions. The basis of the trust in the Food and Drug Administration (FDA) drug approval and regulatory process is public scrutiny of the data used in its decision-making. As medication experts, pharmacists play a critical role in educating the public and other clinicians regarding the drug approval process. This education includes helping to explain FDA decision-making related to medications in order to maintain both public trust in FDA and clinician acceptance of FDA's drug approval processes. ASHP supports efforts to improve public and professional confidence in the FDA's drug approval and regulatory process by expanding public access to relevant data used in FDA decision-making.

1804
DRUG DOSING IN CONDITIONS THAT MODIFY PHARMACOKINETICS OR PHARMACODYNAMICS

This policy was superseded by ASHP policy 2606.

1805
MEDICATION FORMULARY SYSTEM MANAGEMENT

This policy was superseded by ASHP policy 2016.

1806

MANUFACTURER-SPONSORED PATIENT ASSISTANCE PROGRAMS

Source: Council on Pharmacy Management

To advocate that pharmaceutical manufacturers extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients, regardless of distribution channels; further,

To advocate expansion of PAPs to inpatient settings; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance the efficiency of PAPs by standardizing application criteria, processes, and forms; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and visibility of PAPs to pharmacy personnel and other healthcare providers; further,

To encourage pharmacy personnel, other healthcare providers, and pharmaceutical manufacturers to work cooperatively to ensure PAPs include the essential elements of pharmacist patient care, are patient-centered, and are transparent; further,

To develop education for pharmacy personnel and other healthcare providers on the risks and benefits of PAPs.

This policy supersedes ASHP policy 1420.

This policy was reviewed in 2023 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale

ASHP recognizes the value of patient assistance programs (PAPs) in improving continuity of care while controlling costs and advocates expanded use of these programs for uninsured and underinsured patients in ambulatory and inpatient care settings. Some organizations have demonstrated success in achieving the benefits of these programs through dedicated resources and a mastery of the many programs available. Simplification of these programs (similar eligibility criteria, a common data format) would reduce the resources required to participate and improve access and utilization. Other barriers for enrolling patients in PAPs include annual out-of-pocket spend requirements to re-enroll, confusing forms, and inability to renew in advance of new year. ASHP notes that while the number of PAPs in ambulatory care settings has increased, there has been little growth in programs for inpatients. Hospitals must then absorb the costs of patient care, which results in fewer resources in the overall healthcare system. ASHP believes that expansion of PAPs to indigent inpatients would significantly offset some of the costs to hospitals and ultimately improve care. In addition, interprofessional cooperation will be needed to support patients in accessing drug products when the PAP doesn't cover the cost of the drug product due to high deductibles or co-pays. To ensure that these programs achieve their objectives, ASHP advocates that development of these programs

ensure that they contain the elements of pharmacist patient care to enhance access to and visibility of PAPs.

1807
REIMBURSEMENT AND PHARMACIST COMPENSATION FOR DRUG PRODUCT DISPENSING

This policy was superseded by ASHP policy 2232.

1809
HEALTH INSURANCE POLICY DESIGN
Source: Council on Pharmacy Management

To advocate that all health insurance policies be designed and coverage decisions made in a way that preserves the patient–practitioner relationship; further,

To advocate that health insurance payers and pharmacy benefit managers provide public transparency regarding and accept accountability for coverage decisions and policies; further,

To oppose provisions in health insurance policies that interfere with established drug distribution and clinical services designed to ensure patient safety, quality, and continuity of care; further,

To advocate for the inclusion of hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

This policy supersedes ASHP policy 1520.

This policy was reviewed in 2023 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Evolving practices by health insurers are negatively affecting patient care decisions and impacting the relationships between patients and their care providers. One common health insurance practice restricts management of and access to certain drugs to specialty suppliers. Another problematic practice is that certain drugs are not reimbursed by the insurer when used as part of the patient's hospital or health-system care. Medicare, for example, deems certain drugs as self-administered drugs, which are not reimbursed when provided to a patient because they are not considered integral to the reason for admission. These practices increase the number of patients that "brown bag" medications when they are admitted to a hospital to avoid being charged personally for the uncovered medications. ASHP has identified a number of concerns about these practices, including impact on continuity of care, integrity of the drug supply, patient satisfaction, and public perception of healthcare organizations.

It is the responsibility of the pharmacist to ensure the integrity of drugs used in the care of patients in the healthcare facility in which he or she practices. Having to verify products that

patients bring with them from multiple suppliers disrupts the care process. Having patients go unreimbursed for a medication because it was administered in and supplied by the healthcare organization is confusing to the patient and damaging to the patient–provider relationship. More broadly, lack of understanding of the differing payment systems in different care settings leads to public relations challenges. In addition, the lack of transparency regarding how payers make certain coverage determinations and apply performance penalties (e.g., direct and indirect remuneration fees) creates a significant challenge for healthcare providers as they care for patients.

ASHP advocates reforming these insurance practices. Coverage of medications should not interfere with the safe and effective provision of care and should recognize the responsibility of pharmacists to ensure product integrity for care provided where they practice. In addition, ASHP advocates that the Centers for Medicare & Medicaid Services, commercial payers, and others include hospital and health-system outpatient and ambulatory care services in health insurance coverage determinations for their patients.

1810
PHARMACY ACCREDITATIONS, CERTIFICATIONS, AND LICENSES

This policy was superseded by ASHP policy 2311.

1811
USE OF INTERNATIONAL SYSTEM OF UNITS FOR PATIENT- AND MEDICATION-RELATED MEASUREMENTS

Source: Council on Pharmacy Practice

To advocate that the U.S. healthcare system adopt and only use the International System of Units (SI units) for all patient- and medication-related measurements and calculations; further,

To advocate that healthcare organizations use clinical decision support systems, equipment, and devices that allow input and display of patient- and medication-related measurements and calculations in SI format only; further,

To advocate that health information technology manufacturers utilize only SI units in their product designs for patient- and medication-related measurements; further,

To promote education in the use of SI units and the importance of using SI units to prevent medical errors.

This policy was reviewed in 2023 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

National healthcare, quality, and safety organizations have for years promoted the sole use of SI units for dosing and weight measurements. Errors in conversion from pounds to kilograms have caused two-fold overdosing and significant underdosing, particularly among pediatric patients, where even small dosing changes can have profound effects. Conversion to and from English units of volume (e.g., from milliliters to teaspoons) has long been identified as a source of dosing errors. These types of errors have been reported in all phases of the medication-use process (e.g., prescribing, preparation, dispensing, and administration) in all patient care settings.

Official labeling for U.S. drug products provides weight-based dosing only in SI units (e.g., mg/kg), so use of any other units introduces a risk of error. ASHP endorses national and institutional efforts to standardize the measurement and communication of patient weight using only SI units (i.e., grams and kilograms) but recognizes that other patient measures are sometimes used in dosing and other health-related calculations (e.g., body surface area, creatinine clearance, glomerular filtration rate, body mass index, or adjusted body weight). ASHP therefore advocates sole use of SI units by healthcare providers during prescribing, preparation, dispensing, and administration of medications in all patient care settings. To promote that practice, clinical decision support systems (e.g., electronic health record) and equipment (e.g., scales, stadiometers, infusion pumps) be structured to allow input and display of patient-related measurements and calculations in SI format only. Finally, education in how to use SI units, and about the importance of using SI units to prevent medical errors, will be required to overcome cultural resistance by healthcare providers, caregivers, and patients regarding SI unit use.

1812

AVAILABILITY AND USE OF APPROPRIATE VIAL SIZES

Source: Council on Pharmacy Practice

To advocate that pharmaceutical manufacturers provide drug products in vial sizes that reduce pharmaceutical waste and enhance safety; further,

To collaborate with regulators, manufacturers, and other healthcare providers to develop best practices on the safe and appropriate use of single-dose, single-use, and multiple-dose vials.

This policy was reviewed in 2023 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

A 2016 study estimated that the U.S. may spend close to $2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Since that landmark study, policymakers, healthcare providers, and payers have been calling for action on vial sizes. The Centers for Medicare & Medicaid Services (CMS) has begun to require that billing for Part B drug products distinguish between claims for those received by a patient and those for discarded drug product, and the Office of

the Inspector General (OIG) of the Department of Health and Human Services has initiated a study to determine the cost of such waste. Considerable savings could be gained if vial sizes more closely matched doses, and one of the goals of the OIG study is to determine how much could be saved by using vial sizes available overseas that more closely match doses. As one analysis has pointed out, pharmacoeconomic analyses done in the U.S. typically do not incorporate leftover drug product in cost calculations, which may inflate cost-effectiveness ratios, and drug manufacturers may be exploiting that omission. In contrast, the United Kingdom National Institute for Clinical Excellence requires manufacturers to include the cost of leftover drug in manufacturers' submissions, and vials of two cancer drugs studied (bortezomib and pembrolizumab) contain 1 mg and 50 mg, respectively, in the U.K., and 3.5 mg and 100 mg in the U.S. Further, the availability of different vial sizes can enhance patient and worker safety. Vial sizes that more closely match doses can minimize preparation time and steps, reducing employee fatigue and the number of opportunities for error.

ASHP advocates that pharmaceutical manufacturers provide drug products in vial sizes that reduce drug waste (e.g., multiple-dose vials or single-dose vials of differing doses), and that regulators, manufacturers, and healthcare providers cooperate to develop and implement best practices for drug vial optimization.

1813

USE OF CLOSED-SYSTEM TRANSFER DEVICES TO REDUCE DRUG WASTE

Source: Council on Pharmacy Practice

To recognize that a growing body of evidence supports the ability of specific closed-system transfer devices (CSTDs) to maintain sterility beyond the in-use time currently recommended by United States Pharmacopeia Chapter 797, when those CSTDs are used with aseptic technique and following current sterile compounding standards; further,

To foster additional research on and develop standards and best practices for use of CSTDs for drug vial optimization; further,

To educate healthcare professionals, especially pharmacists and pharmacy technicians, about standards and best practices for use of CSTDs in drug vial optimization.

This policy was reviewed in 2023 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

A 2016 study estimated that the U.S. may spend close to $2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Considerable savings are gained when the leftover contents of those vials are used. One practice that has shown promise in optimizing use of leftover drug product is the use of closed-system transfer devices (CSTDs) to facilitate the transfer of drug product from one reservoir to another. CSTDs prevent the release of hazardous drugs during compounding and administration and have primarily been used throughout the medication-use process to minimize healthcare workers’ exposure to hazardous drugs. Some CSTDs use a

mechanical barrier that can also prevent the ingress of environmental contaminants, which has prompted study of their ability to safely prolong the sterility of drug product in vials. A growing number of studies have been generating data that indicate specific CSTDs have the possibility of maintaining sterility and extending in-use time when used under sterile conditions defined by United States Pharmacopeia Chapter 797. Although some CSTDs have an FDA-approved indication for use to prevent microbial ingress with studied dwell times of up to 168 hours when maintained in an ISO Class 5 environment using proper aseptic technique, they do not have an explicit indication for extending the in-use time of drug products. Until the data from the studies can be validated and applied, standard-setting entities and regulators will not permit this practice. ASHP therefore advocates that the existing evidence that supports the ability of properly used CSTDs to maintain sterility and extend in-use times be recognized, and encourages research and development of guidance by standard-setting entities and regulators regarding safe use of CSTDs for drug vial optimization.

1814

DIRECT AND INDIRECT REMUNERATION FEES

Source: Council on Public Policy

To advocate that payers and pharmacy benefit managers be prohibited from recovering direct and indirect remuneration fees from pharmacies on adjudicated dispensing claims; further,

To oppose the application of plan-level quality measures on specific providers, such as participating pharmacies.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Direct and indirect remuneration (DIR) fees are a growing concern among pharmacies that dispense medications in a retail pharmacy or outpatient clinic setting. Created under the Medicare Part D Program, DIR fees were originally intended as a way for the Centers for Medicare & Medicaid Services (CMS) to account for the true cost of the drug dispensed, including manufacturer rebates and pharmacy concessions. Often these rebates and concessions were unknown until the drug was dispensed and the claim adjudicated. Recently, a concerning trend has emerged in which pharmacy benefit managers (PBMs) charge DIR fees to pharmacy providers, applying their own plan performance measures as a way to assess fees on pharmacies dispensing covered Part D drugs. These fees are problematic for the following reasons:

- The fees are arbitrary and appear to result from an unintended application of measures meant for total plan performance as opposed to pharmacy-level metrics.
- The quality measures applied tend to be based on maintenance medications such as blood pressure or medications used to treat diabetes. These measures were never intended to be applied to specialty medications, or other specialized disease states such

as oncology, yet PBMs assess DIR fees against the gross reimbursement for all prescriptions received by pharmacy providers, not just maintenance medications.
- PBMs are not required to define, justify, or explain to providers or to CMS the rationale or process for imposing their DIR fees.

Pharmacies providing specialty medications have been especially hard hit by DIR fees, due to the fee structure. DIR fees can be a flat rate (a fixed amount per dollar per claim) or a percentage (typically 3-9%) of the total reimbursement per claim. When the percentage-based structure is applied, the fees increase markedly for specialty drugs, which are typically much more expensive than maintenance medications.

Even more disturbing is that the fees are assessed retroactively, sometimes months after the claim has been adjudicated, providing no recourse for the pharmacy impacted by the assessment. Questions also remain as to whether Part D plan sponsors have the authority to assess DIR fees on pharmacies. There are no references to DIR fees collected on pharmacies in either the Medicare Modernization Act or corresponding CMS regulations.

DIR fees have led to higher cost-sharing responsibilities for Medicare beneficiaries, causing more of them to enter the Part D "donut hole" in which they are solely responsible for the cost of a drug. Because of higher costs, adherence rates tend to be lower among beneficiaries in the donut hole. These higher costs are a perverse result contrary to the very reason DIR fees were created – passing savings onto beneficiaries.

Pharmacies are not alone in their concern. In January 2017, CMS published a fact sheet expressing concern over DIR fees and cited them as contributing to increased drug costs, beneficiary out-of-pocket spending, and Medicare spending overall. ASHP supports legislation that would address the problem of DIR fees. For example, H.R. 1038/S. 413, the Improving Transparency and Accuracy in Medicare Part D Drug Spending Act, would prohibit Medicare Part D plan sponsors from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D.

1815

IMPACT OF DRUG LITIGATION ADS ON PATIENT CARE

Source: Council on Public Policy

To oppose drug litigation advertisements that do not provide a clear and conspicuous warning that patients should not modify or discontinue drug therapy without seeking the advice of their healthcare provider.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Many law firms use advertising as a means to generate clients for future litigation, including litigation regarding drugs. These advertisements can generate unnecessary fear for patients taking those drugs and may lead them to modify or discontinue medically necessary therapies. Abruptly discontinuing a drug without consulting a healthcare provider can lead to failed therapy and other adverse effects (e.g., some drugs require a tapered withdrawal to be safely

discontinued, and patients on multiple medications may require new dosing or drug interaction assessments). Other than truth-in-advertising laws, there is currently no oversight of these advertisements and no requirement to warn patients about the potential harmful effects of discontinuing their drugs. ASHP agrees with the American Medical Association that such ads should be required to have clear and conspicuous warnings that direct patients to speak with their healthcare providers before modifying or discontinuing any drug therapy.

1816
BIOSIMILAR MEDICATIONS

This policy was superseded by ASHP policy 2307.

1817
340B DRUG PRICING PROGRAM SUSTAINABILITY

This policy was superseded by ASHP policy 1908.

1818
FEDERAL QUALITY RATING PROGRAM FOR PHARMACEUTICAL MANUFACTURERS
Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) assign quality ratings to pharmaceutical manufacturers based on the quality of their manufacturing processes, sourcing of active pharmaceutical ingredients and excipients, selection of contract manufacturers, and business continuity plans; further,

To advocate that the FDA consider offering incentives for manufacturers to participate in the program.

This policy supersedes ASHP policy 0814.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
Shortages of critical drug products in hospitals and health systems continue to pose a significant threat to public health, and pharmacists and other clinicians are often challenged with locating supplies of life-saving or life-sustaining drug products at a moment's notice and with very few options to choose from. While the number of new shortages has fallen considerably since 2011, a number of drug products remain in short supply. Drug product shortages are often caused by a manufacturing problem (e.g., contamination) that halts production until the problem is resolved. To address the issue of quality in drug product manufacturing, the FDA has proposed the creation of a manufacturing quality initiative that would highlight companies that employ the best quality manufacturing processes by establishing a rating system that would assign a rating to companies based on their level of quality in the manufacturing process. This rating

system could be made public to enable prospective customers to see which companies employ the best quality practices. Further, the rating system could serve as a basis for FDA to offer incentives to companies who consistently rate higher than competitors.

1819
INTRAVENOUS FLUID MANUFACTURING FACILITIES AS CRITICAL PUBLIC HEALTH INFRASTRUCTURE
Source: Council on Public Policy

To advocate that federal and state governments recognize intravenous fluid and associated supply manufacturing facilities as critical public health infrastructure.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
In the wake of hurricane Maria's impact on Puerto Rico in 2017, there has been rising interest in examining drug shortages from a national security perspective. The vulnerability of drug manufacturing on the island of Puerto Rico underscored a need to more closely evaluate the potential impacts of natural disasters on drug manufacturing and the production of critical pharmaceutical supplies. The Department of Homeland Security's list of key infrastructure includes public health infrastructure. ASHP advocates that public health infrastructure be defined to include manufacturing sites of intravenous fluids and associated supplies (i.e., components needed to administer intravenous fluids), and that those sites be afforded the same protections as other critical infrastructure. Such protections should include an evaluation of manufacturing vulnerabilities such as geographic location, vulnerability of surrounding infrastructure such as roads or ports, and whether the company has developed business continuity plans or redundancies in manufacturing. Entities deemed critical public health infrastructure should be required to make necessary changes to ensure that manufacturing is not at risk for a supply disruption.

1820
MEDICAL DEVICES
Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) and manufacturers of drug preparation, drug distribution, and drug administration devices and associated new technologies ensure transparency, clarity, and evidence be provided on the intended use of devices and technologies in all phases of the medication-use process; further,

To advocate that the FDA and device manufacturers ensure compatibility between the intended use of any device and the drugs to be used with that device.

This policy supersedes ASHP policy 9106.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The lines between devices, drugs, and technology are blurring as new and innovative technologies combine drugs and devices. Because drugs and medical devices undergo different approval processes, it is important that compatibility between the intended use of any device and the drugs to be used with that device be ensured during the approval process so that unintended and possibly detrimental consequences do not occur. In addition, clinicians require information about the intended use of devices in all phases of the medication-use process in order to make the best-informed decisions about patient care.

1821

ENSURING EFFECTIVENESS, SAFETY, AND ACCESS TO ORPHAN DRUG PRODUCTS

Source: Council on Therapeutics

To encourage continued awareness of, research on, and development of orphan drug products; further,

To advocate for the use of innovative strategies and incentives to expand the breadth of rare diseases addressed by this program; further,

To encourage postmarketing research to support the safe and effective use of orphan drug products for approved and off-label indications; further,

To advocate that health policymakers, payers, and pharmaceutical manufacturers ensure continuity of care and patient access to orphan drug products; further,

To advocate federal review to evaluate whether orphan drug designation is being used inappropriately to receive FDA approval, extend patents, decrease competition, or limit discounts, thereby reducing patient access.

This policy supersedes ASHP policy 1413.

This policy was reviewed in 2023 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

The U.S. Orphan Drug Act of 1983 and similar programs in other countries have greatly expanded the number of therapies available to treat rare diseases through the use of financial and other incentives that encourage drug manufacturers to develop medications for limited patient populations. Despite the overall success of orphan drug programs, concerns have been raised about the breadth of drugs approved through these mechanisms. Although there are more than 7,000 designated orphan diseases in the United States, oncology drugs represent approximately 33 percent of all orphan drug approvals. ASHP believes that there is a significant

need to develop a more comprehensive approach to orphan drug development in order to encourage drug manufacturers to expand the breadth of rare conditions treated by these therapies.

Once an orphan drug is approved, it may be used without restrictions, and these therapies are frequently used to treat patients and conditions that were not assessed during pre-approval clinical studies. While this use can spur innovation and lead to advances in the treatment of common diseases, ASHP believes that this use is also associated with the potential for increased patient harm, given the small patient populations and other characteristics common to studies used to support orphan drug approval. Research is necessary to evaluate the safety and effectiveness of these therapies under real-use conditions. In addition to manufacturer-conducted research, ASHP encourages private and public sector research in order to provide sufficient evidence to support off-label use.

ASHP is concerned about the high cost of these therapies, which contributes to increased healthcare costs and potentially decreases patient access, especially among those who are under- or uninsured. Further, some orphan drugs have later been discontinued by the drug manufacturer—an occurrence that often leaves patients with rare conditions without a treatment alternative. It is essential that stakeholders (e.g., health policymakers, payers, and pharmaceutical manufacturers) continue efforts to provide patient access to these therapies, including developing strategies to ensure that the cost of these therapies does not create an unreasonable barrier to patient access.

There are additional challenges regarding patient access to orphan drugs. There is a need for more emphasis on increasing patient access and addressing 340B issues, especially with critical access facilities. Orphan drug development and marketing in the U.S. is concentrated in a few therapeutic areas. Despite the increase in the number of orphan drugs approved by the Food and Drug Administration (FDA), the unmet needs of patients with rare diseases provide evidence that the current incentives are not efficiently stimulating orphan drug development. There is need to balance economic incentives to stimulate the development and marketing of orphan drugs without jeopardizing patients' access to treatment.

Finally, one study (Sarpatwari A, Beall RF, Abdurrob A et al. Evaluating The Impact Of The Orphan Drug Act's Seven-Year Market Exclusivity Period. *Health Aff.* 2018; 37:732–7. doi:10.1377/hlthaff.2017.1179) concluded that the orphan drug incentive of 7-year exclusivity only benefits about 33% of orphan drugs. The remainder have 20-year patent exclusivity that outlives the orphan drug incentive. Despite this discrepancy, the number of orphan drugs still grows every year, which may stem from manufacturers' unfettered freedom to price these new drugs as they see fit. ASHP encourages federal review of current incentives to evaluate whether orphan drug designation is being used inappropriately to receive FDA approval, extend patents, decrease competition, or limit discounts, which can raise prices and reduce patient access. .

1822

RATIONAL USE OF MEDICATIONS

Source: Council on Therapeutics

To promote evidence-based prescribing and deprescribing for indication, efficacy, safety, duration, cost, and suitability for the patient; further,

To advocate that pharmacists lead interprofessional efforts to promote the rational use of medications, including engaging in strategies to monitor, detect, and address patterns of irrational medication use in patient populations.

This policy supersedes ASHP policy 1312.

This policy was reviewed in 2023 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

The World Health Organization (WHO) identifies that rational use of medications requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community." The overuse, underuse, or misuse of medicines results in wastage of scarce resources and widespread health hazards. Examples of irrational use of medicines include use of too many medicines per patient, inappropriate use of antimicrobials, inadequate dosage, overuse of injections when oral formulations would be more appropriate, failure to prescribe in accordance with clinical guidelines, inappropriate self-medication, decreased access to medicines, and nonadherence to dosing regimens. These actions can negatively affect the quality of patient care, raise healthcare costs, and increase the number of adverse reactions and events, and may cause adverse reactions or negative psychosocial effects.

Strategies to address irrational medication use can be characterized as educational, managerial, economic, or regulatory in nature. Furthermore, the WHO advocates 12 key interventions to promote more rational use of medications:

- establishment of a multidisciplinary national body to coordinate policies on medication use;
- use of clinical guidelines;
- development and use of national essential medications list;
- establishment of drug and therapeutics committees in districts and hospitals;
- inclusion of problem-based pharmacotherapy training in undergraduate curricula;
- continuing in-service medical education as a licensure requirement;
- supervision, audit, and feedback;
- use of independent information on medications;
- public education about medications;
- avoidance of perverse financial incentives;
- use of appropriate and enforced regulation; and
- sufficient government expenditure to ensure availability of medications and staff.

These recommendations are echoed by the Joint Commission of Pharmacy Practitioners, whose tenets of the pharmacists' patient care process include the collection of necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient; assessment of information collected and analysis of the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal

care; development of an individualized patient-centered care plan, in collaboration with other healthcare professionals and the patient or caregiver that is evidence-based and cost-effective; implementation of the care plan in collaboration with other healthcare professionals and the patient or caregiver; and monitoring and evaluation of the effectiveness of the care plan and modification of the plan in collaboration with other healthcare professionals and the patient or caregiver as needed. ASHP also supports the use of stewardship programs with pharmacists in a lead role, as these have been shown to demonstrate the rational use of medications.

1823
RESPONSIBLE MEDICATION-RELATED CLINICAL TESTING AND MONITORING

This policy was superseded by ASHP policy 2315.

1824
USE OF BIOMARKERS IN CLINICAL PRACTICE
Source: Council on Therapeutics

To promote appropriate, evidence-based use of biomarkers in clinical practice; further,

To encourage research that evaluates the clinical and safety implications of biomarkers in the care of patients and to guide clinical practice; further,

To promote Food and Drug Administration qualified biomarkers in drug development, regulation, and use in clinical practice; further,

To foster the development of timely and readily available resources about biomarkers and their evidence-based application in clinical practice.

This policy was reviewed in 2023 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
Developed jointly by the Food and Drug Administration (FDA) and National Institutes of Health (NIH) through the FDA-NIH Biomarker Working Group, The Biomarkers, EndpointS, and other Tools (BEST) resource serves as a living document to clarify and promote consistent terminology surrounding the use of biomarkers. As defined by the FDA-NIH Biomarker Working Group, a biomarker is “a defined characteristic that is measured as an indicator of normal biological processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how a patient feels, functions, or survives.” In comparison to a clinical endpoint, a biomarker is strictly objective and quantifiable, whereas a clinical endpoint reflects the subject’s well-being and health status from the subject’s perspective. Biomarkers are classified by BEST in the following seven categories: susceptibility/risk biomarker, diagnostic biomarker, monitoring biomarker, prognostic

biomarker, predictive biomarker, pharmacodynamic/response biomarker, and safety biomarker.

Further, the FDA and its Center for Drug Evaluation and Research are involved in regulating biomarkers in drug development, regulation, and use in clinical practice. Under the FDA Biomarker Qualification Program, researchers can request qualification of a biomarker in the use of drug development. The FDA's involvement in biomarker qualifications allows for the development of a regulatory process to investigate the safety and efficacy of biomarkers. Innovative and newly discovered biomarkers are investigated or found unexpectedly in clinical research. Recently published articles demonstrate newly discovered biomarkers that potentially show clinical efficacy; however, there is debate about how to conduct further research to establish a biomarker's clinical efficacy.

This growth in discovery and application of established biomarkers in practice presents several practice issues, including use of recognized biomarkers, collaborating with practitioners concerning newly discovered or rising biomarkers, conducting research on the outcomes of the use of various biomarkers, and integrating use of biomarkers into practice.

1825
CLINICIAN WELL-BEING AND RESILIENCE

This policy was superseded by ASHP policy 2329.

1826
STUDENT PHARMACIST DRUG TESTING
Source: Council on Education and Workforce Development

To advocate for the use of pre-enrollment, random, and for-cause drug testing throughout pharmacy education and pharmacy practice experiences, based on defined criteria with appropriate testing validation procedures; further,

To encourage colleges of pharmacy to develop policies and processes to identify impaired individuals; further,

To encourage colleges of pharmacy to facilitate access to and promote programs for treatment and to support recovery; further,

To encourage colleges of pharmacy to use validated testing panels that have demonstrated effectiveness detecting commonly misused, abused, or illegally used substances.

This policy was reviewed in 2023 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale
The Mental Health Parity Act of 1996 stipulated that large group health plans cannot impose annual or lifetime dollar limits on mental health benefits that are less favorable that those imposed on medical or surgical benefits. Therefore, health insurers and group health plans are

required to provide the same level of benefits for mental health and/or substance use treatment and services that they do for medical or surgical care. The Affordable Care Act (ACA) later amended this law to also include individual health plans. The ACA also embraces substance use disorders as one of the ten elements of essential health benefits.

Most colleges of pharmacy require students to be enrolled in health insurance and therefore should receive similar benefits for mental health and substance use services and treatment. Despite regulation of opioid prescriptions, opioid-related overdoses are at an all-time high. Research indicates that the best help for someone with a substance use problem or disorder is early interventions. With the growth of substance use disorder clinics and increasing coverage from insurance, recovery is now an obtainable outcome. Efficacy of treatment and rehabilitation as well as the accessibility of such programs further supports the importance of colleges of pharmacy facilitating access to students seeking services or treatment for substance use problems or disorders.

In addition, drug testing should be supported by an addiction recovery program, as outlined in the ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance.

1827

COLLABORATION ON EXPERIENTIAL EDUCATION

Source: Council on Education and Workforce Development

To encourage practitioner contributions to pharmacy education; further,

To encourage pharmacists and pharmacy leaders to recognize their professional responsibility to contribute to the development of new pharmacy practitioners; further,

To promote collaboration of experiential teaching sites with the colleges of pharmacy (nationally or regionally), for the purpose of fostering preceptor development, standardization of experiential rotation schedule dates and evaluation tools, and other related matters; further,

To encourage colleges of pharmacy and health systems to define and develop collaborative organizational relationships that support patient care and advance the missions of both institutions in a mutually beneficial manner.

This policy supersedes ASHP policies 0315 and 0804.

This policy was reviewed in 2023 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

As stated in the ASHP Statement on Professionalism, one of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession's ideals and mission. Because the principles of institutional pharmacy practice are not emphasized in typical pharmacy curricula, professional socialization is especially important for pharmacists who practice in those settings. The experiential education experience of student pharmacists is

a partnership between colleges of pharmacy and the experiential teaching sites. Collaboration between the colleges of pharmacy and experiential training sites on preceptor development, standardized rotation schedule dates, evaluation tools, and other materials helps to assure the best possible experience for student pharmacists, preceptors, and the experiential education site. In addition, collaboration allows both entities to fulfill their missions by participating in mutually beneficial activities, improving patient outcomes, and helping students and their institutions achieve educational and research objectives.

1828
PROMOTING THE IMAGE OF PHARMACISTS AND PHARMACY TECHNICIANS

This policy was superseded by ASHP policy 2336.

1829
PHARMACY TRAINING MODELS

This policy was superseded by ASHP policy 2106.

1830
ASHP STATEMENT ON ADVOCACY AS A PROFESSIONAL OBLIGATION
Source: Council on Public Policy

To approve the ASHP Statement on Advocacy as a Professional Obligation.

1831
SAFE AND EFFECTIVE USE OF IV PROMETHAZINE

This policy was superseded by ASHP policy 2328.

2017 Policy Positions

1701
ENSURING PATIENT SAFETY AND DATA INTEGRITY DURING CYBER-ATTACKS

This policy was superseded by ASHP policy 2147.

1702
REDUCTION OF UNUSED PRESCRIPTION DRUG PRODUCTS

This policy was superseded by ASHP policy 2145.

1703
PHARMACIST'S LEADERSHIP ROLE IN ANTICOAGULATION THERAPY MANAGEMENT

This policy was superseded by ASHP policy 2006.

1704
MEDICAL AID IN DYING
Source: Board of Directors

To affirm that a pharmacist's decision to participate or decline to participate in medical aid in dying for competent, terminally ill patients, where legal, is one of individual conscience; further,

To reaffirm that pharmacists have a right to participate or decline to participate in medical aid in dying without retribution; further,

To take a stance of studied neutrality on legislation that would permit medical aid in dying for competent, terminally ill patients.

This policy supersedes ASHP policy 9915.

This policy was reviewed in 2022 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Medical aid in dying (also called physician-assisted dying, physician-assisted suicide, physician aid in dying, physician-assisted death, hastened death, medically assisted dying, and death with dignity) has been legal in some areas of the U.S. since Oregon passed its Death with Dignity Law in 1995. By 2016, one sixth of U.S. citizens lived in a jurisdiction in which medical aid in dying was available, and more states were contemplating legislation to legalize it. Experience in Oregon and elsewhere demonstrates that pharmacists in those jurisdictions may be confronted with the difficult ethical question of whether to participate in medical aid in dying.

For purposes of this policy position, ASHP adapts a common definition of medical aid in dying: the practice in which a physician provides a prescription for a lethal dose of medication to a terminally ill, competent patient at the patient's request that the patient can self-administer at a time of his or her choosing to end his or her life. ASHP notes that many of the terms commonly used to describe this practice ignore the patient care and dispensing roles of pharmacists as well as the roles of other healthcare professionals, such as hospice nurses, in providing care for patients requesting medical aid in dying. ASHP recognizes the utility of a term such as "medical aid in dying" that addresses the roles of all healthcare providers involved in or affected by the practice but acknowledges the term's ambiguity regarding self-administration of the lethal dose. ASHP therefore explicitly distinguishes medical aid in dying from all forms of euthanasia, which is not the subject of this policy.

ASHP takes a position of studied neutrality on whether pharmacists should participate in medical aid in dying. Studied neutrality has been defined as "the careful or premeditated practice of being neutral in a dispute" and has as it goals "to foster a respectful culture among people of diverse views and to guide action that does not afford material advantage to a [particular] group." (Johnstone M-J. Organization Position Statements and the Stance of ''Studied Neutrality'' on Euthanasia in Palliative Care. *J Pain Symp Manag.* 2012; 44:896-907.) ASHP respects the diversity of views of its members and other pharmacists on medical aid in dying and adopts a position of studied neutrality to promote patient autonomy and access to care and to protect pharmacists' professional integrity and comity.

The Code of Ethics for Pharmacists states that "a pharmacist promises to help individuals achieve optimum benefit from their medications [and] to be committed to their welfare" and that "a pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health." In pharmacist decision-making about participation in medical aid in dying, those principles may clash. Self-determination dictates that patients should be free to exercise their ethical and legal right to choose or decline any legally available treatment. Many healthcare professionals, and their organizations (including the American Medical Association, the American College of Physicians, and the American Nurses Association), question whether death is ever an acceptable therapeutic goal. Others (including the American Academy of Hospice and Palliative Medicine and the American Psychological Association) acknowledge in their statements of neutrality that society may determine that medical aid in dying falls within a spectrum of treatments and withholding of treatments that has as its goal the relief of suffering through a compassionately hastened death, even while recognizing the risks of such a practice.

Pharmacists, like other healthcare professionals, have a right to examine and act on the moral and ethical issues involved in providing care to patients. ASHP policy position 2615, Pharmacist's Right of Conscience and Patient's Right of Access to Therapy, outlines the rights and responsibilities of pharmacists and other pharmacy employees who decline to participate in therapies that they find morally, religiously, or ethically troubling, including the right to reasonable accommodation of their right to conscience in a nonpunitive manner. Procedures should be in place to ensure that healthcare organizations can provide mission-compatible care to patients, and that healthcare providers practicing there are not a barrier to the organization's ability to provide that care. In adopting its position of studied neutrality on pharmacist involvement in medical aid in dying, ASHP recognizes that adopting a position in

favor of participation would infringe on the moral and ethical prerogatives of pharmacists. ASHP similarly recognizes that a stance against participation would make the same infringement and in addition present the risk of legal or professional sanction for pharmacists who participate in medical aid in dying where it is legal.

ASHP also takes a position of studied neutrality on whether medical aid in dying should be legally permitted for competent, terminally ill patients. ASHP recognizes that society may interpret the principle of patient autonomy to include the right to therapies that some may find morally, religiously, or ethically troubling, including medical aid in dying. Recognizing as well the role of healthcare professionals as guardians against practices that would undermine patient autonomy, ASHP advocates that, when permitted, medical aid in dying only be available to competent, terminally ill patients who freely and knowledgeably make that choice.

ASHP joins other healthcare professional organizations in noting that medical aid in dying is inextricably linked with hospice, palliative, and other end-of-life care. ASHP will therefore continue to advocate that patients receive appropriate pharmacist care at the end of life, including pain management (ASHP policy 2254), support in dying (ASHP policy 2333), and hospice and palliative care.

1706

ASHP GUIDELINES, STATEMENTS, AND PROFESSIONAL POLICIES AS AN INTEGRAL PART OF THE EDUCATIONAL PROCESS

Source: Council on Education and Workforce Development

To encourage all educators of the pharmacy workforce to use ASHP statements, guidelines, and professional policies as an integral part of education and training.

This policy supersedes ASHP policy 0705.

This policy was reviewed in 2022 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

ASHP members create professional policy that reflect best practices and influence the future direction of the profession and patient care. ASHP's professional policies contain varying levels of detail, but all contain guiding principles for the profession. The use of professional policy should be incorporated into all forms of professional education, including pharmacy and technician students, residents, and practitioners and widely used across the pharmacy profession.

1708

MOBILE HEALTH TOOLS, CLINICAL APPS, AND ASSOCIATED DEVICES

This policy was superseded by ASHP policy 2204.

1709
CONTROLLED SUBSTANCE DIVERSION PREVENTION

This policy was superseded by ASHP policy 2042.

1710
REVENUE CYCLE COMPLIANCE AND MANAGEMENT

This policy was superseded by ASHP policy 2232.

1711
READY-TO-ADMINISTER PACKAGING FOR HAZARDOUS DRUG PRODUCTS INTENDED FOR HOME USE
Source: Council on Pharmacy Practice

To advocate that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that regulators (e.g., the Food and Drug Administration) have the authority to impose requirements on pharmaceutical manufacturers to provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that when hazardous drug products intended for home use are not available from manufacturers in ready-to-administer packaging, pharmacies repackage those drug products to minimize the risk of exposure; further,

To advocate that hazardous drug products intended for home use be labeled to warn that special handling is required for safety; further,

To advocate that pharmacists provide education to patients and caregivers regarding safe handling and appropriate disposal of hazardous drug products intended for home use.

This policy was reviewed in 2022 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Home use of oral chemotherapy increases patient convenience and lowers healthcare costs, but it presents unique safety risks. In a hospital or clinic setting, healthcare professionals manage the risks posed by hazardous drugs, defined as any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing hazardous drugs in structure or toxicity (NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings). In the home environment, however, patients and caregivers must be prepared to fill that role. Ready-to-administer packaging of hazardous drugs minimizes patient, caregiver, and family

exposure to hazardous drugs, promotes patient adherence, and enhances safe medication use. Ready-to-administer packaging is defined as packaging that provides the product in a way that requires no manipulation before the patient or caregiver can administer the medication. In contrast, ready-to-use packaging may require a small amount of manipulation (e.g., reconstitution). These definitions are consistent with United States Pharmacopeia and Institute for Safe Medication Practices terminology. ASHP advocates that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging, and that regulators have the authority to require manufacturers to (1) provide hazardous drug products intended for home use in ready-to-administer packaging, and (2) label hazardous drug products intended for home use to warn that special handling is required to ensure safety. ASHP further advocates that when hazardous drug products intended for home use are not available in ready-to-administer packaging, pharmacies repackage those drug products to minimize exposure risk for caregivers and others in the patient's household. For example, intravenous drug products should be dispensed in a container designed so the patient or caregiver does not have to puncture a vial; tablets are split or crushed prior to dispensing; compounding of liquid medications is done by the pharmacy, if stability information for the drug product supports advanced compounding and transport; and all liquid medications are dispensed with a dispensing cap that can accommodate attachment of an oral syringe. Finally, ASHP advocates that patients and caregivers be provided education regarding safe handling of hazardous drug products from a qualified healthcare professional, preferably a pharmacist experienced in managing the risks of hazardous drug products.

1712
EXPIRATION DATING OF PHARMACEUTICAL PRODUCTS

This policy was superseded by ASHP 2146.

1713
PARTIAL FILLING OF SCHEDULE II PRESCRIPTIONS
Source: Council on Public Policy

To advocate that state legislatures and boards of pharmacy create consistent laws and rules to allow partial filling of Schedule II drugs; further,

To advocate that public and private entities construct criteria for partial filling to minimize the additional burden on patients, pharmacists, and healthcare organizations; further,

To advocate that pharmacists educate prescribers and patients about options for filling prescriptions for Schedule II drugs, including the risks of overprescribing, while recognizing the patient or caregiver's rights to make their own care and management decisions.

This policy was reviewed in 2022 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The issue of opioid abuse and addiction has been at the forefront of federal and state activity. Increasing addiction rates of patients taking powerful opioids have spurred calls for action to help address this growing problem. The issue has become national in scope and has generated discussion among policymakers and healthcare practitioners alike. In mid-2016, Congress passed the Comprehensive Addiction and Recovery Act of 2016, legislation aimed at curbing opioid abuse and enhancing access to addiction treatment. States have been considering their own legislative initiatives to address what is increasingly described as an epidemic.

One solution proposed by policymakers is to allow pharmacists to dispense only a portion of the quantity of a Schedule II drug prescribed (e.g., 7 days of the prescribed quantity of the drug rather than an entire 30-day supply). Such "partial filling" of Schedule II drug prescriptions reduces the potential of opioid addiction for the patient and the risk of diversion for others. Federal law has been changed to permit partial filling of Schedule II drugs, and Massachusetts and Maine have passed laws to allow for partial filling of Schedule II drugs. ASHP advocates that other state legislatures and boards of pharmacy amend pharmacy practice acts and rules to allow for partial filling of Schedule II drugs, and that such laws and rules be made consistent across states. However, ASHP has concerns about quantity and duration limits applied across the board and not on an as-needed basis (e.g., for oncology and palliative care patients). ASHP believes that each patient must be evaluated individually and that polices that allow for partial filling are not indiscriminately applied as an across-the-board mandatory rule. ASHP encourages public and private payers to recognize the additional burden placed on patients and pharmacies by partial filling and to minimize these burdens when possible, including providing appropriate reimbursement for pharmacist activities. ASHP encourages pharmacists to serve as patient advocates by educating prescribers and patients about options for filling prescriptions for Schedule II drugs.

1714

RESTRICTED DRUG DISTRIBUTION

Source: Council on Public Policy

To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) are not supported by publicly available evidence that they are the least restrictive means to improve patient safety; (7) interfere with the professional practice of healthcare providers; or (8) are created for any reason other than patient safety.

This policy supersedes ASHP policy 0714.

This policy was reviewed in 2022 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Restricted drug distribution systems (RDDSes) that are not created solely for patient safety reasons (e.g., those that misuse risk evaluation and mitigation strategies [REMS] programs for

the purposes of limiting distribution) significantly restrict patient access to medications. These systems were justified as a means to closely monitor patient use of medications that could potentially pose a safety risk. They were never intended to allow drug manufacturers to reduce pharmacists' access to medications through limited distribution networks. Using restricted distribution as a tool to gain marketplace advantage rather than for patient safety undermines the justification for such limited systems. Similarly, the use of insurer-imposed restrictions to artificially limit drug distribution creates access problems for patients and administrative issues for providers. However, hospital- and health system-owned or -operated specialty pharmacies do not result in the same access concerns, as they generally reduce prior approval burdens and ensure patient access to medications.

ASHP opposes the use of RDDSes (e.g., the misuse of REMS and insurer-forced limited distribution) for anything other than patient safety and encourages the FDA or other appropriate authorities to investigate whether REMS-related RDDSes are being used in a manner inconsistent with the original intent. In addition, both REMS-related and insurer-forced RDDSes may compromise continuity of care or interfere with pharmacists' accountability for care to certain patient populations, such as when an RDDS prevents a patient's pharmacist from obtaining it. Some investigational drugs approved for marketing under an RDDS are no longer available for qualifying patients on admission through the institution, despite the institution having a history of managing the drug while it was investigational. Such circumstances force the patient to seek care elsewhere or require them and their healthcare providers to unnecessarily utilize additional resources to provide care. In addition, healthcare organizations, responsible for the total care of the patient, including maintaining the patient's medical records, may lose the established patient-care relationship when a patient must go to a specialty pharmacy for a drug the healthcare organization cannot access. RDDSes fragment the healthcare delivery system at a time when public and private payers are increasing incentives to integrate patient care.

1715

COLLABORATIVE PRACTICE

Source: Council on Public Policy

To pursue the development of federal and state laws and regulations that authorize pharmacists as providers within collaborative practice; further,

To advocate expansion of federal and state laws and regulations that optimize pharmacists' ability to provide the full range of professional services within their scope of expertise; further,

To advocate for federal and state laws and regulations that would allow pharmacists to prescribe and transmit prescriptions electronically; further,

To acknowledge that as part of these advanced collaborative practices, pharmacists, as active members in team-based care, must be responsible and accountable for medication-related outcomes; further,

To support affiliated state societies in their pursuit of state-level regulations allowing collaborative practice for pharmacists.

This policy supersedes ASHP policy 1217.

This policy was reviewed in 2022 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Although many states permit pharmacists to serve as providers in collaborative practice, there is great variability in the authority granted to pharmacists. ASHP supports collaborative practice and advocates its expansion to all states, in a variety of diverse practice settings, and at the highest level of pharmacy practice. As new pharmacy practice models emerge, collaborative practice should be a part of those innovations. One of the common barriers to the highest level of collaborative practice is the prohibition of pharmacists transmitting prescriptions electronically. The expansion of collaborative practice, including electronic transmission of prescriptions, will aid in moving the profession forward to the highest level of team-based practice and will enable pharmacists to practice at the top of their licenses, accountable to the patient and the team for medication-related outcomes. Further, expansion of these team-based models will require both federal and state reimbursement models sufficient to support the practice, including advancement of state-level pay parity acts that ensure payment for pharmacists at least equivalent to that of other providers.

1716

GREATER COMPETITION AMONG GENERIC AND BIOSIMILAR MANUFACTURERS

Source: Council on Public Policy

To advocate for legislation and regulations that promote greater competition among generic and biosimilar pharmaceutical manufacturers.

This policy supersedes ASHP policy 0222.

This policy was reviewed in 2022 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

A healthy market for generic drug products and biosimilars increases patient access to drugs and lowers drug costs. ASHP recognizes several threats to the health of that market and advocates legislative and regulatory solutions: speeding FDA approval of generic drug applications, especially for lifesaving drugs; reducing drug monopolies by incentivizing competition for additional market entrants; targeting exclusivity protections to truly innovative products; and curbing abuse of risk evaluation and mitigation strategies (REMS) and misuse of FDA's citizen petition process. In 2015, the FDA faced a backlog of nearly 4,000 generic drug applications, with the approval process taking three years or more. ASHP advocates that the FDA be provided the resources needed to evaluate and approve generic drug applications in a

safe and timely manner. ASHP also advocates government and market incentives to increase competition for expensive drugs where no competitors exist and encourage additional market entrants. ASHP has long recognized that agreements between generic and brand-name manufacturers when a product's market exclusivity is about to expire have the effect of delaying the marketing of competitor products and limiting patient access to affordable generic drugs. ASHP advocates for legislative and regulatory solutions to limit such agreements, as well as solutions to prevent brand-name manufacturers from extending market exclusivity and preventing market entry by generics by slightly altering the formulation of a product. ASHP further advocates legislation that would prevent frivolous patent infringement litigation by brand-name manufacturers, which is reported to have been initiated with the sole intent to extend market exclusivity. Another solution advocated by ASHP is curbing misuse of REMS, which are reported to have been used to prevent generic manufacturers from accessing drug products. In addition, ASHP advocates for more consumer-accessible information on drug prices and rebates, including an annual report on increases in drug prices, which would provide patients and their healthcare providers with the information they need to make drug purchasing choices. Finally, ASHP encourages appropriate federal review of anticompetitive practices by pharmaceutical manufacturers.

1717
DRUG TESTING

This policy was superseded by ASHP policy 2209.

1719
PHARMACIST'S LEADERSHIP ROLE IN GLYCEMIC CONTROL

This policy was discontinued in 2022.

1721
CLINICAL SIGNIFICANCE OF ACCURATE AND TIMELY HEIGHT AND WEIGHT MEASUREMENTS

This policy was superseded by ASHP policy 2514.

1722
PAIN MANAGEMENT

This policy was superseded by ASHP policy 2254.

1723
CLINICAL INVESTIGATIONS OF DRUGS USED IN ELDERLY AND PEDIATRIC PATIENTS

This policy was superseded by ASHP policy 2243.

1724

SAFE AND EFFECTIVE THERAPEUTIC USE OF INVERTEBRATES

This policy was superseded by ASHP policy 2212.

1725
DRUG DOSING IN EXTRACORPOREAL THERAPIES
Source: Council on Therapeutics

To encourage research on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To support development and use of standardized models of assessment of the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To collaborate with stakeholders in enhancing aggregation of data on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To encourage the education of the pharmacy workforce and other healthcare providers regarding the basic principles of and drug dosing in extracorporeal therapies.

This policy supersedes ASHP policy 1606.

This policy was reviewed in 2022 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

There are few resources and recommendations for drug dosing in patients receiving the varied forms of extracorporeal therapies, including renal replacement therapy, extracorporeal membrane oxygenation (ECMO) support, apheresis, plasmapheresis, molecular adsorbent recirculating system (MARS) support, single pass albumin dialysis (SPAD), fractionated plasma separation and adsorption (PROMETHEUS), therapeutic plasma exchange (TPE), extracorporeal liver assist device (ELAD) support, modular extracorporeal liver (MELS) support, peritoneal dialysis, and use of ventricular assist devices.

Appropriate dosing is very important in optimizing patient outcomes and achieving goals of therapy. Often drug properties are used to make educated guesses on appropriate dosing and are based on estimations of clearance. In the critically ill population, serious infections and renal issues often occur simultaneously. Solute removal has a significant impact on dosing and appropriate dosing. Many patient characteristics and device variables need to be considered when dosing patients receiving these therapies. These factors include flow rate, membrane pore size, volume of distribution, and patient status. Protein binding helps sustain the drug in tissue, and drugs with a large molecular weight may clog the porous membranes.

Research on drug removal by these extracorporeal means is scarce, and ASHP encourages independent clinical and practice-based research to further define clinical use of drugs for patients receiving these modes of treatment as well as clinician reporting of patient experience via published articles and clinical registries. ASHP also encourages education of the

pharmacy workforce and other healthcare providers regarding the basic principles of and drug dosing in extracorporeal therapies.

2016 Policy Positions

1602
DRUG PRODUCT SUPPLY CHAIN INTEGRITY

This policy was superseded by ASHP policy 2043.

1603
STEWARDSHIP OF DRUGS WITH POTENTIAL FOR ABUSE
Source: Council on Therapeutics

To advocate for the inclusion of a clinically appropriate indication of use, the intended duration, and the goals of therapy when prescribing drugs with potential for abuse; further,

To encourage pharmacists to engage in interprofessional efforts to promote the appropriate, but judicious, use of drugs with the potential for abuse, including education, monitoring, assessment of clinical progress, and discontinuation of therapy or dose reduction, where appropriate; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of drugs with potential for abuse, including engaging in strategies to detect and address patterns of use in patient populations at increased risk for adverse outcomes; further,

To facilitate the development of best practices for prescription drug monitoring programs and drug take-back disposal programs for drugs with potential for abuse.

This policy was reviewed in 2021 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
Drug abuse in the U.S. has reached epidemic proportions. In 2011, 110 people died every day from drug poisonings, and prescription drugs were involved in 41,300 deaths. According to the CDC, almost 5% of the U.S. population over 12 years used opioid pain relievers for non-medical reasons in 2010. The CDC estimates the cost to insurance companies to be 70 billion annually. The Centers for Disease Control and Prevention (CDC) and White House continue to prioritize drug abuse issue as a national concern. SAMHSA has released a toolkit on opioid overdose, and state prescription drug monitoring programs are increasingly sharing information among states. In 2013, ASHP and others successfully advocated for the rescheduling of hydrocodone combination products due to safety concerns. ASHP has also advocates broader access to naloxone for opioid reversal as part of the nation's collective efforts to reduce harm from drugs of abuse.

Drugs of abuse consist of a variety of classes of medications and are not limited to opioids, however. The Substance Abuse and Mental Health Services Administration (SAMHSA) acknowledges that drugs of abuse include sedatives, stimulants, and antidepressants, in

addition to opioids. Despite their risk for abuse, prescription medications for short-term symptomatic reliefs are often refilled well beyond recommended treatment time periods. Counseling on chronic long-term therapy is important for those prescribed these drugs, which may require well-planned titration schedules for safe and effective discontinuation. Patients may not have sufficient information on discontinuation of therapy and disposal of agents.

Including a clinically appropriate indication of use, the intended duration, and the goals of therapy in the health record when drugs with potential for abuse are prescribed will foster the appropriate but judicious use of those drugs. Pharmacists, as medication-use experts, should engage in efforts to prevent inappropriate use of drugs with potential for abuse by promoting education, monitoring, assessment of clinical progress, and discontinuation of therapy or dose reduction, where appropriate, and should provide leadership in developing strategies to prevent adverse outcomes from drugs with potential for abuse and optimize prescription drug monitoring programs and drug take-back disposal programs for those drugs as well.

1604

APPROPRIATE USE OF ANTIPSYCHOTIC DRUG THERAPIES

Source: Council on Therapeutics

To advocate for the documentation of appropriate indication and goals of therapy to promote the judicious use of antipsychotic drugs and reduce the potential for harm; further,

To support the participation of pharmacists in the management of antipsychotic drug use, which is an interprofessional, collaborative process for selecting appropriate drug therapies, educating patients or their caregivers, monitoring patients, continually assessing outcomes of therapy, and identifying opportunities for discontinuation or dose adjustment; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of antipsychotic drugs, including engaging in strategies to detect and address patterns of use in patient populations at increased risk for adverse outcomes.

This policy was reviewed in 2021 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

Antipsychotic drugs are often prescribed and continued in nursing homes after transition from other care settings without appropriate justification. Although there is currently no FDA-approved drug for behavioral and psychological symptoms of dementia (BPSD), antipsychotic drugs are consistently used off-label for BPSD. According to the Agency for Healthcare Research and Quality, there is medium-level evidence to suggest effectiveness of olanzapine, risperidone, and quetiapine to reduce agitation and behavioral disturbances for people with dementia.

Some nursing homes are turning away patients with these conditions because of changes to the CMS Five-Star Quality Rating System for nursing homes, which includes two

quality measures on antipsychotic drug use. These quality measures exclude patients with schizophrenia, Huntington's disease, and Tourette syndrome.

Antipsychotic drugs have a black-box warning for increased mortality in the elderly population. In certain patients there is a benefit for use, and these patients may require more intense monitoring and assessment. Some studies suggest a significant increase in cognitive function for Alzheimer's patients with aggressive behavior (Vigen 2011). Another study (Bonner 2015) looked at rationales for prescribing and found vague, generalized indications such as anger and agitation, which is not appropriate, according to guidelines. Nonpharmacological interventions are also supported in managing BPSD. These interventions may be more appropriate in the elderly population, despite being time consuming and labor-intensive
In recent years, the use of antipsychotics has expanded into the prehospital setting, most commonly with the ketamine, a dissociative anesthetic used as a treatment for the control of delirium in acute psychotic emergencies. Ketamine has been shown to be an effective treatment for this condition but does not come without risks and should be used in the appropriate clinical scenario. The American Society of Anesthesiologists and American College of Emergency Physicians recently issued a joint statement on the Safe Use of Ketamine in Prehospital Care that opposes its use for conditions other than pain management, sedation, excited delirium syndrome, and drug intoxications, as reports of using this medication as a chemical restraint outside of these indication were on the rise, often with deadly effect.

1605
SAFETY OF EPIDURAL STEROID INJECTIONS
Source: Council on Therapeutics

To encourage healthcare providers to 1) inform patients about the significant risks and potential lack of efficacy of epidural steroid injections, 2) request their informed consent, and 3) inform patients of alternative therapies and their risks and benefits; further,

To recommend pharmacist involvement in the medication-use process associated with epidural steroid injections when such injections are medically necessary.

This policy was reviewed in 2021 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
Use of epidural steroid injections to treat low back pain is increasing, despite not being a labeled indication and sparse literature confirming the safety and efficacy of the treatment. These drugs, in this route of administration, have narrow therapeutic indices, and there are quality assurance issues related to the compounding of the preparations used in epidural injections. The safety of epidural steroid injections has been referred to in the FDA Safe Use Initiative (SUI), in which 13 stakeholders were involved in assessing evidence of neurological complications of injections. Several recommended practices resulted, including a controversial preference for nonparticulate steroid injections for use in cervical transforaminal injections. In addition to the concerns about particulates in the injections, there are very significant safety concerns due to the proximity of intrathecal, epidural, and subdural spaces and how the

injections are administered. Skillful technique is required to appropriately administer these drugs. Radiographic contrast is often used to guide the needle to injection sites. Improper technique can cause vasospasm and stroke, which is not related to particulates in the injection.

In April 2014 the FDA released a drug safety communication stating that rare and serious neurological effects can result from epidural steroid injections. The safety communication noted that "the effectiveness and safety of epidural administration of corticosteroids have not been established, and FDA has not approved corticosteroids for this use" and recommended that healthcare providers "discuss with patients the benefits and risks of epidural corticosteroid injections and other possible treatments." ASHP concurs with those recommendations and encourages use of an informed consent process in addition to other institutional protocols, including pharmacist involvement in the medication-use process when such injections are medically necessary, to promote the safe use of epidural steroid injections.

1606
DRUG DOSING IN RENAL REPLACEMENT THERAPY

This policy was superseded by ASHP policy 1725.

1607
USE OF METHADONE TO TREAT PAIN
Source: Council on Therapeutics

To acknowledge that methadone has a role in pain management and that its pharmacologic properties present unique risks to patients; further,

To oppose the payer-driven use of methadone as a preferred treatment option for pain; further,

To advocate that pain management experts, payers, and manufacturers collaborate to provide educational programs for healthcare professionals on treating pain with opioids, including the proper place in therapy for methadone; further,

To advocate that all facilities that dispense methadone, including addiction treatment programs, participate in state prescription drug monitoring programs.

This policy was reviewed in 2021 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
Over 16,000 people die each year in the U.S. from opioid overdose. Although methadone accounts for only two percent of opioid prescriptions each year, it is estimated to be responsible for over one third of overdose deaths, according to a 2012 Mortality and Morbidity Weekly Report (MMRW) Vital Signs report. The use of methadone to treat pain and its contribution to overdose deaths is an urgent public health concern.

Methadone was approved in 1947 as an analgesic and antitussive, and in 1972 it received approval for use in treating opioid addiction. In 1995, over 100,000 people in the U.S. received addiction treatment with methadone.

There are significant risks associated with the use of methadone for pain management because of its pharmacokinetic and pharmacodynamic properties. Methadone has a long half-life and short duration of analgesic effect. The respiratory effects last longer, and there is also a risk of QT interval prolongation. In 2006, the FDA released a medication safety alert on the dangers of methadone use for the treatment of pain that included a black-box warning and increased the recommended dosing interval from 3 to 8 hours. In 2008, the Drug Enforcement Agency requested manufacturers to restrict distribution of high-dose formulations to addiction treatment programs and hospitals. Federal regulations restrict the dispensing of methadone; for example, dispensing for opioid addiction treatment is limited to programs certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and for emergency situations to bridge patients to a treatment program.

Despite these dangers, 30 state Medicaid programs include methadone on the preferred drug list for treatment of pain, primarily due to its low cost. The Centers for Disease Control and Prevention (CDC) has recommended that insurance companies and other payers remove methadone from the preferred lists for treating noncancer pain. Several organizations and federal agencies have recommended against the use of methadone as a first-line agent to treat pain, including the FDA, CDC, the American Academy of Pain Medicine (AAPM), and the American Society of Interventional Pain Physicians. In May 2015, the Energy and Commerce Committee of the U.S. Senate held a hearing to assess what the federal government is doing to combat the opioid abuse epidemic and identified use of methadone for treatment of pain as a concern. ASHP joins AAPM in advocating that pain management experts, payers, and manufacturers collaborate to provide educational programs on best practices for prescribing opioids, including methadone.

1609
PHARMACY TECHNICIAN TRAINING AND CERTIFICATION

This policy was superseded by ASHP policy 1912.

1610
CAREER OPPORTUNITIES FOR PHARMACY TECHNICIANS

This policy was superseded by ASHP policy 2130.

1612
INTERPROFESSIONAL EDUCATION AND TRAINING

This policy was superseded by ASHP policy 2105.

1614
CONTROLLED SUBSTANCE DIVERSION AND PATIENT ACCESS

This policy was superseded by ASHP policy 2042.

1615
PROTECTING WORKERS FROM EXPOSURE TO HAZARDOUS DRUGS

This policy was superseded by ASHP policy 2415.

1616
PATIENT EXPERIENCE

This policy was superseded by ASHP policy 2108.

1617
AUTOMATED PREPARATION AND DISPENSING TECHNOLOGY FOR STERILE PREPARATIONS

This policy was superseded by ASHP policy 1903.

1618
INTEGRATED APPROACH FOR THE PHARMACY ENTERPRISE

This policy was discontinued in 2021.

1619
PREVENTING EXPOSURE TO ALLERGENS

This policy was superseded by ASHP policy 2124.

1620
MANUFACTURER PROMOTION OF OFF-LABEL USES
Source: Council on Public Policy

To advocate for authority for the Food and Drug Administration (FDA) to regulate the promotion and dissemination of information about off-label uses of medications and medication-containing devices by manufacturers and their representatives; further,

To advocate that such off-label promotion and marketing be limited to the FDA-regulated dissemination of unbiased, truthful, and scientifically accurate information based on peer-reviewed literature not included in the New Drug Approval process.

This policy was reviewed in 2021 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Congress is considering significant changes in the way drugs are developed, approved, and marketed in the United States. A provision in the House-passed 21st Century Cures bill (H.R. 6) would allow pharmaceutical manufacturers to promote off-label uses of their products to clinicians and formulary committees. This change has raised concerns about the accuracy and sources of such information. Sources of such information, if unreliable, could put patient safety at risk. Despite these concerns about promotion of off-label uses by manufacturers and their drug representatives, ASHP has suggested an amendment that would require Food and Drug Administration (FDA) oversight of such promotion and require promotional materials to be unbiased, truthful, scientifically accurate, and based upon peer-reviewed literature not included in the approved labeling of the drug. Materials would therefore require approval by the proper authority (FDA), meet certain requirements, and be truthful and scientifically accurate. This policy is not intended to curtail the ability of clinicians to use, or discuss the use of, products off-label.

1621
TIMELY BOARD OF PHARMACY LICENSING

This policy was superseded by ASHP policy 2507.

1622
INCLUSION OF DRUG PRODUCT SHORTAGES IN STATE PRICE-GOUGING LAWS

This policy was superseded by ASHP policy 2112.

1623
HOME INTRAVENOUS THERAPY
Source: Council on Public Policy

To support the continuation of a home intravenous therapy benefit under federal and private health insurance plans and expansion of the home infusion benefit under Medicare at an appropriate level of reimbursement for pharmacists' patient care services provided, medications, supplies, and equipment.

This policy was reviewed in 2021 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
The Medicare Modernization Act of 2003 created an outpatient prescription drug benefit for Medicare beneficiaries, Medicare Part D. The new benefit provided prescription drug coverage for Medicare beneficiaries by private health plans and pharmacy benefit managers (PBMs).

Although the law requires certain basic coverage packages across the plan continuum, it provides no coverage for services and supplies used in home infusion. The result is that the drug products used in home infusion may be covered, but the supplies (e.g., IV bags, tubing) and services related to providing and administering the drug products are not.

The 21st Century Cures Act of 2016 redefined coverage for home infusion services, establishing a new benefit in Medicare Part B that covers professional services associated with home infusion. However, the benefit does not take effect until 2021, and the current benefit reimbursement is far lower than the value of the services. Although there is a transitional gap program to slightly buffer providers from the low reimbursement rates, the cuts have taken a toll on home infusion providers, making it essential that Centers for Medicare & Medicaid Services implement the higher reimbursement rate for 2021. ASHP also remains concerned that under the new Cures Act benefit, reimbursement is made only to the pharmacy, not the pharmacist. Continued advocacy is needed to allow pharmacists to bill directly for the benefit.

1624

BAN ON DIRECT-TO-CONSUMER ADVERTISING FOR PRESCRIPTION DRUGS AND MEDICATION-CONTAINING DEVICES

Source: Council on Public Policy

To advocate that Congress ban direct-to-consumer advertising for prescription drugs and medication-containing devices.

This policy supersedes ASHP policy 1119.

This policy was reviewed in 2021 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Direct-to-consumer advertising (DTCA) of prescription drugs and drug-containing implantable medical devices has both positive and negative potential effects. The positive potential effects include broader public awareness and use of therapies, increased patient engagement in their healthcare, and better return on investment in drug and medical device research. These potential benefits need to be weighed against the potential negative effects, however, which include higher drug and device costs, inappropriate prescribing of more costly new drugs or devices without any justifying improvement in patient outcomes, and increased adverse effects. In 2015, the American Medical Association (AMA) adopted a policy calling for a ban on DTCA of prescription drugs and implantable medical devices due to its impacts on drug prices and physician prescribing practices.

Public health researchers have characterized the U.S. experience with direct-to-consumer advertising (DTCA) of prescription drugs since 1997 as "a large and expensive uncontrolled experiment in population health, which to date shows decidedly mixed effects."[1]

1 Frosch DL, Grande D, Tarn DM, et al. A decade of controversy: Balancing policy with evidence in the regulation of prescription drug advertising. *Am J Publ Health* 2010; 100: 24-32. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2791253/ (accessed 2016 Jun 22).

Those researchers and others[2,3,4,5] have identified major impacts of DTCA on public health, including an increase in inappropriate prescribing and adverse effects, medicalization of symptoms previously not defined as illness, and increased costs due to inappropriate prescribing.

The impact of DTCA on the prescriber-patient relationship is hard to quantify. In some surveys, physicians have indicated that they fulfilled questionable DTCA-prompted patient requests for prescriptions. A Food and Drug Administration (FDA) survey the found that "many physicians felt some pressure to prescribe something" when patients mentioned a drug they learned about through DTCA. Studies of claims data support the conclusion that DTCA led to inappropriate prescribing of COX-2 inhibitors and proton pump inhibitors, and experimental evidence suggests that DTCA could induce clinically questionable prescribing of antidepressants for adjustment disorder. Although the connection cannot be proved, it has been suggested that the increasing reliance of physician payments on patient satisfaction surveys could present an economic risk to prescribers who deny patient requests. Studies show that DTCA increases prescribing volume and patient demand, and shifts prescribing. DTCA's effects include overuse of prescription drugs, a shift to less appropriate prescribing, and switches to less cost-effective treatment. In addition, differential effects by patient price sensitivity have been implicated in sustained sales despite a price increase. Researchers have concluded that the overall effects of DTCA on physician–patient communication are unclear, and that the effects of DTCA on improving the quality of care are mixed or lacking in evidence.

The educational value of DTCA has also been questioned. Consumers of DTCA recall more benefit than risk information. Critics of the educational value of DTCA also note that DCTA could exacerbate health disparities due to differing levels of health literacy and lack of incentive to advertise to low-income populations. Researchers have questioned whether purported improvements in adherence, based mainly on negative trials, stand up to scrutiny.

ASHP recognizes that banning a constitutionally protected right to free speech, even commercial speech, must be reinforced by evidence that indicates the banned speech negatively impacts society. In the case of DCTA, those negative impacts, including intrusion on the patient-prescriber relationship and increased healthcare costs, are evident and overwhelming. Given the outsized role prescription drug products have as a cost driver to the healthcare system, the detrimental effects of DCTA, and the limited potential benefits, ASHP has concluded that a ban on DTCA of prescription drugs and drug-containing implantable medical devices is warranted.

1626
ASHP STATEMENT ON TELEPHARMACY

2 http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm
3 Mintzes B. Advertising of prescription-only medicines to the public: Does evidence of benefit counterbalance harm? *Annu Rev Publ Health* 2012; 33: 259-77. DOI: 10.1146/annurev-publhealth-031811-124540.
4Donohue JM, Cevasco M, Rosenthal MB. N Engl J Med. 2007; 357:673-81. DOI: 10.1056/NEJMsa070502 Available at www.nejm.org/doi/full/10.1056/NEJMsa070502 (accessed 2016 Jun 22).
5 Dhaval D, Henry S. Impact of direct-to-consumer advertising on pharmaceutical prices and demand. *Southern Econ J.* 2012; 79: 97–126.

This policy was superseded by ASHP policy 2227.

2015 Policy Positions

1501
PHARMACIST PARTICIPATION IN HEALTH POLICY DEVELOPMENT
Source: Council on Public Policy

To advocate that pharmacists participate with policymakers and stakeholders in the development of health-related policies at the national, state, and community levels; further,

To develop tools and resources to assist pharmacists in fully participating in health policy development at all levels.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
Health policy developed at the federal, state, and local levels increasingly impacts medication use, particularly as payment and delivery models require the interprofessional healthcare team to collaboratively deliver care to meet quality and outcomes measures. The perspective of the pharmacy workforce practicing in hospital and ambulatory care settings is essential to the development of health policy. At the federal level, policy development includes drug development, distribution, and control; coverage for medication therapy; interoperability of health information; and all aspects of patient safety. Those federal issues also exist at the state and local level, but also include the full range of scope of practice issues.

The absence of pharmacy workforce perspectives in health policy development leads to suboptimal public policy, inefficient use of resources (public and private), and the potential for suboptimal patient care at the individual patient level and with specific patient populations. Furthermore, poorly developed public policy results in the pharmacy workforce being unable to practice at the top of their licenses. Full engagement of the pharmacy workforce in health policy development will require support from employers and schools to allow pharmacist, pharmacy technician, and student participation in professional advocacy (e.g., time off for advocacy, etc.).

1502
PHARMACIST RECOGNITION AS A HEALTHCARE PROVIDER

This policy was superseded by ASHP policy 2506.

1503
PHARMACEUTICAL PRODUCT AND SUPPLY CHAIN INTEGRITY

This policy was superseded by ASHP policy 1602.

1504
PATIENT ADHERENCE PROGRAMS AS PART OF HEALTH INSURANCE COVERAGE
Source: Council on Public Policy

This policy was discontinued in 2025.

1505
STATUTORY PROTECTION FOR MEDICATION-ERROR REPORTING
Source: Council on Public Policy

To collaborate with other healthcare providers, professions, and stakeholders to advocate and support state and federal legislative and regulatory initiatives that provide liability protection for the reporting of actual and potential medication errors by individuals and healthcare providers; further,

To provide education on the role that patient safety organizations play in liability protection.

This policy supersedes ASHP policy 0011.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Medication-error reporting at the state and federal level has been shown to improve medication-use systems and aid in conducting a root cause analysis of a medication error. Liability protection for such reporting at the federal is necessary to achieve this analysis and improve patient safety. Pharmacists need to be aware of legal protection for error reporting under the federal Patient Safety and Quality Improvement Act of 2005. The Act set up a network of federally sanctioned Patient Safety Organizations (PSOs) that provide protection for healthcare providers, including pharmacy personnel. A PSO is prohibited from identifying individuals or organizations that report and the information used for educational purposes must be de-identified, including contextually as necessary. The Act overrides state protections and supports the collaboration sought among providers who report and work with a PSO.

1506
PREMARKETING COMPARATIVE CLINICAL STUDIES

This policy was superseded by ASHP policy 2040.

1507
FUNDING, EXPERTISE, AND OVERSIGHT OF STATE BOARDS OF PHARMACY

This policy was superseded by ASHP policy 2021.

1508
SUPPORT FOR FDA EXPANDED ACCESS (COMPASSIONATE USE) PROGRAM

This policy was superseded by ASHP policy 2306.

1510
NALOXONE AVAILABILITY

This policy was superseded by ASHP policy 2014.

1511
COMPLEMENTARY AND ALTERNATIVE MEDICINE IN PATIENT CARE

This policy was superseded by ASHP policy 2039.

1512
DEVELOPMENT OF ABUSE-RESISTANT NARCOTICS

This policy was superseded by ASHP policy 2004.

1513
QUALITY PATIENT MEDICATION INFORMATION

This policy was superseded by ASHP policy 2015.

1514
SAFETY AND EFFECTIVENESS OF ETHANOL TREATMENT FOR ALCOHOL WITHDRAWAL SYNDROME

This policy was superseded by ASHP policy 2001.

1516
CHEMOTHERAPY PARITY

This policy was superseded by ASHP policy 2003.

1517
DOCUMENTATION OF PENICILLIN ALLERGY AS A COMPONENT OF ANTIMICROBIAL STEWARDSHIP

This policy was superseded by ASHP policy 1921.

1518
DEVELOPING LEADERSHIP COMPETENCIES

This policy was superseded by ASHP policy 1611.

1519
PHARMACY TECHNICIAN TRAINING AND CERTIFICATION

This policy was superseded by ASHP policy 1609.

1520
IMPACT OF INSURANCE COVERAGE DESIGN ON PATIENT CARE DECISION

This policy was superseded by ASHP policy 1809.

1521
IDENTIFICATION OF PRESCRIPTION DRUG COVERAGE AND ELIGIBILITY FOR PATIENT ASSISTANCE PROGRAMS
Source: Council on Pharmacy Management

To advocate that pharmacists or pharmacy technicians ensure that the use of patient assistance programs is optimized and documented to promote continuity of care and patient access to needed medications; further,

To advocate that patient assistance programs should incorporate the pharmacist-patient relationship, including evaluation by a pharmacist as part of comprehensive medication management; further,

To support the principle that medications provided through manufacturer patient assistance programs should be stored, packaged, labeled, dispensed, and recorded using systems that ensure the same level of safety as prescription-based programs that incorporate a pharmacist-patient relationship.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Ensuring accurate medication histories and continuity of medication therapies are critical pharmacists‘ roles in monitoring and documenting patient transition through the healthcare system. Additionally, pharmacists have an important role in ensuring patients have means to access their medications, both upon hospital admission and discharge. With the numerous channels patients use to obtain their medications, it has become increasingly difficult to verify this information and, in some cases, obtain the medications needed to care for a patient.

Patient assistance programs (PAPs) present a unique challenge for healthcare providers. Documentation of the utilization of a PAP by a patient is important information for providers

accessing the patient electronic health record and improving that documentation should be a priority for healthcare providers. Additionally, pharmacists need to provide leadership in facilitating the utilization of PAPs to ensure continuity of care, the patient's ability to access needed medications when appropriate, and a comprehensive pharmacist-patient relationship.

1522
DISPOSITION OF ILLICIT SUBSTANCES
Source: Council on Pharmacy Management

To advocate that healthcare organizations be required to develop procedures for the disposition of illicit substances brought into a facility that ensure compliance with applicable laws and accreditation standards; further,

To advocate that healthcare organizations be required to include pharmacy leaders in formulating such procedures.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Hospitals and health systems often treat patients that have in their possession illicit substances (e.g., illegal or illegally possessed substances), which requires the facility to make decisions about how to secure the substances, ensure the appropriate chain of custody, and document possession in the patient's medical record, as well as decide whether to inform law enforcement. Such decisions benefit from the organization's legal counsel making a determination for the organization, in consultation with pharmacy leaders who can help interpret the pharmacist-in-charge's legal requirements and related accreditation standards.

1523
PHARMACIST'S ROLE IN POPULATION HEALTH MANAGEMENT
Source: Council on Pharmacy Management

To recognize the importance of medication management in patient-care outcomes and the vital role of pharmacists in population health management; further,

To encourage healthcare organizations to engage pharmacists and pharmacy leaders in identifying appropriate patient cohorts, anticipating their healthcare needs, and implementing the models of care that optimize outcomes for patients and the healthcare organization; further,

To encourage the development of complexity index tools and resources to support the identification of high-risk, high-cost, and other patient cohorts to facilitate patient-care provider panel determinations and workload balancing; further,

To promote collaboration among members of the interprofessional healthcare team to develop meaningful measures of individual patient and population care outcomes; further,

To advocate for education to prepare pharmacists for their role in population health management.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale

As hospital and health systems become larger and adjust to new payment models (e.g., readmissions penalties and reduced Medicare payments), the need for health-system and pharmacy leaders to determine the safest, most efficient, and most economical way to care for identified patient populations has become a significant challenge. Pharmacists have an important role in managing medication therapies for individual patients as well as participating in the development of care models for patient populations with the interprofessional teams they work within. The utilization of "big data" by health systems is a growing domain of research, and it will be important for pharmacists and pharmacy leaders to make use of this information when developing strategic plans and resource allocations. Similar to the workload and productivity issues traditionally facing hospital leaders, the need to stratify total patient populations, anticipate their healthcare resource needs, and then assign the best site and model of care to obtain the ideal return on investment for both the patient and organization has become of paramount importance. The need for identifying the ideal patient panel sizes and the demographics of these panels will be important for patients and pharmacists as pharmacists practice more in the ambulatory care environment. To accomplish these goals, pharmacists will require education to prepare for their role in population health management.

1524

SUPPORT FOR SECOND VICTIMS

Source: Council on Pharmacy Practice

To acknowledge that the patient is the primary victim in any medical error, unanticipated adverse patient event, or patient-related injury; further,

To acknowledge that involvement by healthcare personnel in such events may cause them to become second victims; further,

To recognize that a just culture and a healthy culture of safety embrace a support system for second victims; further,

To encourage healthcare organizations to establish programs to support second victims; further,

To educate healthcare professionals (including those in training), health organization administrators, and regulatory agencies about the second-victim effect and available resources.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

The University of Missouri Health System has defined second victims as "healthcare providers who are involved in an unanticipated adverse patient event, in a medical error and/or a patient-related injury and become victimized in the sense that the provider is traumatized by the event." Frequently, these individuals feel personally responsible for the patient outcome. Many feel as though they have failed the patient, second-guessing their clinical skills and knowledge base. Individuals involved in a serious adverse patient event may experience the symptoms of post-traumatic stress disorder and may require support to successfully manage the experience.

Healthcare organizations have emphasized establishing a just culture environment to encourage individuals to speak up when they are aware of medication errors. Studies have indicated that many second victims did not feel they received organizational support after these events, however. The Joint Commission, the Institute for Healthcare Improvement, the Institute for Safe Medication Practices (ISMP), and others have advocated for support systems for second victims. The Joint Commission Leadership Standards state that leaders will "make support systems available for staff that have been involved in an adverse or sentinel event."

Healthcare organizations will have to tailor these support systems to their needs. Such support systems may, for example, be tiered, with the first tier being unit or department support; the second tier, trained peer support, including patient-safety and risk-management staff; and the third tier, professional counseling support, such as employee assistance programs or social workers. Education of staff on resources available to support the second victim is critical to avoiding adverse impact on the second victim.

1525

STANDARDIZATION OF DOSES

Source: Council on Pharmacy Practice

To recognize that standardization of medication doses reduces medication errors and improves information technology interoperability, operational efficiency, and transitions of care; further,

To encourage development of universal standardized doses for specific patient populations; further,

To encourage healthcare organizations to adopt standardized doses and to promote publication and education about best practices.

This policy was reviewed in 2020 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

Standardization and simplification are widely accepted methods for reducing variability in processes with risk for error. Standardization of medication doses reduces waste and improves efficiency. Computer databases could be constructed with standard dosage forms, facilitating information technology interoperability. Simplified instruction for patients and caregivers improves administration in the home as well as patient adherence.

The standardization of liquid doses has been successfully accomplished in hospitals, but standardization of doses is also applicable to parenteral nutrition solutions and other injectable dosage forms. Standardization of doses within a hospital or health system would reduce waste and the potential for errors in those settings. The strict application of pediatric weight-based dosing, for example, leads to a large number of different doses being used, and many of those doses must then be prepackaged dose-by-dose due to limited stability of liquid and injectable dosage forms.

Standardization of doses within organizations would be made easier by the development of universal standardized doses for specific patient populations, which will require substantial research. Additional studies to determine best practices for standardization of medication doses and education of healthcare practitioners are also needed to facilitate broad adoption of this practice.

1526
PRESCRIPTION DRUG ABUSE

This policy was discontinued in 2020.

1527
PHARMACIST'S ROLE IN URGENT AND EMERGENCY SITUATIONS
Source: Council on Pharmacy Practice

To affirm that pharmacists should participate in planning and providing emergency treatment team services; further,

To advocate that pharmacists participate in decision-making about the medications and supplies used in medical emergencies; further,

To advocate that pharmacists serve in all emergency responses, and that those pharmacists receive appropriate training and maintain appropriate certifications.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Pharmacists have a leadership role in many hospitals in planning for emergency treatment team services. Data from the 2021 ASHP National Survey indicates that approximately 70% of hospitals have pharmacist participation in cardiopulmonary resuscitation (CPR), or code, teams and 36% have pharmacist participation on rapid response teams. This role includes developing policy on the contents of code carts and other supplies as well as establishing the role of the pharmacist in supporting these services. The literature demonstrates that pharmacists can make significant contributions to CPR and other emergency response teams as medication-use leaders and as participants, and there is evidence that better patient outcomes result when pharmacists participate. Pharmacists participating in this role should receive appropriate training and certification (e.g., Basic Life Support, Advanced Cardiopulmonary Life support, and

Pediatric Acute Life Support). The ASHP Guidelines on Emergency Medicine Pharmacist Services reference many of the patient care services that pharmacists provide during urgent and emergency situations including but not limited to direct patient care activities, medication information, resuscitation, high-alert medication handling procedures, medication selection and preparation, medication order review and medication therapy monitoring, patient and caregiver education, and medication reconciliation.

1528
EXCIPIENTS IN DRUG PRODUCTS

This policy was superseded by ASHP policy 2002.

1529
ONLINE PHARMACY AND INTERNET PRESCRIBING
Source: Council on Pharmacy Practice

To support efforts to regulate prescribing and dispensing of medications via the Internet; further,

To support legislation or regulation that requires online pharmacies to list the states in which the pharmacy and pharmacists are licensed, and, if prescribing services are offered, requires that the sites (1) ensure that a legitimate patient-prescriber relationship exists (consistent with professional practice standards) and (2) list the states in which the prescribers are licensed; further,

To support mandatory accreditation of online pharmacies by the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Sites or Veterinary-Verified Internet Pharmacy Practice Sites; further,

To support appropriate consumer education about the risks and benefits of using online pharmacies; further,

To support the principle that any medication distribution or drug therapy management system must provide timely access to, and interaction with, appropriate professional pharmacist patient-care services.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
ASHP's vision to make medication use safe, optimal, and effective includes supporting efforts to protect the public from unscrupulous website operators who illegally provide medications online. Patients are entitled to know whether the healthcare providers prescribing and dispensing their medications are licensed, and in which states they are licensed. ASHP supports legislation and regulations that would require online pharmacies to provide such information.

To further guarantee patient safety, ASHP advocates for mandatory accreditation of such sites by the National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) and Veterinary-Verified Internet Pharmacy Practice Sites (Vet-VIPPS) accreditation programs for online pharmacies to assure the public that the pharmacies are compliant with federal and state regulations and NABP criteria. The Institute for Safe Medication Practices also supports the NABP searchable list of accredited online pharmacies and asserts an increased risk of counterfeit drugs due to an increased presence of unregulated online marketplaces posing as legitimate pharmacies. The Food and Drug Administration also offers patient resources for evaluating the legitimacy of online pharmacies through their BeSafeRx campaign. Education of consumers will be required to ensure that online pharmacies are used wisely, and use of online pharmacies should involve appropriate pharmacist counseling. Pharmacists and other healthcare professionals should consider the source and quality of products obtained from an online pharmacy as part of the medication history collection.

1530

STANDARDIZATION OF SMALL-BORE CONNECTORS TO AVOID WRONG-ROUTE ERRORS

Source: Council on Pharmacy Practice

To support the use of medication administration device connectors and fittings that are designed to prevent misconnections and wrong-route errors; further,

To encourage healthcare organizations to prepare for safe transition to use of medication delivery device connectors and adapters that meet International Organization for Standardization standards; further,

To identify and promote the implementation of best practices for preventing wrong-route errors.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

Interconnectivity among drug delivery devices and their fittings is a significant and preventable cause of serious or fatal wrong-route errors. Connector and tubing design unique to the route of administration that cannot be linked to a device used for a different route is the strongest type of control for these errors. While some solutions have been advanced to minimize misconnections and improve patient safety, such as the availability of NRFit for neuraxial administration and ENFit for enteral administration, standards and best practices are still needed. Previously, an international joint working group composed of the International Organization for Standardization (ISO), Association for the Advancement of Medical Instrumentation (AAMI), Food and Drug Administration (FDA), manufacturers, clinicians, and other regulators developed ISO connector standards that were voluntary and intended to facilitate global standardization of medical devices. Subsequently, the first ISO standard for enteral device connectors (ANSI/AAMI/ISO 80369-1) was adopted industrywide. Also in response, the Joint Commission published Sentinel Event Alert #53, *Managing risk and*

transition during transition to new ISO tubing connector standards. The provided alert suggested actions from the 2014 *Get Connected* campaign provided by the Global Enteral Device Supplier Association (GEDSA) as well as updates to the recommendations from the 2006 Sentinel Event Alert #36 on tubing misconnections. Since then, the FDA and other organizations have continued advancing standards for connector designs until they become universally adopted in healthcare facilities.

Until this happens, healthcare workers are encouraged to reference StayConnected.org, maintained by GEDSA, and to follow these recommendations from the FDA to prevent device misconnections: Assess equipment, Communicate, and Trace.

1531
PHARMACIST ROLE IN CAPITAL PUNISHMENT
Source: Council on Pharmacy Practice

To acknowledge that an individual's opinion about capital punishment is a personal moral decision; further,

To oppose pharmacist participation in capital punishment; further,

To reaffirm that pharmacists have a right to decline to participate in capital punishment without retribution.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

Since 1977, when Oklahoma became the first state to adopt execution by lethal injection, many healthcare professional organizations have adopted policies opposing participation by members of their respective professions in capital punishment. The American Medical Association (AMA), the American Nurses Association (ANA), and the American Pharmacists Association (APhA) are among these groups; however, a wide variety of organizations have spoken out on the issue. The consistent theme of the opposition of those organizations is that the intentional infliction of death is contrary to the mission of healthcare and therefore unethical. ASHP's previous policy on pharmacist participation in capital punishment, which was adopted in 1984 and has been reaffirmed several times since, emphasized the pharmacist right to conscience when deciding whether to participate in capital punishment.

The role of pharmacists in execution by lethal injection changed substantially after Hospira relocated its thiopental sodium manufacturing to Italy in 2011. The European Union bans the export of thiopental sodium to countries where it may be used in executions, including the U.S. The ban resulted in severe shortages of the drug, which was the cornerstone of the three-drug cocktail used in lethal injections. (At least nine drug manufacturers have followed suit in prohibiting use of their products for lethal injection.) States responded by substituting compounded anesthetic preparations or instituting other drug protocols, which came under criticism after several executions in which prisoners appeared to suffer despite being medicated. These developments increased the role of pharmacists in preparing and/or

compounding drugs for execution by lethal injection, which in turn increased the scrutiny of that role both inside and outside the profession. However, in states that allow execution, there may be specific policy regarding healthcare professional and institutional involvement in the preparation and administration of lethal injections. For example, Florida does not allow preparation of lethal injections in hospital settings.

1532
ASHP STATEMENT ON THE ROLES AND RESPONSIBILITIES OF THE PHARMACY EXECUTIVE
Source: Council on Pharmacy Management

This statement was superseded by ASHP policy 2143.

1533
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN SUBSTANCE ABUSE PREVENTION, EDUCATION, AND ASSISTANCE

This statement was superseded by ASHP policy 2522.

1534
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN CLINICAL INFORMATICS
Source: Section of Pharmacy Informatics and Technology
To approve the *ASHP Statement on the Pharmacist's Role in Clinical Informatics*.

1535
NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS
Source: Council on Public Policy

This policy was discontinued in 2025.

1536
APPROPRIATE USE OF TESTOSTERONE

This policy was discontinued in 2020.

1537
ASHP STATEMENT ON THE ROLES OF PHARMACY TECHNICIANS
Source: Section of Inpatient Care Practitioners
To approve the *ASHP Statement on the Roles of Pharmacy Technicians*.

2014 Policy Positions

1401
STANDARDIZATION OF ORAL LIQUID MEDICATION CONCENTRATIONS

This policy was discontinued in 2023.

1402
SAFE USE OF RADIOPHARMACEUTICALS
Source: Council on Pharmacy Practice

To affirm that radiopharmaceuticals require the same standards for safe medication use as other medications, including but not limited to standards for procurement, storage and control, prescribing, preparation, dispensing, administration, documentation, clinical and regulatory monitoring, disposal, and formulary consideration; further,

To advocate that pharmacy departments, in cooperation with departments of nuclear medicine, radiology, and radiation safety, provide oversight of radiopharmaceuticals to assure safe use; further,

To advocate for incorporation of information on radiopharmaceuticals into college of pharmacy curricula and increased pharmacy continuing education on radiopharmaceuticals.

This policy was reviewed in 2024 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Many hospitals utilize radiopharmaceuticals for diagnostic imaging tests or for treatment. Hospitals and pharmacy departments need to comply with applicable standards, such as U.S. Pharmacopeia (USP) General Chapter 825 Radiopharmaceuticals, to ensure patient and health worker safety with their use. USP 825 outlines minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and nonsterile radiopharmaceuticals. The chapter provides information on facilities and engineering controls, personnel training and qualifications, and procedural standards for healthcare settings that utilize radiopharmaceuticals.

Pharmacy departments need to have oversight and engagement in the acquisition, safe handling, and disposal of radiopharmaceuticals, including and especially those outsourced from external suppliers. Reports of improper handling, storage, and disposal suggest that these products should have similar oversight as other drug products used in hospitals, and that pharmacists, pharmacy students, and pharmacy technicians require education regarding their safe use.

1403
PHARMACIST'S ROLE ON ETHICS COMMITTEES

This policy was superseded by ASHP policy 2414.

1404
SAFE USE OF FENTANYL TRANSDERMAL SYSTEM PATCHES

This policy was superseded by ASHP policy 2018.

1405
AUTOMATIC STOP ORDERS
Source: Council on Pharmacy Practice

To advocate that the Centers for Medicare & Medicaid Services (1) remove the requirement in the Hospital Conditions of Participation that all medication orders automatically stop after an arbitrarily assigned period to include other options to protect patients from indefinite, open-ended medication orders, and (2) revise the remainder of the medication management regulations and interpretive guidelines to be consistent with this practice; further,

To affirm that the requirement for automatic stop orders for all medications is a potential source of medication errors and patient harm; further,

To encourage pharmacists to participate in interprofessional efforts to establish standardized methods to assure appropriate duration of therapy.

This policy was reviewed in 2024 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Automatic stop orders on medications are intended to safeguard patients against unnecessary or prolonged drug therapy, yet they also have been shown to cause medication errors when critical therapy is inadvertently and arbitrarily discontinued. The Centers for Medicare & Medicaid Services Hospital Conditions of Participation (CMS COP) continue to require automatic stop orders for all orders, including medications, not accounting for shorter lengths of stay and other means of reviewing drug therapy for appropriateness. The CMS COP should be revised to reflect better, more effective approaches to re-evaluating the appropriateness of medications. Because the CMS COP refers to all orders, advocating for this change represents an opportunity to engage with multiple stakeholders, including but not limited to the Institute for Safe Medication Practices, to advocate for the CMS COP revisions and ensure safe implementation and interpretation of the requirements.

1406

FEDERAL AND STATE REGULATION OF COMPOUNDING

Source: Council on Public Policy

To advocate that the applicable compendial standards of the United States Pharmacopeia be included in state and federal laws and regulations that govern compounding by any health professional; further,

To advocate for mandatory state registration of compounding facilities (e.g., pharmacies, physician offices, clinics, ambulatory surgery centers) that provide products for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders; further,

To advocate for mandatory Food and Drug Administration registration and current good manufacturing practices requirements for outsourcing facilities that compound and sell products without patient-specific prescriptions across state lines; further,

To advocate for improved patient safety and care through education of regulatory inspectors, increased frequency and improved effectiveness of compliance inspections, and enhancing interagency communications; further,

To advocate that state and federal agencies develop standardized definitions and nomenclature relating to sterile and nonsterile compounding, including but not limited to definitions of compounding, manufacturing, repackaging, and relabeling.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The practice of compounding has evolved along with the profession of pharmacy. With the advancement of pharmaceutical manufacturing, the preparation of individualized medications based on a prescription or medication order has also evolved. In particular, sterile preparation and related best practices (e.g., ASHP guidelines) and standards of practice (relevant USP chapters) have also evolved. However, cases of contamination, adulteration, and misbranding have persisted, culminating in the meningitis tragedy caused by contaminated sterile preparations compounded by the New England Compounding Center (NECC). That contamination resulted in 64 deaths and over 700 patient cases, as reported by the Centers for Disease Control and Prevention.

The NECC case highlighted the need for accountability and clear regulatory jurisdiction between state boards of pharmacy and the federal Food and Drug Administration. Since 1997, there has been discussion and debate over the proper oversight of compounding. The NECC case demonstrated the real and potential national public health threat posed by the lack of oversight of the practice of compounding. This threat is particularly acute when high-risk sterile products are prepared in large quantities and sold across state lines without adherence to either relevant USP chapters or Food and Drug Administration (FDA) current good

manufacturing practices (cGMPs). Over the past 16 years, a series of court decisions in various federal circuits has resulted in a patchwork application of Section 503A of the Federal Food Drug and Cosmetic Act. In addition, a new type of supplier of sterile compounded preparations has emerged to fill a critical need for high-risk sterile preparations for hospitals and health systems. Those health systems are often unable to make the capital and/or human resource investments to prepare these high-risk preparations and seek to use outside suppliers to meet their patients' needs. In 2013, Congress passed H.R. 3204, the Drug Quality and Security Act (DQSA) and President Obama signed it into law (P.L. 113-54) on November 27, 2013. Prior to the passage of the DQSA, these outside suppliers operated as licensed pharmacies and in some cases also registered as drug establishments with the FDA. However, the authority for FDA to inspect and enforce either cGMPs or USP standards was unclear. DQSA is designed to provide that clarity as well as delineate the accountability between the FDA and state boards.

ASHP advocates federal oversight of certain entities that compound and engage in interstate commerce to address the wider public health threat when these preparations can potentially be distributed nationwide. ASHP continues to call for state regulation of compounding by health professionals (including pharmacists, physicians, and nurses) that would require meeting the applicable USP standards. ASHP believes that federally registered compounding facilities should be required to meet applicable cGMPs and that state-registered facilities engaged in "traditional compounding" (i.e., compounding for specific patient prescriptions or in anticipation of specific patient prescriptions or medication orders) be required to meet applicable USP standards. ASHP also advocates for inspection by the relevant regulatory body, training of inspectors, and enhanced communication among federal and state regulatory authorities. Finally, ASHP calls for standard definitions and nomenclature for certain terms that may have different definitions within federal law and regulation and between federal and state law and regulation (FDA, Drug Enforcement Administration [DEA], pharmacy practice act and regulation).

1407
340B DRUG PRICING PROGRAM SUSTAINABILITY

This policy was superseded by ASHP policy 1908.

1408
STATE PRESCRIPTION DRUG MONITORING PROGRAMS

This policy was superseded by ASHP policy 2417.

1410
ACCESS TO ORAL CONTRACEPTIVES THROUGH AN INTERMEDIATE CATEGORY OF DRUG PRODUCTS

This policy was superseded by ASHP policy 2326.

1411

EXPEDITED PATHWAYS FOR FDA DRUG APPROVAL

Source: Council on Therapeutics

To support the use of expedited pathways for Food and Drug Administration (FDA) approval of new drugs that expand access to innovative therapies while protecting patient safety; further,

To advocate for the development of unique labeling requirements that would be used on an interim basis to identify products approved by these pathways in order to increase awareness of data limitations and guide clinician use of these drugs until additional evidence becomes available; further,

To advocate that the FDA be diligent in enforcing postmarketing commitments for drug products approved via expedited pathways, including utilizing its existing authority to enforce penalties when these requirements are not met; further,

To encourage research to evaluate the impact of expedited pathways on drug product development and patient care, including drug development timelines and costs, overall health care costs, patient access to care, and the effectiveness and safety of these therapies.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale

Expedited approval programs provided by the FDA have resulted in substantial public health benefits as illustrated by the use of surrogate endpoints to approve therapies for HIV and AIDS in the 1990s. The FDA provides four mechanisms to expedite the development and review process for drugs: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The structure and requirements for each of these mechanisms differs as described in a 2013 draft guidance for industry. However, to qualify for any of these programs a drug must (1) address an unmet medical need, (2) provide benefit over available drug treatments, and (3) be used in the treatment of a serious or life-threatening condition. Further, the FDA guidance states that these programs are "intended to help ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks." Processes used to ensure a favorable risk–benefit profile include, but are not limited to, requirements for postmarketing studies to evaluate safety and effectiveness of the drug as used in real-world scenarios. However, the accelerated approval program is the only program that includes postmarketing studies as a requirement of the program. The FDA has discretion to require additional studies on a case-by-case basis for drug products approved via the other expedited mechanisms. Despite these safeguards, some features of these programs (e.g., smaller clinical trials, alternate trial designs, or limited-duration trials) can result in increased patient risk because less is known about a drug's side effect profile and efficacy due to limited patient exposure. In addition, as with all

drugs, safety assessments benefit from use of the drug in post-approval patient populations, which better reflect real-world use as compared to the controlled environment of a clinical trial.

Because these drugs represent medical advances, their post-approval use can be extensive. Further, off-label use of these drug products, like all therapies, is common. However, prescribers and other clinicians are frequently unaware that an expedited pathway was utilized and that evidence limitations exist. This scenario raises significant concerns about whether there is sufficient clinician awareness to ensure appropriate use of drugs approved via these pathways. Therefore, ASHP proposes unique labeling requirements that would increase awareness through use of a logo or other mechanism that would be used on an interim basis to inform clinicians about data limitations and provide guidance on appropriate use. This labeling would describe appropriate patient populations and monitoring parameters. Similar labeling requirements have been proposed for a new pathway being considered for the development of antibiotics used to treat life-threatening infections. ASHP supports the approach, but recommends that the increased labeling requirements be discontinued once the drug product manufacturer and FDA agree that sufficient data is available to support safe and effective use, or after the drug manufacturer completes any required postmarketing study commitments.

Given data limitations associated with approval of these therapies, ASHP advocates that the FDA be extremely diligent in ensuring that postmarketing commitments are met. Within the Department of Health and Human Services, the Office of Inspector General reviewed the accelerated approval pathway in 2022. Results suggest there is still a need for the FDA to have stricter oversight of the process. Results show an increase in accelerated approvals more recently, and that over a third of these approvals are still incomplete and overdue confirmatory trials. Once drugs are available to the market through accelerated approval, the incentives for both sponsors and patients to complete further studies may go down. The combination of decreased incentives and the FDA's prolonged process of removing drugs from the market once they are approved by the accelerated approval process can lead to medications being prescribed to patients without well understood clinical benefit. Further, the FDA should use its existing authority as described under 21 CFR 314 subpart H and 21 CFR 601 subpart E if timelines or expectations for these commitments are not satisfactory. This authority allows the FDA to take legal action through penalties that include requiring labeling changes or rescinding marketing approval.

Finally, ASHP believes that there is a need for research to determine whether these expedited pathways are achieving the desired benefits, which include decreasing the time and costs associated with drug product development, lowering overall health care costs, and increasing patient access to safe and effective drug therapies.

1412

FDA OVERSIGHT OF LABORATORY-DEVELOPED TESTS

Source: Council on Therapeutics

To advocate that the Food and Drug Administration be granted increased authority to regulate laboratory-developed tests as medical devices, including tests used for pharmacogenetic testing; further,

To support development of a risk-based framework for regulatory oversight of laboratory-developed tests that promotes innovation while providing a mechanism to ensure that test results are reliable, reproducible, and clinically relevant; further,

To encourage expanded availability of commercially marketed pharmacogenetic tests that would be available for use by laboratory and health care professionals to guide drug therapy.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The use of *in vitro* pharmacogenetic tests has become increasingly common as efforts continue to achieve the promise of personalized medicine. However, the current system of regulatory oversight of these and other laboratory tests used to guide drug therapy is complex and inconsistent. Some laboratory tests (e.g., companion diagnostics devices) receive premarket review and approval by the Food and Drug Administration (FDA) when the test is either developed in tandem with drug development or following the drug's approval. Other tests, commonly called laboratory-developed tests (LDTs), are proprietary tests that are developed and validated for use at specific laboratory facilities. These tests do not undergo premarket review and approval by the FDA. LDTs currently fall under a mixed system of oversight by the FDA and Centers for Medicare & Medicaid Services (CMS), which regulates these tests based on facilities' compliance to the Clinical Laboratory Improvement Amendments (CLIA). CLIA compliance serves as the primary mechanism for oversight, as the FDA has traditionally practiced discretionary authority, meaning that only a few of the most complex tests are scrutinized by that agency. While an LDT is monitored for validity and reliability at the laboratory where it is conducted, results may not be reproducible if the test is conducted at a different laboratory site. This variability complicates the interpretation and application of this information in patient care. Therefore, ASHP advocates for the FDA to have increased authority to regulate these LDTs as medical devices to ensure that results are reliable, reproducible, and clinically relevant to patient care.

Development of a risk-based framework represents the ideal model to provide sufficient oversight while creating conditions that support continued innovation in this field. Further, the development of nationally validated and marketed tests that are available for use by laboratory and health care professionals is desirable. ASHP believes that this scenario would provide the most assurance to pharmacists and other health care professionals that the results of these tests are reliable, reproducible, and clinically relevant to patient care.

1413

ENSURING EFFECTIVENESS, SAFETY, AND ACCESS TO ORPHAN DRUG PRODUCTS

This policy was superseded by ASHP policy 1821.

1415

CREDENTIALING, PRIVILEGING, AND COMPETENCY ASSESSMENT

Source: Council on Education and Workforce Development

To support the use of post-licensure credentialing, privileging, and competency assessment to practice pharmacy as a direct patient-care practitioner; further,

To advocate that all post-licensure pharmacy credentialing programs meet the guiding principles established by the Council on Credentialing in Pharmacy; further,

To recognize that pharmacists are responsible for maintaining competency to practice in direct patient care.

This policy was reviewed in 2025 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

Pharmacists engaged in direct patient care should possess the education, training, and experience necessary to function effectively, efficiently, and responsibly in that role. As their role in direct patient care has increased, pharmacists have recognized that they are independently responsible for maintaining their credentials and competencies. Currently, no specific objective measures are available for determining competence to provide direct patient care, however. Until such measures are available, pharmacists can establish their competence through post-licensure education, training, and certification, and health care organizations can ensure that practitioners with the right skills are matched to the scope of practice expected through competency assessment and their credentialing and privileging processes.

Although many avenues of credentialing and competency assessment currently exist, hospital and health-system credentialing and privileging of pharmacists is a relatively recent phenomenon. ASHP and the Council on Credentialing in Pharmacy (CCP) are in agreement that pharmacists should be expected to participate in credentialing and privileging processes to ensure they have attained and maintain competency to provide the scope of services and quality of care that are required in their practices (Council on Credentialing in Pharmacy Guiding Principles for Post-Licensure Credentialing of Pharmacists, August 2020.) To ensure the quality of post-licensure credentialing programs, they should be required to adhere to the guiding principles developed by CCP. In addition, CCP has created a list of certification programs that pharmacists can use for credentialing (Certification Programs for Pharmacists, November 2022), and ASHP offers several professional certificates in clinical topics, practice and general development topics, and sterile compounding for practitioners and pharmacy personnel.

Note that several definitions are integral to proper understanding of this policy (definitions taken from the Council on Credentialing in Pharmacy, Credentialing in Pharmacy: A Resource Paper, except as noted):

Credential: documentation of professional qualifications. Academic degrees, residency certificates, and board certification are all examples of credentials.

Credentialing: a) The process of granting a credential (a designation that indicates

qualifications in a subject or area) by an entity (i.e., a credential-granting entity/organization), or b) The process by which an organization, institution, or payer obtains, verifies, and assesses an individual's qualifications to provide patient care services.
Privileging: the process by which an oversight body of a health care organization or other appropriate provider body, having reviewed an individual health care provider's credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that setting.
Competence: The ability of the individual to perform his/her duties accurately, make correct judgments, and interact appropriately with patients and colleagues.
Competency: A distinct knowledge, skill, attitude, or value that is essential to the practice of a profession.
Direct patient care: involves the pharmacist's direct observation of the patient and his or her (i.e., the pharmacist's) contributions to the selection, modification, and monitoring of patient-specific drug therapy. This is often accomplished within an interprofessional team or through collaborative practice with another health care provider. (American College of Clinical Pharmacy definition, as endorsed in: Council on Credentialing in Pharmacy. Scope of contemporary pharmacy practice: roles, responsibilities, and functions of pharmacists and pharmacy technicians.)

1416
PHARMACY DEPARTMENT BUSINESS PARTNERSHIPS

This policy was superseded by ASHP policy 1915.

1417
INTEGRATION OF PHARMACY SERVICES IN MULTIFACILITY HEALTH SYSTEMS
Source: Council on Pharmacy Management

To advocate that pharmacists are responsible for organizational efforts to standardize and integrate pharmacy services throughout the entire pharmacy enterprise in multifacility health systems and integrated delivery networks; further,

To educate health-system administrators about the importance of pharmacy leadership in setting system-wide policy regarding the safe and effective use of medications; further,

To advocate for the regulations and resources needed to support efforts to achieve optimal patient health outcomes in multifacility organizations.

This policy was reviewed in 2024 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Data from a fiscal year 2021 American Hospital Association survey of hospitals indicate that 3514 of 5157 (68%) of community hospitals were part of either a system or a network,

reflecting the evolution of the healthcare enterprise from single hospitals to integrated systems and networks. Multiple hospitals organized and owned by the same system have been common in the U.S. for decades, but the rapidly changing marketplace will invariably lead to a future in which every hospital in the country will be part of a system. These systems have become increasingly complex as they also delve into nonhospital-based businesses and seek to standardize and gain economies of scale across the organization.

These new organizations and the recognition of the importance of medication management to the overall health of these organizations have led to new roles and new challenges for pharmacy leaders (see ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive). The pharmacy enterprise is more sophisticated and corporate in its nature than in the past. Pharmacy leaders at both the local hospital and at the corporate levels have to more than ever examine their pharmacy services in the context of the goals and needs of the organization or health system and determine the most efficient and effective means to provide these services. Leadership of the pharmacy must evolve from a department leader in a single facility to an effective corporate leader of medication use across a wide array of business units, care settings, and organizations. Centralization of medication management services is no longer confined to drug distribution but also includes human resources management, integrity of the electronic health record and related patient-care information, and oversight of various business partners. Pharmacy leaders within these evolving health systems will have many challenges, ranging from communication among the pharmacy management team, decisions on pharmacy infrastructure purchases and contracting, identification of critical services and standardization, succession planning and workforce development, supply chain management, human resource coordination, and strategic planning across diverse hospitals within the system. An additional challenge to these health-system pharmacy leaders is the need to coordinate and integrate pharmacy services across larger geographical regions to improve cost-effectiveness and patient care outcomes.

The nature and culture of decision-making will be changed as some decisions become more centralized and corporatized and new practice models are developed to capitalize and adapt to the changing marketplace. Especially as merged systems extend beyond local and regional markets, healthcare will likely become even more business-like in its decision-making, and fewer decisions will be made at the local facility level. The pharmacy enterprise will need to adapt to this changing environment. Many important decisions that influence medication-use policy will be made at the level of corporate leadership, and it will be critical that pharmacists provide leadership in this corporate decision-making. The ability to demonstrate the financial impact of pharmacy services will be critical and the development and implementation of effective drug-use policy across the enterprise will be crucial to success.

Along with increasing consolidation and integration of health systems, the business model for healthcare is also evolving. Pharmacy leaders will need to become familiar with changing business imperatives and align the pharmacy business plan with that of the health system. Planning must integrate at both the strategic and tactical level. Pharmacy needs to be envisioned as a service rather than a department. These changes have resulted in the need to evaluate best practices, legal and regulatory requirements, and leadership structure.

1419
DOCUMENTATION OF PATIENT-CARE SERVICES IN THE PERMANENT HEALTH RECORD

This policy was superseded by ASHP policy 2421.

1420
MANUFACTURER-SPONSORED PATIENT-ASSISTANCE PROGRAMS

This policy was superseded by ASHP policy 1806.

1421
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN CLINICAL PHARMACOGENOMICS

This statement was superseded by ASHP policy 2120.

2013 Policy Positions

1301
PAYER PROCESSES FOR PAYMENT AUTHORIZATION AND COVERAGE VERIFICATION
Source: Council on Pharmacy Management

To advocate that public and private payers collaborate with each other and with health care providers to create standardized and efficient processes for authorizing payment or verifying coverage for care; further,

To advocate that payment authorization and coverage verification processes (1) facilitate communication among patients, providers, and payers prior to therapy; (2) provide timely payment or coverage decisions; (3) facilitate access to information that allows the pharmacist to provide prescribed medications and medication therapy management to the patient; and (4) foster continuity in patient care.

This policy was reviewed in 2023 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Patients and health care providers are required to navigate an array of payment requirements from private and public payers. Private insurers enforce their own prior authorization procedures, state Medicaid programs have their individual program requirements, and Medicare has its local and national coverage determinations. These payment authorization and verification processes vary considerably from payer to payer and are time consuming and needlessly complex. The required data, forms of documentation required, submission processes, coverage verification procedures, and delivery of approval vary widely among payers. These processes are often not integrated into the patient-care process and require manual documentation and submission. The lack of timely review and approval may delay patient care. Payment authorization and verification processes should effectively facilitate communication among both patients and providers, should be standardized and automated, and should result in timely decisions that do not disrupt patient care.

1302
INTEROPERABILITY OF PATIENT-CARE TECHNOLOGIES

This policy was superseded by ASHP policy 2303.

1304
DRUG PRODUCT REIMBURSEMENT

This policy was superseded by ASHP policy 1807.

1305
EDUCATION ABOUT PERFORMANCE-ENHANCING SUBSTANCES

This policy was superseded by ASHP policy 2305.

1306
STANDARDIZATION OF INTRAVENOUS DRUG CONCENTRATIONS

This policy was superseded by ASHP policy 2319.

1308
COMPOUNDING BY HEALTH PROFESSIONALS

This policy was superseded by ASHP policy 1406.

1310
REGULATION OF TELEPHARMACY SERVICES
Source: Council on Public Policy

To advocate that state governments adopt laws and regulations that standardize telepharmacy practices across state lines and facilitate the use of United States-based telepharmacy services; further,

To advocate that boards of pharmacy and state agencies that regulate pharmacy practice include the following in regulations for telepharmacy services: (1) education and training of participating pharmacists; (2) education, training, certification by the Pharmacy Technician Certification Board, and licensure of participating pharmacy technicians; (3) communication and information systems requirements; (4) remote order entry, prospective order review, verification of the completed medication order before dispensing, and dispensing; (5) direct patient-care services, including medication therapy management services and patient counseling and education; (6) licensure (including reciprocity) of participating pharmacies and pharmacists; (7) service arrangements that cross state borders; (8) service arrangements within the same corporate entity or between different corporate entities; (9) service arrangements for workload relief in the point-of-care pharmacy during peak periods; (10) pharmacist access to all applicable patient information; and (11) development and monitoring of patient safety, quality, and outcomes measures; further,

To identify additional legal and professional issues in the provision of telepharmacy services to and from sites located outside the United States.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

In light of continuing advances in technology, there an increasingly urgent need for state board of pharmacy regulation of the provision of pharmacist care services from offsite locations through electronic technology, which is often referred to, especially in regulation, as *telepharmacy*. In the ASHP Statement on Telehealth Pharmacy Practice, ASHP explains why it prefers the term *telehealth pharmacy practice* to describe both the provision of team-based patient care and oversight of aspects of pharmacy operations (e.g., remote dispensing, order verification, supervision of staff) by pharmacists using electronic information and telecommunications technology.

It is important to acknowledge the regulatory purview of state boards of pharmacy regarding the use of telepharmacy and recognize that the intent of such regulations should be to balance protection of the public health with the increased patient access to the patient care services of pharmacists provided by telepharmacy. Although such regulations should allow for various arrangements across state borders and within or between health systems, they all need to address a number of common concerns.

ASHP advocates that the provision of medication therapy management and other direct patient care services be addressed in any regulation of telepharmacy services and that patient safety, quality, and outcomes measures for these services be developed and monitored. Further, ASHP urges state governments to harmonize the practice of pharmacy across state lines and to require that pharmacy technicians providing telepharmacy services be certified by the Pharmacy Technician Certification Board and licensed by the state board of pharmacy. Finally, ASHP recognizes the need to continue efforts to identify additional legal and professional issues in the provision of international telepharmacy services.

1311

REGULATION OF CENTRALIZED ORDER FULFILLMENT

Source: Council on Public Policy

To advocate changes in federal and state laws, regulations, and policies to permit centralized medication order fulfillment within health care facilities under common ownership.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Health systems use centralized facilities to provide a range of medications in order to improve efficiency, decrease redundancy, optimize preparation expertise, and decrease overhead and inventory costs. Importantly, health systems use centralized facilities to provide medications that are in short supply or are difficult to compound safely.

The Drug Enforcement Administration prohibits central repackaging and distribution of controlled substances to other facilities that are part of the same health system. Moreover, health systems with facilities in multiple states find additional requirements in each state by boards of pharmacy and other state regulators when providing medications across state borders from a centralized facility.

ASHP recognizes the importance of maintaining practice standards and related safeguards to assure patient safety. In fact, health systems use centralized facilities in order to

ha ve the most-qualified personnel prepare these medications in the safest facility. Regulatory changes are needed at the state and federal level to optimally use centralized facilities that are under the common ownership and therefore quality control of the health system.

1312
MEDICATION OVERUSE

This policy was superseded by ASHP policy 1822.

1313
DRUG-CONTAINING DEVICES
Source: Council on Therapeutics

To recognize that use of drug-containing devices (also known as combination devices) has important clinical and safety implications for patient care; further,

To advocate that use of such devices be documented in the patient's medical record to support clinical decision-making; further,

To encourage pharmacists to participate in interprofessional efforts to evaluate and create guidance on the use of these products through the pharmacy and therapeutics committee process to ensure patient safety and promote cost-effectiveness; further,

To advocate that the Food and Drug Administration (FDA) and device manufacturers increase the transparency of the FDA approval process for drug-containing devices, including access to data used to support approval; further,

To encourage research that evaluates the clinical and safety implications of drug-containing devices to inform product development and guide clinical practice.

This policy was reviewed in 2023 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
As defined by the FDA, a combination product is “a product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity” or “two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products.” Examples include, but are not limited to, antibiotic-loaded bone cement (ALBC), drug-eluting catheters and stents, and hemostatic sponges and other products used for wound care. Drugs in these products have a therapeutic effect, impact overall patient care, and in some instances may result in drug interactions and adverse drug events. For these reasons, ASHP advocates for documentation of the use of these products in patients’ medical records.

Pharmacists usually are not involved in decisions about how these products will be used within the health system but often end up playing a role in the set-up, programming, maintenance, and education of patients and providers in the use of devices. In addition to patient safety concerns, other shortcomings of this approach include lost revenue because these products are frequently not accurately billed or tracked as inventory. ASHP encourages pharmacists to participate in interprofessional discussions concerning use of these products and suggested that the pharmacy and therapeutics committee may provide the ideal mechanism to conduct these evaluations.

The FDA provides recommendations for drug-device development in *Guidance for Industry and Staff: Early Development Considerations for Innovative Combination Products*, including a suggestion that additional preclinical or clinical studies may be needed to evaluate "the potential for change in the established or understood safety, effectiveness, and/or dosing requirements" when a previously approved drug product is incorporated into a combination device. However, these studies are recommended, not required, by the FDA, and even when these studies are completed, information from these studies is not widely available or easily accessible. Finally, it is not always apparent why a specific combination product receives a primary product assignment as a device or drug, which is important because this assignment can impact the approval pathway. ASHP advocates that the FDA and manufacturers of drug-containing devices improve the transparency of the approval process and access to information.

There is often little research concerning the interplay of drugs and devices (e.g., the rate and extent of drug release from the device) or pharmacodynamics once these devices are administered, applied, or implanted in the patient. Further, little is known about the contribution of ALBC or antibiotic beads and spacers to antimicrobial resistance. Therefore, ASHP encourages research that could inform product manufacturers during the development process and provide information to clinicians about use of these products in patient care.

1314
DEA SCHEDULING OF HYDROCODONE COMBINATION PRODUCTS

This policy was discontinued in 2018.

1315
DEA SCHEDULING OF CONTROLLED SUBSTANCES

This policy was superseded by ASHP policy 2323.

1316
PHARMACY RESIDENT AND STUDENT ROLES IN NEW PRACTICE MODELS

This policy was superseded by ASHP policy 1829.

1317
EDUCATION AND TRAINING IN HEALTH CARE INFORMATICS
Source: Council on Education and Workforce Development

To recognize the significant and vast impacts of health-system information systems, automation, and technology changes on safe and effective use of medications; further,

To foster, promote, and lead the development of and participation in formal health care informatics educational programs for pharmacists, pharmacy technicians, and student pharmacists.

This policy was reviewed in 2023 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale
With growing use of automation and technology, there is a growing need for informatics-trained pharmacists and pharmacy technicians, yet there are few training programs or residencies. This shortage of trained individuals has led to on-the-job training and potentially less-than-optimal implementation of new information systems and technology. New educational programs, or adaptation of existing ones, would help ease this lack of trained individuals and lead to better technology outcomes. To most effectively accomplish this goal, ASHP must lead the development of such programs and encourage participation by pharmacists, pharmacy students, and pharmacy technicians.

1319
ASHP STATEMENT ON THE PHARMACY TECHNICIAN'S ROLE IN PHARMACY INFORMATICS

This policy was superseded by ASHP policy 2215.

2012 Policy Positions

1201
PRECEPTOR SKILLS AND ABILITIES

This policy was superseded by ASHP policy 2203.

1203
QUALIFICATIONS OF PHARMACY TECHNICIANS IN ADVANCED ROLES

This policy was superseded by ASHP policy 2424.

1204
ROLE OF STUDENTS IN PHARMACY PRACTICE MODELS

This policy was superseded by ASHP policy 1829.

1205
REVENUE CYCLE COMPLIANCE AND MANAGEMENT

This policy was superseded by ASHP policy 1710.

1206
PAYMENT AUTHORIZATION AND VERIFICATION PROCESSES

This policy was superseded by ASHP policy 1301.

1207
FINANCIAL MANAGEMENT SKILLS

This policy was superseded by ASHP policy 2234.

1208
TRANSITIONS OF CARE

This policy was superseded by ASHP policy 2205.

1209
VALUE-BASED PURCHASING

This policy was superseded by ASHP policy 2233.

1210
ROLE OF CORPORATE PHARMACIST LEADERSHIP IN MULTIFACILITY ORGANIZATIONS

This policy was superseded by ASHP policy 1417.

1211
PHARMACIST'S ROLE IN HEALTH CARE INFORMATION SYSTEMS

This policy was superseded by ASHP policy 2147.

1212
CLINICAL DECISION SUPPORT SYSTEMS
Source: Council on Pharmacy Management

To advocate for the development of clinical decision support (CDS) systems that are proven to improve medication-use outcomes and that include the following capabilities: (1) alerts, notifications, and summary data views provided to the appropriate people at the appropriate times in clinical workflows, based on (a) a rich set of patient-specific data, (b) standardized, evidence-based medication-use best practices, and (c) identifiable patterns in medication-use data in the electronic health record; (2) audit trails of all CDS alerts, notifications, and follow-up activity; (3) structured clinical documentation functionality linked to individual CDS alerts and notifications; and (4) highly accessible and detailed management reporting capabilities that facilitate assessment of the quality and completeness of CDS responses and the effects of CDS on patient outcomes.

This policy was reviewed in 2023 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Clinical decision support (CDS) systems provide timely information, usually at the point of care, to help inform decisions about a patient's care. CDS can effectively improve patient outcomes and lead to higher-quality healthcare. CDS systems are now commonly administered through electronic medical records and other computerized clinical workflows, which has been facilitated by increasing global adoption of electronic medical records with advanced capabilities. Despite these advances, there remain unknowns regarding the effect CDS systems have on the providers who use them, patient outcomes, and costs. There have been numerous published examples of CDS system success stories, but notable setbacks have also demonstrated that CDS systems are not without risks. Ongoing advocacy is needed for evidence-based improvements in CDS systems that minimize risk in design, implementation, evaluation, and maintenance; provide actionable data analytics; and support the medication-use process.

1214

PHARMACIST'S ROLE IN ACCOUNTABLE CARE ORGANIZATIONS

Source: Council on Pharmacy Practice

To recognize that pharmacist participation in collaborative health care teams improves outcomes from medication use and lowers costs; further,

To advocate to health policymakers, payers, and other stakeholders for the inclusion of pharmacists as health care providers within accountable care organizations (ACOs) and other models of integrated health care delivery; further,

To advocate that pharmacist-provided care (including care coordination services) be appropriately recognized in reimbursement models for ACOs; further,

To advocate that pharmacists be included as health care providers in demonstration projects for ACOs; further,

To encourage comparative effectiveness research and measurement of key outcomes (e.g., clinical, economic, quality, access) for pharmacist services in ACOs; further,

To encourage pharmacy leaders to develop strategic plans for positioning pharmacists in key roles within ACOs.

This policy was reviewed in 2022 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

The Affordable Care Act of 2009 encourages the formation of accountable care organizations (ACOs). Similar in concept to health maintenance organizations, these entities consist of alliances between physicians, other health care providers, and hospitals that provide comprehensive and coordinated health care to a population of patients. ACOs emphasize primary and preventive care, are provider-led, and receive reimbursement linked to increasing health care quality and lowering per capita costs. The ACO model is based on the premise that care coordinated in this manner and incentivized by a shared-risk reimbursement model will improve health care quality and slow the growth of health care spending. One significant deterrent to pharmacist participation in the fee-for-service care model, lack of provider status, is less of a barrier in the ACO model because reimbursement is tied to quality and reduced costs rather than specific services.

Integrated systems present an important opportunity for pharmacists to demonstrate their value to the quality of care. Pharmacists could contribute to the success of ACOs by providing the following patient care services:

- Developing, implementing, and monitoring patient-specific, evidence-based drug therapy as an active participant in team-based care.
- Improving transitions in care with coordinated MTM services for patients in the hospital as well as post-discharge in ambulatory clinics and physician practices.

- Monitoring the therapy of patients with multiple chronic conditions or complex medication regimens.
- Preventing and managing adverse drug events.

Although a number of ACOs have already evolved from existing disease management and medical home programs, not much is known about the elements of success for ACOs, and implementation is likely to be challenging. To establish these elements of success, pharmacists will need to be included in ACO demonstration projects and pharmacist services will need to be the subject of research on ACO effectiveness.

As pharmacists assume the expanded roles outlined in the PPMI recommendations, pharmacy leaders should use their expertise to explore innovative strategies to meet the broader goals of ACOs. This payment model is an opportunity to demonstrate how pharmacists can help these organizations reach clinical and financial performance targets set by the Centers for Medicare & Medicaid Services (CMS), i.e., improved patient results and lower health care costs. Pharmacy managers and other pharmacy leaders should prepare now to participate in emerging ACOs by developing strategic plans for positioning pharmacists in roles where their expertise can be best applied to these goals.

1215
PHARMACIST'S ROLE IN TEAM-BASED CARE

This policy was superseded by ASHP policy 2208.

1216
PHARMACY TECHNICIANS
Source: Council on Public Policy

To advocate that pharmacy move toward the following model with respect to the evolving pharmacy technician workforce as the optimal approach to protecting public health and safety: (1) development and adoption of uniform state laws and regulations regarding pharmacy technicians, (2) mandatory completion of an ASHP-accredited program of education and training as a prerequisite to pharmacy technician certification, (3) mandatory certification by the Pharmacy Technician Certification Board as a prerequisite to licensure by the state board of pharmacy, and (4) licensure of pharmacy technicians by state boards of pharmacy granting the technician permission to engage in the full scope of responsibilities authorized by the state; further,

To advocate, with respect to certification, as an interim measure until the optimal model is fully implemented, that individuals be required either (1) to have completed an ASHP-accredited program of education and training or (2) to have at least one year of full-time equivalent experience as pharmacy technicians before they are eligible to become certified; further,

To advocate that all pharmacy functions be performed under the general supervision of a licensed pharmacist and that licensed pharmacists and technicians be held accountable for the quality of pharmacy services provided.

(*Note:* Licensure is the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected. Certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.)

This policy was reviewed in 2022 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Licensure is the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected. Certification is the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association.

Recommendation D8 of the 2010 Pharmacy Practice Model Initiative Summit and subsequent discussion by the ASHP Board of Directors called for licensure of pharmacy technicians. Subsequent ASHP initiatives, including the Pharmacy Advancement Initiatives 2030, support licensure and certification of pharmacy technicians.

Optimal use of pharmacy technicians will enable pharmacists to devote more time to drug therapy management. Uniformity among state laws is essential to achieve the preferred vision for practice. Moreover, requiring licensure rather than registration will enable state boards to require competency, impose disciplinary sanctions, and hold technicians accountable for their actions.

The process proposed for pharmacy technicians to achieve licensure follows the same steps outlined in ASHP policy 0815: education and training, followed by examination and certification, as prerequisites to licensure. The movement to technician licensure was essential to assure the public that the medication-use system includes individuals competent to assist pharmacists to provide and manage their medication regimens. Licensure will provide state boards with the tools necessary to provide that assurance to the public.

1217

COLLABORATIVE DRUG THERAPY MANAGEMENT

This policy was superseded by ASHP policy 1715.

1219
STABLE FUNDING FOR HRSA OFFICE OF PHARMACY AFFAIRS
Source: Council on Public Policy

To advocate for a sustainable level of funding, including appropriations, sufficient to support the public health mission of the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs; further,

To support initiatives of the Office of Pharmacy Affairs, including the 340B Drug Pricing Program and innovative pharmacy service models in HRSA-funded programs; further,

To encourage research on the potential impact of any proposed fees or alternative funding sources for the Office of Pharmacy Affairs.

This policy was reviewed in 2022 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
The Office of Pharmacy Affairs (OPA) currently relies on general funding from its parent agency, HRSA, and not a line-item annual appropriation to administer the 340B Drug Discount Program. The OPA and HRSA have sought funding to establish a cost recovery (user fee) program to administer the program. The initial fee would be 0.1 percent of the total 340B drug purchases paid by participating covered entities. HRSA and OPA contend that the cost recovery fee will create a sustainable funding source to meet the demands of the existing and projected growth of the 340B program, the changing marketplace, and new statutory program requirements. There is a need for stable and sustainable funding for the OPA. A variety of funding sources should be considered, perhaps involving entities that do not participate in the 340B program. Any user fee program should include an annual review of the percentage used to determine the annual fee charged to participating entities. In addition, OPA should not be solely dependent on user fees for its program administration; some level of congressional appropriations would serve as an important to safeguard against such a dependency.

1220
STANDARDIZED IMMUNIZATION AUTHORITY TO IMPROVE PUBLIC HEALTH

This policy was superseded by ASHP policy 1309.

1221
CRITERIA FOR MEDICATION USE IN GERIATRIC PATIENTS

This policy was superseded by ASHP policy 2213.

1222
MEDICATION ADHERENCE

This policy was superseded by ASHP policy 2214.

1223
GLOBALIZATION OF CLINICAL TRIALS
Source: Council on Therapeutics

To encourage the Food and Drug Administration (FDA) to use its existing authority to increase monitoring and inspection of foreign clinical trials to ensure the integrity and quality of those studies; further,

To advocate that the FDA expand its oversight of clinical trials conducted abroad by continuing to pursue innovative strategies, such as increased collaboration with foreign regulatory agencies and changes in domestic regulatory processes that support timely submission of foreign clinical trial information; further,

To encourage the FDA to establish a standardized electronic format and reporting standards that would be required for submission of data from foreign clinical trials; further,

To support the ethical treatment of patients in foreign clinical trials in accordance with international standards designed to protect human subjects; further,

To encourage public and private research to study the impact of the globalization of clinical trials on patient care.

This policy was reviewed in 2022 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
More than 80% of marketing applications for drugs approved in fiscal year 2008 were supported by data from foreign clinical trials, and more than 50% were based on data from trials that were conducted entirely outside of the United States. This trend toward the globalization of clinical trials is expected to continue because of potential benefits to drug manufacturers (e.g., decreased costs, availability of treatment-naive patients). ASHP is concerned that limited experience with clinical trials in some countries could affect data integrity and questioned whether results from foreign clinical trials could always be generalized to patients in the United States because of differences in genetics and cultural factors (e.g., diet, use of supplements). Existing FDA authority allows for oversight of foreign clinical trials, including a requirement for mandatory reporting. However, according to the 2010 Office of Inspector General (OIG) report, *Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials*, only 0.7 percent of foreign trial investigators were inspected in FY 2008 (compared to 1.9% of investigators in the United States). The FDA should increase oversight of

foreign clinical trials given the potential for inconsistencies in protocol implementation and concerns about the availability and integrity of data noted in the OIG report. Development of innovative approaches to expand oversight given limited FDA resources is also encouraged. ASHP supports a recent FDA agreement with the European Medicines Agency to share information from inspections conducted by that agency and encourages the FDA to establish this type of agreement with other countries, including those whose experience with clinical trials is limited. The FDA should also explore regulatory changes that would support more timely submission of foreign clinical trial information. This recommendation is based on concern that some aspects of current regulations may encourage drug manufacturers to favor foreign clinical trials. For example, submission of an investigational new drug (IND) application triggers FDA oversight, including required submission of clinical trial protocols. Timely submission of an IND is necessary for studies conducted within the United States because it provides an exemption from interstate commerce laws, which is needed to conduct clinical trials. However, interstate commerce laws do not apply abroad. Therefore, there is no requirement or incentive for manufacturers to submit study protocols for foreign trials if they are conducted prior to the IND submission. However, results from those trials are sometimes used to support marketing applications for drug approval. While the FDA can review protocol and data from these studies retrospectively, data omissions and other factors limit the effectiveness of this approach. Earlier submission of this information would enhance the effectiveness of FDA's oversight. Standardization and electronic submission of data from foreign clinical trials should also be encouraged, given the OIG finding that data from these trials was sometimes not available to FDA reviewers. Ethical concerns associated with foreign clinical trials, including documented lapses in informed consent, support the need for improved adherence to ethical standards for conducting clinical research, such as those described in the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice, the Declaration of Helsinki, and other international guidelines. Finally, the FDA and private entities are encouraged to study the potential patient care impact of the globalization of clinical trials to determine whether there is an impact even when studies are conducted appropriately.

1224
TOBACCO AND TOBACCO PRODUCTS

This policy was superseded by ASHP policy 1625.

1225
BOARD CERTIFICATION FOR PHARMACISTS
Source: Section of Clinical Specialists and Scientists

To support the principle that pharmacists who practice where a pharmacy specialty has been formally recognized by the profession should become board certified in the appropriate specialty area; further,

To recognize the Board of Pharmacy Specialties (BPS) as an appropriate organization through which specialties are formally recognized and specialty pharmacy certification should occur; further,

To advocate prioritization for recognition of new specialties in those areas where sufficient numbers of postgraduate year two residency training programs are established and where adequate numbers of pharmacists are completing accredited training programs to prepare them to practice in the specialty area; further,

To advocate for standardization of credentialing eligibility and recertification requirements to include consistent requirements for advanced postgraduate residency training; further,

To promote a future vision encouraging accredited training as an eventual prerequisite for board certification; further,

To encourage BPS to be sensitive to the needs of current practitioners as prerequisites evolve; further,

To actively encourage and support the development of effective training and recertification programs that prepare specialists for certification examination and ensure the maintenance of core competencies in their area of specialization.

This policy was reviewed in 2022 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

As medication therapies become more complex, the need for specialized expertise increases. Some areas of health care practice evolve to the point where certification, based on formal accredited training and psychometrically valid examination, is needed to assure the public and other health care professionals of a level of competence, quality, and consistency among specialists practicing in that field. Certification, as defined by Council on Credentialing in Pharmacy, is the process by which a nongovernmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization. Formal recognition of pharmacy specialties demonstrates the unique knowledge, skills, and abilities of pharmacists in well-defined areas of practice and provides the assurance the public and other health care professionals need.

ASHP has long recognized the value of specialty certification. ASHP has been involved in multiple petitions to the Board of Pharmacy Specialties (BPS) requesting recognition of new pharmacy specialties. The ASHP Long Range Vision for Pharmacy Work Force in Hospitals and Health Systems states that pharmacists who provide services in an area where specialty certification exists should be certified in that specialty, and the ASHP Supplemental Standards for Postgraduate Training require such certification of residency program directors only.

It is also important to distinguish the recognition of specialties within the practice of pharmacy from other multidisciplinary certifications. Although some similarities exist in the nature of such programs, they also do not represent the recognition of a unique area of

specialization and the development of processes recognized by the pharmacy profession to ensure the quality of specialty practice.

The profession should be more strategic in its efforts to grow and mature new specialties. A methodical specialty development process would prioritize recognition of areas of practice for which a sufficient number of high-quality training programs exist and would promote development of training programs in emerging areas of pharmacy specialization in advance of specialty recognition.

Eligibility requirements for Board certification vary widely among currently recognized specialties. Although it may not currently be possible to require residency training as a prerequisite for all BPS specialty certification applicants, over time postgraduate year two residency training should become the preferred prerequisite to establish consistent requirements across specialties and provide a stronger linkage between training and certification. ASHP policy currently supports the principle that accredited training is an important prerequisite for pharmacy technicians prior to certification by the Pharmacy Technician Certification Board. This same principle that accredited training should precede certification should also apply to specialists in our profession. It will be important for BPS to plan for this future vision and evolve requirements in a manner that is sensitive to the needs of existing practitioners.

1226

ASHP STATEMENT ON THE ROLE OF THE MEDICATION SAFETY LEADER

This statement was superseded by ASHP policy 1919.

1227

ASHP STATEMENT ON THE PHARMACIST'S ROLE IN MEDICATION RECONCILIATION

Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Pharmacist's Role in Medication Reconciliation.

This policy was reviewed in 2017 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

1228

ASHP STATEMENT ON USE OF SOCIAL MEDIA BY PHARMACY PROFESSIONALS

Source: Pharmacy Student Forum and Section of Pharmacy Informatics and Technology

To approve the ASHP Statement on Use of Social Media by Pharmacy Professionals.

2011 Policy Positions

1101
MEDICAL MARIJUANA

This policy was superseded by ASHP policy 2115.

1102
AGRICULTURAL USE OF HORMONE AND PROHORMONE THERAPIES

This policy was superseded by ASHP policy 2144.

1107
PATIENT-REPORTED OUTCOMES TOOLS
Source: Council on Therapeutics

To advocate for expanded use of validated patient-reported outcomes (PRO) tools in clinical research and direct patient care; further,

To support development of validated PRO tools that are sensitive to differences in cultural and health literacy; further,

To encourage additional research on PRO tools, including studies to assess their correlation to overall patient outcomes; further,

To educate clinicians and patients about the appropriate use of PRO tools.

This policy was reviewed in 2025 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
Patient-reported outcome measures (PROMs) are validated assessments of patient satisfaction, health-related quality of life, or symptom burden that come directly from the patient rather than through clinician interpretation. These measures, ranging from structured checklists and open-ended questionnaires to spontaneous reporting systems, can be general or tailored to specific clinical conditions or symptoms. Their use aligns with the growing emphasis on patient-centered care and patient-focused drug development promoted by the Food and Drug Administration, the Institute of Medicine, and other quality improvement initiatives.

Although PROMs were originally developed for use in research to gain a more holistic understanding of patient experiences during drug therapy, they have been increasingly applied in direct patient care settings. PROMs help integrate the patient perspective into the assessment and management of a wide variety of disease states (e.g. oncology, orthopedics, mental health, maternity care, cardiovascular and metabolic diseases, respiratory conditions,

transplantation) while also supporting patient engagement. Of particular relevance to pharmacy practice, PROMs have been used for assessing medication treatment satisfaction and identifying adverse events. Interventions based on PROMs have been associated with improved clinical outcomes, especially when feedback is provided to patients and providers and used to connect patients with appropriate care pathways. Most notably, integrating PROMs into the clinical care of patients with cancer was associated with improvement in overall survival and short-term health-related quality of life in a 2024 meta-analysis of 45 randomized clinical trials.

Development of validated PROMs that account for variability in cultural values, health literacy, and digital proficiency are recommended to ensure equitable use. Continued research is encouraged to better define the relationship between PROMs and overall patient outcomes, especially because data remain limited outside the field of oncology. Additional directions for future research include expanding electronic platforms using PROMs, leveraging mobile health tools such as smartphones, apps, and wearable devices for real-time patient monitoring, and integrating artificial intelligence for advanced analysis of data and prediction of outcomes from PROMs. Researchers are advised to adopt standardized reporting frameworks such as the 2021 SPIRIT-PROM Extension to improve data quality, transparency, and reproducibility. Clinician and patient education on the appropriate use of PROMs is needed for effective implementation, including the importance of instructing clinicians to select PROMs that are validated in patient populations that are similar to the populations in which they will be used.

1108
QUALITY OF PHARMACY EDUCATION AND EXPANSION OF COLLEGES OF PHARMACY

This policy was superseded by ASHP policy 2609.

1109
RESIDENCY EQUIVALENCY
Source: Council on Education and Workforce Development

To acknowledge the distinct role of ASHP-accredited residency training in preparing pharmacists to be direct patient-care providers; further,

To recognize the importance of clinical experience in developing practitioner expertise; further,

To affirm that there are no objective means to convert or express clinical experience as equivalent to or a substitute for the successful completion of an ASHP-accredited residency.

This policy was reviewed in 2021 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale
ASHP's position on the need for residency-trained pharmacists is well established and described in the *ASHP Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems*. It has been suggested that a way to achieve the goal of having all pharmacists in direct patient-

care roles be residency trained would be to establish a process for reviewing a "portfolio" against pre-established criteria to grant a "residency equivalency." The Council, Board, and House concluded that both residency training and experience are important and valuable, but different, and that it would not be appropriate to create a process that attempts to convert one into the other. The intent of the goal of having all new college of pharmacy graduates who provide direct patient care residency trained by 2020 is to enhance the skills of those practitioners, and the creation of a residency equivalency process might dilute the value of that residency training and undermine achievement of the goal.

The Council, Board, and House also discussed the process used by ASHP to waive the requirement for a postgraduate year one (PGY1) residency for experienced practitioners who wish to enter a postgraduate year two (PGY2) residency directly. While this process does consider total experience in granting the waiver, and may seem to contradict the recommended policy, the applicant still completes a residency, ultimately gaining those experiences unique to residency training.

1110
PHARMACY INTERNSHIPS

This policy was superseded by ASHP policy 2107.

1111
STATE-SPECIFIC REQUIREMENTS FOR PHARMACIST CONTINUING EDUCATION

This policy was superseded by ASHP policy 2201.

1112
INNOVATIVE RESIDENCY MODELS
Source: Council on Education and Workforce Development

To support the development of innovative residency models that meet ASHP accreditation requirements.

This policy was reviewed in 2021 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale
A growing number of residency programs have developed residency positions that are "nontraditional," in that they do not occur in a contiguous 12-month period beginning in July and finishing the following June. Some of these innovative programs schedule the participant for one month as a resident, followed by two months as staff, with this cycle repeated over a three-year period. This allows some individuals, usually experienced individuals already on staff at the institution, to complete a residency while maintaining a more consistent work schedule and lifestyle. Some other settings have adopted a model geared toward new graduates, alternating months between residency rotation and staffing.

The concept of innovative, nontraditional residencies allows another way for established pharmacists to obtain a pharmacy residency when a conventional 12-month contiguous program is not possible. The Council, Board, and House expressed support for this model as long as ASHP accreditation standards and residency goals and objectives are utilized as they would be in a conventional program.

1113
PROFESSIONAL SOCIALIZATION

This policy was superseded by ASHP policy 2129.

1114
PHARMACIST ACCOUNTABILITY FOR PATIENT OUTCOMES
Source: Council on Pharmacy Practice

To affirm that pharmacists are obligated by their covenantal relationship with patients to ensure that medication use is safe and effective; further,

To declare that pharmacists, pursuant to their authority over a specialized body of knowledge, are autonomous in exercising their professional judgment and accountable as professionals and health care team members for safe and effective medication therapy outcomes; further,

To encourage pharmacists to define practices and associated measures of effectiveness that support their accountability for patient outcomes; further,

To promote pharmacist accountability as a fundamental component of pharmacy practice to other health care professionals, standards-setting and regulatory organizations, and patients.

This policy was reviewed in 2021 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
The Council, Board, and House agreed that a clear, succinct policy communicating the interrelationship of authority and autonomy with accountability for outcomes, good or bad, is needed. The policy should distill and define ASHP's stance on accountability and draw on concepts implicit in current ASHP policy documents. The Council, Board, and House recognized that authority, autonomy, and accountability are inseparable components of professional practice. Without accountability, the pharmacy profession cedes the ultimate authority for decision-making in matters of medication therapy to prescribers, calling into question whether pharmacy is, in fact, a profession.

The pharmacist's covenantal relationship with patients is described in the *Pharmacist's Oath*, to which all pharmacy students profess, and which states in part:

- I will consider the welfare of humanity and relief of suffering my primary concerns.
- I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.
- I will embrace and advocate changes that improve patient care.

The attributes of professional status are defined by sociological, ethical, and legal expectations in literature on this subject. Those commonly cited include:

- Work is based upon the mastery of a complex body of knowledge and skills; a practice founded upon this knowledge is used in the service of others.
- Members are governed by codes of ethics and profess a commitment to competence, integrity, and … promotion of the public good within their domain.
- A social contract exists in which, in exchange for these commitments, society recognizes the profession's authority over the knowledge base, autonomy in practice, and the privilege of self-regulation.
- The profession's members are accountable to those served and society.

Despite strong advocacy by pharmacy thought leaders and a wealth of evidence in its support, the precept that pharmacists are accountable for medication therapy outcomes is not widely accepted by other health care disciplines, nor is it broadly integrated into pharmacy practice. Moreover, many pharmacists may be ambivalent about assuming a role that holds them to high standards of practice and makes them answerable for the welfare of patients.

Accountability is implicit in many ASHP policy documents, most notably in the *ASHP Statement on Pharmaceutical Care*:

> Pharmaceutical care is not a matter of formal credentials or place of work. Rather, it is a matter of a direct personal, professional, responsible relationship with a patient to ensure that the patient's use of medication is optimal and leads to improvements in the patient's quality of life.

The pharmacist's authority over and expertise in use of medications are supported by the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation Interpretive Guidelines, which establish a definition and expectation for pharmaceutical care:

> Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life while minimizing patient risk.

The *Statement on the Future Vision of Pharmacy Practice* from the Joint Commission of Pharmacy Practitioners (JCPP) is explicit in its expectation for pharmacist autonomy and accountability and states in part:

How Pharmacists Will Practice. Pharmacists will have the authority and autonomy to manage medication therapy and will be accountable for patients' therapeutic outcomes. In doing so, they will communicate and collaborate with patients, care givers, health care professionals, and qualified support personnel. As experts regarding medication use, pharmacists will be responsible for rational use of medications, including the measurement and assurance of medication therapy outcomes…. Working cooperatively with practitioners of other disciplines to care for patients, pharmacists will be … valued patient care providers whom health care systems and payers recognize as having responsibility for assuring the desired outcomes of medication use.

The JCPP vision statement encompasses these attributes and clearly illustrates the direction that the pharmacy profession must take. In particular, the Council, Board, and House confirmed that pharmacist accountability is a profession-defining issue that must be urgently addressed, recognizing that the policy is at most a starting point for the transformation that needs to take place in order to realize the JCPP vision.

The Council stated that unless the pharmacy profession commits to actions that translate the policy into practice, pharmacists are at risk of becoming irrelevant. As changes brought about by health care reform are implemented to add value to health care and reduce costs, the extensive training and high salaries of pharmacists cannot be justified if, as noted by the 2007 Council, "pharmacists are responsible and held accountable only for the acquisition, storage, and dispensing of medications."

The Council called on ASHP to be fearless and persistent in promoting and establishing the JCPP vision within the profession. The Council also recommended that ASHP use its influence to create the "pull" for accountability in pharmacy practice by establishing an expectation of pharmacist accountability by other health care providers, standards-setting and regulatory organizations, and payers.

1115
JUST CULTURE
Source: Council on Pharmacy Practice

To recognize that the principles of *just culture* promote an environment in health care organizations in which safety is valued, reporting of safety risks is encouraged, and a fair process is used to hold staff and leaders accountable; further,

To encourage hospitals and health systems to include *just culture* as a component in organizational safety culture surveys and quality improvement initiatives.

This policy was reviewed in 2021 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

The Council, Board, and House agreed that a specific ASHP policy supporting *just culture* principles should be developed, and that education on the topic should be an important focus for ASHP. In developing the policy, the Council reviewed principles and methods established by David Marx, a systems safety engineer and *just culture* educator, and noted the following

(Marx, D. *Whack-a-Mole: The Price We Pay for Expecting Perfection.* Plano, TX: By Your Side Studios; 2009):

- The notion that humans can perform perfectly if they are well trained and continuously vigilant is unrealistic. Humans will never be perfect.
- Safe environments anticipate human error and systems are designed accordingly. However, systems will never be perfect.
- Individuals are accountable for behavioral choices that lead to error and leaders are accountable for establishing environments that encourage reporting of unsafe conditions and adverse events.
- Behaviors that cause or may cause errors are addressed regardless of whether harm occurs.
- Individual culpability for adverse events is assessed using a decision algorithm that defines attributes of behaviors and systems and can be summarized as follows:
  1. **Human error:** inadvertent; a mistake; doing other than what should have been done.
     Origin: System design, processes, procedures, training.
     Manage by: correcting system, supporting employee.
  2. **At-risk behavior:** behavioral choice that increases risk where risk is not recognized or is mistakenly believed to be justified.
     Origin: System inefficiencies, such as steps that create rework, are burdensome, or seem irrelevant to outcome. The system incentivizes workarounds and shortcuts that are unsafe.
     Manage by: Improving procedures or processes to remove incentives and reward safe behaviors.
  3. **Reckless behavior:** choosing to behave in a manner that places others at substantial and unjustifiable risk knowing that harmful outcome is likely but indifferent to it.
     Origin: the individual.
     Manage by: remedial action, punitive action.
  4. **Negligence:** determined by using the substitution test, i.e., would another individual in the same work area with comparable experience and qualifications have behaved any differently?

The Council identified significant advantages to this approach, one of the most important being that it encourages reporting of adverse events and provides essential information for improving systems and processes of care. In addition, holding individuals accountable by using criteria to distinguish between behaviors that do or do not merit punishment was perceived to be the fairer approach than a strictly punitive or strictly blame-free approach. Another positive attribute of *just culture* is that behaviors associated with error are handled with the appropriate responses regardless of whether harm resulted. By focusing on behaviors rather than outcomes, potential errors are averted, safe behaviors are encouraged, and at-risk or reckless behavior is not tolerated.

The Council recognized that while the *just culture* approach has been accepted by safety leaders, implementation is challenging for a number of reasons. The goals of *just culture*--to

sustain a nonpunitive reporting and learning environment, yet hold individuals accountable for their behavior--seem contradictory. Methods for differentiating behaviors for which to hold an individual accountable tend to use subjective, rather than objective, criteria, and may lead to misinterpretation. Maintaining the *just culture* approach is particularly challenging under the pressure of media coverage and legal liability when a patient is harmed or dies from an error. The belief that individual practitioners are solely responsible for their errors continues to predominate in the health care professions.

The Council noted that decision-making tools and education are available to support implementation of a *just culture*. They suggested that ASHP consider providing education and practical tools for implementing fair processes for holding individuals and leadership accountable for medication safety. Council members also characterized *just culture* as a component of the larger issue of culture of safety and proposed that assessment of *just culture* as part of assessing general safety culture should be included in ASHP's national survey.

1116

ETHICAL USE OF PLACEBOS IN CLINICAL PRACTICE

Source: Council on Pharmacy Practice

To affirm that the use of placebos in clinical practice is ethically acceptable only when patients have been informed of and agree to such use as a component of treatment; further,

To encourage hospitals and health systems to develop policies and procedures to guide clinicians in making informed decisions regarding the use of placebos; further,

To oppose the use of pharmacologically active substances or medications as placebos.

This policy was reviewed in 2021 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

As Tilburt et al. pointed out in 2008, "placebo treatment is an unclear and complicated concept that lacks a standard definition." Placebos have been defined to include inert agents that have little or no pharmacological activity (e.g., saline injections, lactose pills) given to promote positive expectation, as well as physiologically active agents prescribed solely or primarily to promote positive psychological effects rather than the agent's recognized physiological effect. (Tilburt JC, Emanuel EJ, Kaptchuk TJ et al. Prescribing "placebo treatments": results of national survey of US internists and rheumatologists. BMJ 2008;337:a1938. doi: https://doi.org/10.1136/bmj.a1938).

The American Medical Association (AMA) Code of Medical Ethics Opinion 2.1.4 does not distinguish between inert and active placebos, defining a placebo as "a substance provided to a patient that the physician believes has no specific pharmacological effect on the condition being treated." The AMA Opinion states that physicians may use placebos for diagnosis or treatment only if they (1) enlist the patient's cooperation, (2) obtain the patient's general consent to administer a placebo, and (3) avoid giving a placebo merely to mollify a difficult patient. ASHP concurs with the AMA opinion that the use of placebos in clinical practice is

ethically acceptable only when patients have been informed of and agree to such use as a component of treatment. ASHP also concurs that only the patient's general consent should be required. The informed consent process should be reserved for research and medical interventions, where a consent contract and oral explanation of the patient's rights are required. Advocating informed consent for placebo use in clinical practice could lead to a mistaken assumption that clinical use requires the review and approval of an institutional review board, which is not the intent of this policy.

ASHP does not concur with the AMA definition of a placebo, however, preferring that placebos be defined to include only inert substances. ASHP opposes the use of pharmacologically active substances or medications as placebos, because all medication use presents some risk. Due to the complex ethical issues presented by clinical use of placebos, hospitals and health systems should develop policies and procedures to guide clinicians in making informed decisions regarding their use.

1117
PHARMACISTS' ROLE IN MEDICATION RECONCILIATION

This policy was discontinued in 2021.

1118
DRUG PRODUCT SHORTAGES

This policy was discontinued in 2016.

1119
DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION AND NONPRESCRIPTION MEDICATIONS

This policy was superseded by ASHP policy 1624.

1120
REGULATION OF OFF-LABEL PROMOTION AND MARKETING

This policy was superseded by ASHP policy 1620.

1121
POISON CONTROL CENTER FUNDING
Source: Council on Public Policy

To advocate that poison control centers be considered an essential emergency service; further,

To advocate for new and stable funding mechanisms for poison control centers to continue to provide these essential and valuable services; further,

To support the integration and coordination of poison control center services where appropriate.

This policy was reviewed in 2021 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The Council reviewed recent trends by state governments to reduce or eliminate funding for poison control centers and concluded that ASHP policy was needed. The Board and House concurred. The Council, Board, and House agreed with observations by the American College of Emergency Physicians in its June 2010 task force report that the centers are an essential emergency service and part of the infrastructure for an all-hazards emergency preparedness system, including pandemic and bioterrorism response. The Council noted that studies have shown a positive financial benefit provided by the centers; a 2012 report from the American Association of Poison Control Centers found that poison control centers save almost $14 in medical costs and lost productivity for every dollar invested, for an annual savings of $1.8 billion.

Although the Coronavirus Aid, Relief, and Economic Security Act of 2020 injected $5 million in funding to address increased poison control center usage during the COVID-19 pandemic, the funding is merely a one-time increase. In light of the stress COVID-19 has created for state and local budgets, it remains likely that poison control center budgets will remain at risk. As such, there is a continued need for new and stable funding. Further, poison control centers should be better integrated and coordinated, and such integration and coordination should be supported where appropriate.

1123

ASHP STATEMENT ON LEADERSHIP AS A PROFESSIONAL OBLIGATION

Source: Council on Pharmacy Management

This statement was superseded by ASHP policy 2312.

2010 Policy Positions

1001
HEALTH INSURANCE COVERAGE FOR U.S. RESIDENTS

This policy was superseded by ASHP policy 2019.

1002
RISK EVALUATION AND MITIGATION STRATEGIES
Source: Council on Public Policy

To advocate for research on the impact of the Food and Drug Administration's Risk Evaluation and Mitigation Strategies (REMS) on patient safety, cost effectiveness, and pharmacy workflow; further,

To advocate pharmacist involvement in the development and implementation of REMS; further,

To urge computer software vendors to assist pharmacists in the identification of and compliance with REMS; further,

To advocate that any REMS that include constraint on traditional drug distribution systems be consistent with ASHP policy on restricted drug distribution.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
Risk Evaluation and Mitigation Strategies (REMS) are part of new authority granted to the Food and Drug Administration (FDA) to ensure that a drug's benefits outweigh its risks. An increasing number of drug products require REMS in order to be marketed, and some REMS require Medication Guides as well as other "elements to assure safe use." These elements beyond a Medication Guide have included prescriber and pharmacist training, patient registry, and additional patient monitoring. ASHP believes that more research should be conducted by either the FDA or drug manufacturers to determine the effectiveness of and need for REMS. Health-system pharmacists have encountered problems with REMS that were developed without input from health-system pharmacy. Pharmacist input in the development of REMS is essential to avoid unnecessary barriers to patients and burdensome interruptions to pharmacy workflow that could impact patient care and safety.

Drug information and knowledge vendors providing information technology and decision support systems will need to include gateways to specific information about REMS so that pharmacists and other health professionals have access to information about all REMS-

required products and the specific requirements for a particular REMS that includes elements to assure safe use.

Finally, REMS that include constraints on traditional drug distribution systems should be consistent with existing ASHP policy on restricted drug distribution.

1003
FDA AUTHORITY ON RECALLS
Source: Council on Public Policy

To strongly encourage the Food and Drug Administration (FDA) to develop a standard recall notification process and format to be used by all manufacturers to facilitate the timely removal of recalled drugs; further,

To advocate that such notification should (1) come from a single source, (2) clearly identify the recalled product, (3) explain why the product is being recalled, (4) provide a way to report having the recalled product, (5) give instructions on what to do with the recalled product, and (6) be provided concurrently to all entities in the supply chain; further,

To advocate that the FDA be given the authority to order mandatory recalls of medications; further,

To urge the FDA to require drug manufacturers and the computer software industry to provide bar codes and data fields for lot number, expiration date, and other necessary and appropriate information on all medication packaging, including unit dose, unit-of-use, and injectable drug packaging, in order to facilitate compliance with recalls or withdrawals and to prevent the administration of recalled products to patients; further,

To urge the FDA to encourage postmarketing reporting of adverse events and product quality issues to enhance the recall system.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
A recall is a manufacturer or distributor's voluntary removal or correction of a marketed product. The Food and Drug Administration (FDA) may request a recall in "urgent situations." For each recall, the manufacturer or distributor develops a recall strategy based upon guidance from the FDA; there is no standard format for recall notices, and communication timelines, format, content, and distribution vary.

Managing product recalls within hospitals and health systems is a complex process. Past recall events have highlighted the complexity of the process and demonstrate the need for improvements to ensure that recalled product can be removed effectively and efficiently to protect patients from inadvertent administration. During the 2008 recall of heparin, for example, 94 hospitals were found to have recalled product remaining on their shelves. Further evaluation of how the recall was implemented revealed flaws in the system. Some pharmacy

departments reported that they never received the recall notice; in other cases, recalled product was shipped to the pharmacy after the hospital had completed its review of supplies and quarantined all recalled product.

The FDA must have the authority to clearly communicate with stakeholders about recalls of marketed products. Inconsistent, unclear, and confusing information has been communicated during past recalls. A standardized recall notification process and format would enable practitioners and others in the drug distribution chain to readily identify and respond to a recall. Such a notification process should contain the following elements: a single source to designate a point of contact and control communication, clear identification of the recalled product to assist in removing the product from stock, an explanation of why the product is being recalled in order to understand the nature of the recall and communicate with patients and other stakeholders, a feedback mechanism (a reporting loop) so manufacturers and the FDA know where recalled product is located, instructions on how to return or dispose of the recalled product, and concurrent notification of all entities in the supply chain.

ASHP advocates that the FDA be given the authority to order a mandatory recall of a product to avoid the miscommunication that has occurred in past voluntary recalls. In addition, ASHP has long encouraged the FDA to require that lot number, expiration date, and other necessary information be provided electronically (e.g., by bar code or radio frequency identification) as part of the manufacturer's information on all unit dose, unit-of-use, and injectable drug packaging.

Finally, postmarketing reporting of adverse events and product quality issues must be encouraged. Voluntary reporting will provide information for FDA to analyze to determine with the manufacturer the correct course of action.

1004
POSTMARKETING COMPARATIVE CLINICAL AND PHARMACOECONOMIC STUDIES

This policy was superseded by ASHP policy 2025.

1005
MEDICATION THERAPY MANAGEMENT

Source: Council on Public Policy

To support medication therapy management (MTM) services as defined in Section 3503 of the Patient Protection and Affordable Care Act (PL 111-148); further,

To affirm that MTM is a partnership between the patient (or a caregiver) and a pharmacist, in collaboration with other health care professionals, that promotes the safe and effective use of medications.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The term "medication therapy management" (MTM) has received widespread use within the pharmacy profession and among health policymakers. The definition of MTM under Part D of the Medicare program is significantly different from the consensus definition developed by national pharmacy organizations, including ASHP, in 2004. Provisions dealing with MTM grant programs contained in Section 3503 of the Patient Protection and Affordable Care Act (PL 111-148) (PPACA) broaden and enhance MTM beyond the Part D definition. Those provisions also refer to collaborative practice agreements as allowed by state practice acts, referred to in ASHP policy and elsewhere as "collaborative drug therapy management" (CDTM). As health care reform evolves and is implemented, it is important to recognize the distinction that state and federal laws and regulations and ASHP policy make between those two terms and to affirm ASHP's support for the broader definition of MTM in PPACA and the central role of pharmacists in MTM. The policy should also not be construed as an endorsement of defining certain practices as MTM to allow billing for a pharmacist code because this can unnecessarily limit practice advancement.

1006

DEFINITION OF MEANINGFUL USE OF HEALTH INFORMATION TECHNOLOGY

This policy was discontinued in 2020.

1007

REGULATION OF HOME MEDICAL EQUIPMENT MEDICATION PRODUCTS AND DEVICES

Source: Council on Public Policy

To advocate for consistent regulatory oversight of all home medical equipment, with the goals of continuity of care, patient safety, and appropriate pharmacist involvement whenever equipment is used for medication administration; further,

To monitor the impact of the Centers for Medicare & Medicaid Services quality standards on the accreditation of suppliers of medication-related durable medical equipment and supplies.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Federal and state regulation of home medical equipment (HME) and durable medical equipment (DME) suppliers creates a gap in pharmacist review and input in medication-related aspects of the services these suppliers provide to patients, particularly when a patient is discharged from the hospital to the home. The Centers for Medicare & Medicaid Services (CMS) provides conditions of participation for home health services, and states may regulate HME and DME suppliers, home health agencies, and suppliers of medical gases. Furthermore, CMS has proposed surety bond requirements for pharmacies that are also DME suppliers. The Council recommended and the Board and House agreed that ASHP should advocate for consistent

regulatory oversight of these medication-related aspects so that this medication-use process ensures patient safety, improves continuity of care, and guarantees appropriate pharmacist involvement.

1008
EMPLOYMENT CLASSIFICATION AND DUTY HOURS OF PHARMACY RESIDENTS
Source: Council on Public Policy

To advocate that pharmacy residents should be classified as exempt employees; further,

To advocate that pharmacy residents be subject to duty hour limits (similar to resident physicians) with respect to all clinical and academic activities during their training program in accordance with the Accreditation Council on Graduate Medical Education (ACGME) standards and ASHP accreditation standards for pharmacy residency programs.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
In some states, pharmacy residents are classified as non-exempt employees (eligible for overtime pay) in accordance with guidance from state employment offices. ASHP believes that there is an important job classification distinction between pharmacists employed by a hospital or health system and pharmacy residents who are part of an organization's residency program. Specifically, pharmacy residents are in an organized, directed, and accredited postgraduate training program that builds upon knowledge, skills, attitudes, and abilities gained from an accredited professional pharmacy-degree program. Pharmacy residents receive a salary and are subject to the same duty hours as physicians. Classifying pharmacy residents as non-exempt employees is overly burdensome and counterproductive to the residency experience and the objectives of the training program. Moreover, such misclassification could inhibit the development of an important component of the pharmacy workforce at a time of increased demand for pharmacist services as health care reform is implemented.

1009
PRESERVATION OF ANTIMICROBIALS FOR MEDICAL TREATMENT

This policy was superseded by ASHP policy 1517.

1010
SAFETY AND EFFECTIVENESS OF ETHANOL FOR TREATMENT OF ALCOHOL WITHDRAWAL SYNDROME

This policy was superseded by ASHP policy 1514.

1011
USE OF SURROGATE ENDPOINTS FOR FDA APPROVAL OF DRUG USES

This policy was superseded by ASHP policy 2007.

1012
QUALITY CONSUMER MEDICATION INFORMATION

This policy was superseded by ASHP policy 1513.

1014
INTERPROFESSIONAL EDUCATION AND TRAINING

This policy was superseded by ASHP policy 1612.

1015
MINIMUM HIRING STANDARDS FOR PHARMACY TECHNICIANS

This policy was superseded by ASHP policy 1519.

1016
PHARMACEUTICAL DISTRIBUTION SYSTEMS

This policy was superseded by ASHP policy 1707.

1017
IMPACT OF INSURANCE COVERAGE DESIGN ON PATIENT CARE DECISIONS

This policy was superseded by ASHP policy 1809.

1018
STANDARDIZATION OF DEVICE CONNECTIONS TO AVOID WRONG-ROUTE ERRORS

This policy was superseded by ASHP policy 1530.

1019
MEDICATION SAFETY OFFICER ROLE

This policy was discontinued in 2015.

1020
ROLE OF PHARMACISTS IN SAFE TECHNOLOGY IMPLEMENTATION

This policy was superseded by ASHP policy 2520.

1021
JUST CULTURE AND REPORTING MEDICATION ERRORS
Source: Council on Pharmacy Practice

To encourage pharmacists to exert leadership in establishing a just culture in their workplaces and a nonpunitive systems approach to addressing medication errors while supporting a nonthreatening reporting environment to encourage pharmacy staff and others to report actual and potential medication errors in a timely manner; further,

To provide leadership in supporting a single, comprehensive, hospital- or health-system-specific medication error reporting program that (1) fosters a confidential, nonthreatening, and nonpunitive environment for the submission of medication error reports; (2) receives and analyzes these confidential reports to identify system-based causes of medication errors or potential errors; and (3) recommends and disseminates error prevention strategies; further,

To provide leadership in encouraging the participation of all stakeholders in the reporting of medication errors to this program.

(*Note:* A just culture is one that has a clear and transparent process for evaluating errors and separating events arising from flawed system design or inadvertent human error from those caused by reckless behavior, defined as a behavioral choice to consciously disregard what is known to be a substantial or unjustifiable risk.)

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
"Just culture" is an approach to medical error management that recognizes individual accountability for behavioral choices that compromise safety. The concept of "just culture" was first introduced by Sidney Dekker, a pilot and systems engineer, who recommended a different approach to the view that management of medical error should take a strict systems approach with a "no blame" attitude regarding individual accountability. David Marx, a lawyer and engineer, added additional background and recommendations, including criteria for determining whether error is "human" (i.e., inadvertent and unintended) or the result of behavioral choices that introduce risk.

"Just culture" differs from the "no blame" approach in two ways: (1) intentional actions that introduce risk or lead to error are acknowledged, and (2) an algorithm or criteria are used to determine the type of corrective action that should be taken (e.g., coaching or disciplinary action). "Just culture" has come to be accepted over the "no blame" approach because it allows

the safety and health care community to address what Dekker and Marx characterize as at-risk and reckless behavior as causes of error.

1022
PATIENT ACCESS TO PHARMACY SERVICES IN SMALL AND RURAL HOSPITALS

This policy was superseded by ASHP policy 2110.

1023
CONSISTENT AND TIMELY ACCESS TO PHARMACIST MEDICATION ORDER VERIFICATION
Source: Council on Pharmacy Practice

To support the principle that all patients should have 24-hour access to a pharmacist responsible for their care, regardless of hospital size or location; further,

To advocate alternative methods of pharmacist review of medication orders (such as remote review) before drug administration when onsite pharmacist review is not available; further,

To support the use of remote medication order review systems that communicate pharmacist approval of orders electronically to the hospital's automated medication distribution system; further,

To promote the importance of pharmacist access to pertinent patient information, regardless of proximity to patient.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Pharmacist prospective order review is a well-supported safety practice that is required by regulatory bodies (e.g., the Centers for Medicare & Medicaid Services Conditions of Participation, Joint Commission accreditation standards for hospitals) and in state practice acts. Current ASHP policy supports pharmacist prospective order review and a consistent standard of care for all patients regardless of where that care is provided, including in emergency department settings.

1025
ASHP STATEMENT ON BAR-CODE VERIFICATION DURING INVENTORY, PREPARATION, AND DISPENSING OF MEDICATIONS
Source: Section of Pharmacy Informatics and Technology

To approve the ASHP Statement on Bar-code Verification During Inventory, Preparation, and Dispensing of Medications.

This statement was reviewed in 2016 by the Section of Pharmacy Informatics and Technology and by the Board of Directors and was found to still be appropriate.

2009 Policy Positions

0901
WORKLOAD MONITORING AND REPORTING
Source: House of Delegates Resolution

To strongly discourage the use of pharmacy workload and productivity measurement systems ("pharmacy benchmarking systems") that are based solely upon dispensing functions (e.g., doses dispensed or billed) or a variant of patient days, because such measures do not accurately assess pharmacy workload, staffing effectiveness, clinical practice contributions to patient care, or impacts on costs of care, and therefore these measurement systems are not valid and should not be used; further,

To advocate the development and implementation of pharmacy benchmarking systems that accurately assess the impact of pharmacy services on patient outcomes and total costs of care; further,

To define pharmacy workload as all activities related to providing pharmacy patient care services; further,

To continue communications with health-system administrators, consulting firms, and professional associations regarding the value of pharmacists' services and the importance of using valid, comprehensive, and evidence-based measures of pharmacy workload and productivity; further,

To encourage practitioners and vendors to develop and use a standard protocol for collecting and reporting pharmacy workload data and patient outcomes; further,

To advocate to health-system administrators, consulting firms, and vendors of performance-measurement services firms the development and implementation of pharmacy benchmarking systems that accurately assess the impact of pharmacy services on patient outcomes and total costs of care.

This policy was reviewed in 2024 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Although the practice of health-system pharmacy has evolved and changed significantly over the past three decades, benchmarking systems used to gauge the value and productivity of health-system pharmacy have remained largely unchanged. Productivity measures based solely on dispensing functions or a variant of patient days are not valid tools to assess current health-system pharmacy practice. These outdated measures do not reflect ASHP's aspirations for health-system pharmacy (e.g., ASHP best practices, ASHP PAI 2030) or the high-value pharmacy enterprise framework. Use of these inappropriate productivity recommendations may result in

inadequate staffing, which increases stress on pharmacy leadership, discourages pharmacists from becoming pharmacy directors, and contributes to the leadership gap in health-system pharmacy. Alternative benchmarking systems that more accurately reflect the value of health-system pharmacy services with respect to productivity, clinical and financial outcomes, and medication safety have been developed.

0902
PHARMACIST'S ROLE IN PROVIDING CARE FOR AN AGING POPULATION

This policy was discontinued in 2023.

0903
PHARMACEUTICAL WASTE
Source: Council on Pharmacy Practice

To collaborate with regulatory bodies and appropriate organizations to develop standards for the disposal of pharmaceutical hazardous waste as defined in the Resource Conservation and Recovery Act (RCRA), for the purpose of simplifying the disposal of these substances by health systems; further,

To encourage pharmaceutical manufacturers and the Environmental Protection Agency (EPA) to provide guidance and assistance to hospitals and health systems in proper pharmaceutical waste disposal and destruction efforts; further,

To advocate that EPA update the list of hazardous substances under RCRA and establish a process for maintaining a current list; further,

To urge federal, state, and local governments to harmonize regulations regarding disposal of hazardous pharmaceutical waste; further,

To advocate that the Food and Drug Administration standardize labeling of drug products with information relating to appropriate disposal; further,

To promote awareness within hospitals and health systems of pharmaceutical waste regulations; further,

To encourage research on the environmental and public health impacts of drug products and metabolites excreted in human waste; further,

To encourage pharmaceutical manufacturers to streamline packaging of drug products to reduce waste materials.

This policy was reviewed in 2024 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale

ASHP seeks to define pharmacists' responsibility to the public for safe disposal of hazardous pharmaceutical waste as well as to assist with their responsibility to comply with applicable regulations. ASHP believes that barriers to safe disposal of hazardous pharmaceutical waste include obsolete waste lists, variability in requirements, inadequate labeling, a lack of research, and a lack of training.

Obsolete lists. The waste stream for hazardous pharmaceuticals is in part determined by the RCRA waste list (i.e., P or U list) to which the drug is assigned. However, these lists do not include all medications, especially newer products. If a drug is not listed, individual organizations either follow the method of disposal listed for similar drugs or drug classes or use no special disposal method at all. Minimally hazardous drugs are included on these lists, creating needlessly burdensome disposal requirements.

Variability in requirements. Regulations vary from state to state and even from county to county. Large hospital systems are forced to create site-specific policies, which complicates communication and education about the appropriate management of waste.

Labeling. Ensuring that products for disposal are directed into the proper waste stream is left up to health care organizations. Many apply auxiliary labeling on-site to communicate this information. It would be more logical and efficient for the manufacturer to include this information in product labeling. Labeling immediate containers with disposal directions would ensure that this information reached the end-user of the product. One example of how this might be done is the method used by the National Fire Protection Agency, which identifies hazards with specific symbols.

Research. Little research or guidance is available on the environmental effect of hazardous metabolites excreted in human waste. More research is needed in this area.

Training. Initial and ongoing training is needed to ensure health care staff are aware of and empowered to adhere to organizational procedures and standards.

0904

AUTOMATIC STOP ORDERS

This policy was superseded by ASHP policy 1405.

0907

PHARMACEUTICAL PRODUCT AND SUPPLY CHAIN INTEGRITY

This policy was superseded by ASHP policy 1503.

0908

PHARMACIST ROLE IN THE HEALTH CARE (MEDICAL) HOME

Source: Council on Public Policy

To advocate to health policymakers, payers, and other stakeholders for the inclusion of pharmacists as a care provider within the health care (medical) home model; further,

To ensure that there are appropriate reimbursement mechanisms for the care that pharmacists provide (including care coordination services) within the health care home model; further,

To advocate to the Centers for Medicare & Medicaid Services that pharmacists be included in demonstration projects for the health care home model; further,

To encourage comparative effectiveness research and measurement of key outcomes (e.g., clinical, economic, quality, access) for pharmacist services in the health care home model.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The concept of a "health care home," also referred to as a "medical home," was first described by the American Academy of Pediatrics in 1992. The health care (medical) home model emphasizes care coordination from a medical practice and uses an interdisciplinary health care team approach to managing a patient's overall health. A recent Medicare Payment Advisory Commission (MedPAC) report discussed a health care home program in Medicare and stated that medication reviews conducted by a health care home would ideally be coordinated by a pharmacist. As the Centers for Medicare & Medicaid Services (CMS) begins health care home demonstration projects, it is important that a pharmacist be included in the health care home model and that pharmacists be factored into the compensation for services provided. To determine the effectiveness of the care that is delivered, research and measurement of key outcomes are important elements of any demonstration or permanent delivery model.

0909

REGULATION OF INTERSTATE PHARMACY PRACTICE

Source: Council on Public Policy

To advocate that state governments, including legislatures and boards of pharmacy, adopt laws and regulations that harmonize the practice of pharmacy across state lines in order to provide a consistent, transparent, safe, and accountable framework for pharmacy practice.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

With the emergence of new technology, state borders are becoming more artificial and coordination between states is increasingly needed. To achieve the highest level of patient safety possible, state regulatory bodies need to work closely together to provide a consistent and transparent regulatory framework for pharmacy practice. Dialogue between the National Association of Boards of Pharmacy and individual state boards can help harmonize the practice of pharmacy across state lines by producing model language that can be adopted by individual states.

0910
REPORTING MEDICATION ERRORS

This policy was superseded by ASHP policy 1021.

0911
STABLE FUNDING FOR OFFICE OF PHARMACY AFFAIRS

This policy was superseded by ASHP policy 1219.

0912
SAFE AND EFFECTIVE USE OF HEPARIN IN NEONATAL PATIENTS
Source: Council on Therapeutics

To support the development and use of nationally standardized concentrations of heparin when used for maintenance and flush of peripheral and central venous lines in neonatal patients; further,

To advocate that hospitals and health systems use manufacturer-prepackaged heparin flush products to improve the safe use of heparin in neonatal patients.

This policy was reviewed in 2024 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

Rationale
The preferential use of saline to maintain peripheral lines and devices in adult patients has largely become the standard of care, but use of heparin in neonates continues because of a lack of consensus and perceived and actual limitations in the evidence in published literature. However, fatal medication errors caused by the use of heparin in this patient population have brought to the forefront concern that the risks of using heparin for this purpose may outweigh the potential benefits. The ASHP Therapeutic Position Statement on the Institutional Use of 0.9% Sodium Chloride Injection to Maintain Patency of Peripheral Indwelling Intermittent Infusion Devices provides evidence for the use of sodium chloride as the preferred solution for maintaining peripheral lines in adult patients but does not address the use of sodium chloride versus heparin in patients younger than 12 years of age, because at the time of publication there was a lack of sufficient evidence regarding the effectiveness of sodium chloride solution for flushing peripheral lines or maintaining their patency in neonatal and pediatric patient populations.

ASHP's Council on Therapeutics has reviewed evidence from evaluations of the use of 0.9% sodium chloride and heparin to maintain and flush arterial and central lines in neonatal patients and reports of medication errors that involved heparin. The advantages of saline include greater compatibility than heparin with concurrently administered drug therapies, lower product costs, fewer potential adverse drug events (e.g., heparin-induced thrombocytopenia, a rare but potentially fatal event for neonatal patients), and prevention of potential medication errors related to improper selection or dilution of heparin products.

Advantages of heparin use include extended line patency and a beneficial antithrombotic effect at the insertion site. The data are conflicting and insufficient to support the recommendation of a preferred solution for line maintenance in neonatal patients at this time. The development of standardized concentrations of heparin to decrease practice variation and the use of manufacturer-prepackaged products are the best ways to improve the safe use of heparin in neonatal patients.

The ASHP Standardize 4 Safety Initiative includes standardized concentrations for heparin in the pediatric population. However, it does not include recommended standardized concentrations of heparin used for maintenance and flush of peripheral and central venous lines in neonatal patients. There is still a need for clear, concise guidance on a recommended standardized dose for this indication in the pediatric population.

In addition, with drug shortages becoming more common, it may not be possible for health systems to use one standard concentration, or it may be necessary to compound products if the manufactured-prepackaged product is not available. It is important for institutions to create multidisciplinary teams to develop allocation strategies based on defined criteria to utilize the quantity at hand (i.e., based on the weight of the patient). In addition, the development and use of standard protocols to ensure safe use of multiple concentrations (e.g., barcode scanning) and promote safe compounding.

0913

PHARMACY STUDENT EXPERIENCES IN MEDICALLY UNDERSERVED AREAS

Source: Council on Education and Workforce Development

To encourage colleges of pharmacy to require student learning experiences in traditionally medically underserved areas and with diverse patient populations.

This policy was reviewed in 2024 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

Numerous reports demonstrate how student pharmacists and practice sites benefit from experiential rotations in rural, rural and remote, and urban settings, especially in settings or areas classified as medically underserved. Students learn about the cultural, financial, language, and other challenges encountered in these settings, and these skills are often invaluable when they enter practice. In addition, a student's exposure to a new practice area may result in more interest in such sites and provide career choices that might otherwise not have been considered. ASHP does not support mandating rotations in these settings, since there are many ways to provide these interactions, and there are concerns about how colleges could develop an infrastructure for providing these experiences.

The challenges of finding good teaching sites in these settings are formidable and include a limited number of sites, a lack of qualified preceptors, and geographic distance from the college that result in housing needs. The Accreditation Council for Pharmacy Education (ACPE) currently requires colleges of pharmacy to ensure that graduates can provide patient-centered care that addresses cultural factors. Although experiential rotations may be the most common way for students to be exposed to diverse patient populations, there are many other

creative ways in which this goal is being accomplished. Some colleges, for example, require students to perform service-learning projects with a focus on underserved populations.

0914
EDUCATION ABOUT PATIENT SAFETY IN THE MEDICATION-USE PROCESS

This policy was discontinued in 2014.

0915
PHARMACY EXPERTISE IN THE PREPARATION AND HANDLING OF INJECTABLE MEDICATIONS

This policy was superseded by ASHP policy 1911.

0916
CONTINUING PROFESSIONAL DEVELOPMENT
Source: Council on Education and Workforce Development

To endorse and promote the concept of continuing professional development (CPD), which involves personal self-appraisal, educational plan development, plan implementation, documentation, and evaluation; further,

To continue the development of a variety of mechanisms and tools that pharmacists can use to assess their CPD needs; further,

To encourage individual pharmacists to embrace CPD as a means of maintaining their own professional competence; further,

To encourage pharmacy managers to promote CPD as the model for ensuring the competence of their staff; further,

To collaborate with other pharmacy organizations, state boards of pharmacy, accrediting bodies, and regulatory bodies in the development of effective methods for implementing CPD; further,

To strongly support objective assessment of the impact of CPD on pharmacist competence; further,

To endorse the efforts of colleges of pharmacy and ASHP-accredited pharmacy residency programs to teach the principles, concepts, and skills of CPD.

This policy was reviewed in 2024 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

Maintaining competence throughout one's career is part of a professional's obligation. Traditionally, this has been done through continuing education (CE) activities, but CE has several shortcomings. There is often no mechanism to ensure that CE is effective, since most CE activities have no summative evaluation component. (Summative evaluation takes place at the completion of a program to determine whether goals and objectives have been met.) In addition, CE programs are not usually curricular, are not always competency-directed, and tend to be content-oriented rather than skill-based. There is little evidence that CE changes practice or has an impact on patient outcomes.

Continuing professional development (CPD) is a model that addresses many of the shortcomings of the CE model. CPD differs from CE in that it is ongoing and includes the entire scope of an individual's practice, it is often undertaken in partnership with the professional's employer, it is practitioner-centered and self-directed, and it is intended to be outcomes-oriented. Many pharmacy professionals already assume responsibility for their professional growth and development by reflecting on their practice, recognizing needs, and seeking educational opportunities and activities that will meet those needs. Even when these activities are not documented or reported, this process incorporates many of the principles of CPD.

CPD is a cyclical, five-step process that begins with a self-appraisal by the individual professional to determine educational needs and progresses through the development of a personal plan to meet those needs, an action phase in which the professional participates in the activities identified in the personal plan, a documentation component in which the professional keeps records of all CPD activities in which he or she participates, and an evaluation phase to determine whether the CPD needs were met, if practice has been improved, if patients have benefited, and if learning was or was not accomplished (and why). This step then feeds back into the self-appraisal stage and the cycle continues.

In the self-appraisal phase, identification of CPD needs may be accomplished through personal assessment, performance review by a manager or supervisor, an audit exercise undertaken with other professionals, or as a requirement of a professional organization or regulatory body. There are a variety of mechanisms that pharmacists can use to self-assess their CPD needs. Self-assessment is not a skill most professionals learn during their professional education and training, however. For CPD to be effective, professionals must learn this skill before entering the CPD cycle, in colleges of pharmacy and residency programs.

In the next phase, the personal plan, the professional identifies resources and actions to meet the identified CPD needs. Activities may be informal, such as study clubs, observation of a colleague's practice, and conversations with colleagues, or they may be more formal, such as CE workshops, short courses, seminars, self-study programs, or graduate-level course work.

Whether formal or informal, managed CPD requires the documentation of participation in these activities. This documentation becomes the foundation of the professional's CPD portfolio. Documentation of participation in formal activities is usually given by the provider, but more informal and self-directed activities, such as observation of a colleague's practice, require the individual to establish a format for documentation in the portfolio.

In the final phase, which feeds back into self-appraisal, the professional self-evaluates, is evaluated by a manager or supervisor, enlists the aid of peers, or is evaluated by an external

(e.g., regulatory) body. It is important in this phase to determine whether learning was or was not accomplished (and if not, why not) and to feed this back into the ongoing CPD cycle.

0917
PHARMACY RESIDENCY TRAINING

This policy was superseded by ASHP policy 2411.

0918
PHARMACIST LEADERSHIP OF THE PHARMACY DEPARTMENT

This policy was superseded by ASHP policy 2334.

0919
INTIMIDATING OR DISRUPTIVE BEHAVIORS

This policy was superseded by ASHP policy 1916.

0920
STANDARDIZED CLINICAL DRUG NOMENCLATURE
Source: Council on Pharmacy Management

To encourage federal agencies, the pharmaceutical industry, pharmacy and medical software providers, and purveyors of clinical data repositories and drug databases to explore the potential benefits of supplementing or modifying the National Drug Code with a coding system that can be used effectively to support patient care, research, and financial management; further,

To encourage that such a coding system encompass prescription drug products, nonprescription medications, and dietary supplements and include both active and inactive ingredients.

This policy was reviewed in 2024 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Clinical decision support systems (CDSS) in computerized provider order entry (CPOE) and pharmacy information systems have been widely used for screening drug interactions and patient allergies. For this screening to be effective, a baseline coding structure for medications must be available, and the coding system needs to include prescription and nonprescription medications, dietary supplements, and drug excipients.

The National Committee on Vital and Health Statistics (NCVHS) has recommended regulatory changes to give the Food and Drug Administration (FDA) full control over the National Drug Code (NDC). Currently, FDA controls only a portion, and manufacturers control the remainder. FDA has made recommendations for uniform standards to enable electronic prescribing (e-prescribing) in ambulatory care. During the past several years, NCVHS has

focused considerable attention on the feasibility and desirability of standards to support e-prescribing and the need for standard terminology for clinical drugs to facilitate automated drug-use review and decision support for patient safety. In previous reports, NCVHS documented NDC shortcomings, most notably concern about perceived weaknesses of the current NDC database and linkage of the NDC to RxNorm concepts. NCVHS expressed the need for harmonization of terminologies to eliminate incompatibilities that impair drug utilization studies and may negatively affect patient safety. RxNorm, a standardized nomenclature for clinical drugs, is produced by the National Library of Medicine. In RxNorm, the name of a clinical drug combines its ingredients, strengths, and form. RxNorm has limitations, however; it does not identify a product's excipients or include herbal products or nonprescription medications.

0921
PHARMACIST'S ROLE IN HEALTH CARE INFORMATION SYSTEMS

This policy was superseded by ASHP policy 1211.

0922
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN ANTIMICROBIAL STEWARDSHIP AND INFECTION PREVENTION AND CONTROL
Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control.

This statement was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

0923
ASHP STATEMENT ON THE HEALTH-SYSTEM PHARMACIST'S ROLE IN NATIONAL HEALTH CARE QUALITY INITIATIVES
Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Health-System Pharmacist's Role in National Health Care Quality Initiatives.

This statement was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

2008 Policy Positions

0801
ALTERNATIVE DRUG CODING SYSTEMS

This policy was superseded by ASHP policy 0920.

0802
ROLE OF PHARMACY INTERNS

This policy was superseded by ASHP policy 1110.

0803
STANDARDIZED PHARMACY TECHNICIAN TRAINING AS A PREREQUISITE FOR CERTIFICATION

This policy was discontinued in 2013.

0804
COLLABORATION REGARDING EXPERIENTIAL EDUCATION

This policy was superseded by ASHP policy 1827.

0805
ENTRY-LEVEL DOCTOR OF PHARMACY DEGREE

This policy was discontinued in 2013.

0806
HEALTH-SYSTEM USE OF MEDICATIONS AND ADMINISTRATION DEVICES SUPPLIED DIRECTLY TO PATIENTS

This policy was superseded by ASHP policies 2032 and 2033.

0808
DISCLOSURE OF EXCIPIENTS IN DRUG PRODUCTS

This policy was superseded by ASHP policy 1528.

0809
MEDICATIONS DERIVED FROM BIOLOGIC SOURCES

This policy was discontinued in 2018.

0810

EDUCATION, PREVENTION, AND ENFORCEMENT CONCERNING WORKPLACE VIOLENCE

Source: Council on Public Policy

To advocate that federal, state, and local governments recognize the risks and consequences of workplace violence in the pharmacy community and enact appropriate criminal penalties; further,

To collaborate with federal, state, and local law enforcement and other government authorities on methods for early detection and prevention of workplace violence; further,

To encourage all workplace environments to develop and implement a policy for pharmacy personnel that (1) educates about prevention and deterrence of workplace violence, (2) identifies escalating situations that can lead to violence and instructs employees on protection and self-defense, and (3) provides continued support and care to heal personnel who were directly or indirectly involved in an incident of workplace violence; further,

To encourage the health care community to develop and maintain a communication network to share information about incidents of potential and real workplace violence.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Workplace violence is defined by the U.S. Department of Labor as "…any act or threat of physical violence, harassment, intimidation, or other threatening disruptive behavior that occurs at the work site." Although workplace violence is a widespread public health issue, the Occupational Safety and Health Administration has recognized that workplace violence in healthcare settings is almost four times greater than in private industry. Pharmacists are high-risk targets due to their public proximity and their access to drugs and money in a pharmacy. This issue has grown in prominence as a result of rising levels of violence in healthcare workplaces as a result of the COVID-19 pandemic. OSHA provides guidelines for the creation and implementation of programs for preventing workplace violence for healthcare and social services workers.

0811

REGULATION OF DIETARY SUPPLEMENTS

Source: Council on Public Policy

To advocate that Congress grant authority to the Food and Drug Administration (FDA) to (1) require that dietary supplements undergo FDA approval for evidence of safety and efficacy; (2) mandate FDA-approved dietary supplement labeling that includes disclosure of excipients; (3) mandate FDA-approved patient information materials that describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; and (4) establish and maintain an adverse-event reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to the FDA; further,

To oppose direct-to-consumer advertising of dietary supplements unless the following criteria are met: (1) federal laws are amended to include all the requirements described above to ensure that dietary supplements are safe and effective; (2) evidence-based information regarding safety and efficacy is provided in a format that allows for informed decision-making by the consumer; (3) the advertising includes a recommendation to consult with a health care professional before initiating use; (4) any known warnings or precautions regarding dietary supplement–medication interactions or dietary supplement–disease interactions are provided as part of the advertising; and (5) the advertising is educational in nature and includes pharmacists as a source of information.

(*Note:* Dietary supplement as used in this policy is defined by the Dietary Supplement Health and Education Act of 1994, as amended; 21 U.S.C. 321.)

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), manufacturers are prohibited from marketing adulterated or misbranded products, and the Food and Drug Administration (FDA) has authority to take action if adulterated or misbranded dietary supplements reach the market. To ensure a safe market for dietary supplements, the FDA needs the authority to require manufacturers to conduct safety and efficacy testing for dietary supplements, provide labeling and information about the content of the product and its safe use, and report suspected adverse reactions to FDA.

In 2007, the FDA announced final regulations requiring current Good Manufacturing Practices (GMPs) for dietary supplements that include testing ingredients and the final product. While the FDA does require all manufacturers to adhere to GMPs, not all supplement manufacturers are GMP certified.

Under the current regulatory and legislative regime, direct-to-consumer advertising of dietary supplements should not occur unless specified criteria are met. Dietary supplement advertising should be strictly regulated by the FDA and the Federal Trade Commission (FTC) to ensure it is truthful and substantiated. The FDA and FTC have published guidance for industry concerning dietary supplement claims. The FDA is primarily responsible for claims on product labeling, while FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials.

0812

APPROPRIATE STAFFING LEVELS

Source: Council on Public Policy

To advocate that pharmacists at each practice site base the site's pharmacist and technician staffing levels on patient safety considerations, taking into account factors such as (1) acuity of care, (2) breadth of services, (3) historical safety data, and (4) results of research on the relationship between staffing patterns and patient safety; further,

To advocate that regulatory bodies not mandate specific, uniform pharmacy personnel ratios but rather ensure that site-specific staffing levels optimize patient safety; further,

To encourage additional research on the relationship between pharmacy staffing patterns and patient safety.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale

The purpose of any staffing level should be to ensure quality patient care as well as patient and provider safety. Factors to be considered in developing an appropriate staffing level include acuity of care, breadth of services, historical safety data, and results of research on the relationship between staffing patterns and patient safety. Given the complexity of determining appropriate staffing, regulatory bodies should not mandate a specific staffing ratio in general or for specific practice settings. Rather, pharmacy leaders should exercise their professional judgment to determine the appropriate staffing level for achieving quality patient care. Such a model allows flexibility to base staffing levels on factors specific to each site. ASHP acknowledges the need for additional research on staffing models to support staffing levels that provide safe and effective patient care to aid pharmacy leaders in making such determinations.

ASHP recognizes the legitimate need for boards of pharmacy to assure minimum standards of practice to protect the public health. The ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals states, "The pharmacy shall employ an adequate number of competent, legally qualified pharmacists to meet the specific medication-use needs of the hospital's patients" and "sufficient support personnel (e.g., pharmacy technicians and clerical or secretarial personnel) shall be employed to facilitate pharmacy services." Pharmacy leaders are the healthcare professionals best suited to making those determinations.

0813

MEDICARE PRESCRIPTION DRUG BENEFIT

Source: Council on Public Policy

To strongly advocate a fully funded prescription drug program for eligible Medicare beneficiaries that maintains continuity of care and ensures the best use of medications; further,

To advocate that essential requirements in the program include (1) appropriate product reimbursement; (2) affordability for patients, including elimination of coverage gaps; (3) payment for indirect costs and practice expenses related to the provision of pharmacist services, based on a study of those costs; (4) appropriate coverage and payment for patient care services provided by pharmacists; (5) open access to the pharmacy provider of the patient's choice; (6) formularies with sufficient flexibility to allow access to medically necessary drugs; and (7) well-publicized, unbiased resources to assist beneficiaries in enrolling in the most appropriate plan for their medication needs.

This policy was reviewed in 2025 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate

Rationale

Fully funded means the federal government will make adequate funds available to fully cover the Medicare program's share of prescription drug program costs. Eligible means the federal government may establish criteria by which Medicare beneficiaries qualify for the prescription drug program.

0814

FEDERAL REVIEW OF ANTICOMPETITIVE PRACTICES BY DRUG PRODUCT MANUFACTURERS

This policy was superseded by ASHP policy 1818.

0815

UNIFORM STATE LAWS AND REGULATIONS REGARDING PHARMACY TECHNICIANS

This policy was superseded by ASHP policy 1216.

0817

GENERIC SUBSTITUTION OF NARROW THERAPEUTIC INDEX DRUGS

Source: Council on Therapeutics

This policy was discontinued in 2025.

0818

ASHP STATEMENT ON BAR-CODE-ENABLED MEDICATION ADMINISTRATION

Source: ASHP Section of Pharmacy Informatics and Technology

To approve the ASHP Statement on Bar-Code-Enabled Medication Administration.

0819

ASHP STATEMENT ON THE ROLES AND RESPONSIBILITIES OF THE PHARMACY EXECUTIVE

Source: Council on Pharmacy Management

This statement was superseded by ASHP policy 1532.

0820

ASHP STATEMENT ON STANDARDS-BASED PHARMACY PRACTICE IN HOSPITALS AND HEALTH SYSTEMS

Source: Council on Pharmacy Management

To approve the ASHP Statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems.

This statement was reviewed in 2023 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

0821
ASHP STATEMENT ON PHARMACY SERVICES TO THE EMERGENCY DEPARTMENT
Source: Council on Pharmacy Practice

This statement was discontinued in 2020.

0822
ASHP STATEMENT ON THE PHARMACY AND THERAPEUTICS COMMITTEE AND THE FORMULARY SYSTEM
Source: Council on Pharmacy Practice
To approve the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System.

This statement was discontinued in 2020.

0823
ASHP STATEMENT ON CONFIDENTIALITY OF PATIENT HEALTH CARE INFORMATION
Source: Council on Public Policy
To approve the ASHP Statement on Confidentiality of Patient Health Care Information.

This statement was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

0824
ASHP STATEMENT ON CRITERIA FOR AN INTERMEDIATE CATEGORY OF DRUG PRODUCTS
Source: Council on Therapeutics

This policy was discontinued in 2023.

2007 Policy Positions

0701
REQUIREMENT FOR RESIDENCY

This policy was superseded by ASHP policy 2027.

0702
PHARMACY TECHNICIAN TRAINING

This policy was superseded by ASHP policy 1519.

0704
RESIDENCY PROGRAMS
Source: Council on Education and Workforce Development
To strongly advocate that all pharmacy residency programs become ASHP-accredited as a means of ensuring and conveying program quality.

This policy was reviewed in 2022 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

0705
ASHP GUIDELINES, STATEMENTS, AND PROFESSIONAL POLICIES AS AN INTEGRAL PART OF THE EDUCATIONAL PROCESS

This policy was superseded by ASHP policy 1706.

0706
ADMINISTERING INJECTABLE MEDICATIONS SUPPLIED DIRECTLY TO PATIENTS

This policy was superseded by ASHP policy 0806.

0707
STANDARD DRUG ADMINISTRATION SCHEDULES

This policy was superseded by ASHP policy 2252.

0708
PAY-FOR-PERFORMANCE REIMBURSEMENT

This policy was superseded by ASHP policy 1209.

0709

PRINCIPLES OF MANAGED CARE

This policy was discontinued in 2013.

0711
INSTITUTIONAL REVIEW BOARDS AND INVESTIGATIONAL USE OF DRUGS

This policy was superseded by ASHP policy 2207.

0712
ELECTRONIC HEALTH AND BUSINESS TECHNOLOGY AND SERVICES
Source: Council on Pharmacy Practice

To encourage pharmacists to assume a leadership role in their hospitals and health systems with respect to strategic planning for and implementation of electronic health and business technology and services; further,

To encourage hospital and health-system administrators to provide dedicated resources for pharmacy departments to design, implement, and maintain electronic health and business technology and services; further,

To advocate the inclusion of electronic health technology and telepharmacy issues and applications in college of pharmacy curricula.

This policy was reviewed in 2017 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

0713
TOBACCO AND TOBACCO PRODUCTS

This policy was superseded by ASHP policy 1224.

0714
RESTRICTED DRUG DISTRIBUTION

This policy was superseded by ASHP policy 1714.

0715
PATIENT ACCESS TO ORPHAN DRUG PRODUCTS

This policy was superseded by ASHP policy 1821.

0716

REGULATION OF TELEPHARMACY SERVICES

This policy was superseded by ASHP policy 1310.

0717
PERSONNEL RATIOS

This policy was superseded by ASHP policy 0812.

0718
DIRECT-TO-CONSUMER ADVERTISING OF DIETARY SUPPLEMENTS

This policy was superseded by ASHP policy 0811.

0719
FDA AUTHORITY TO PROHIBIT REUSE OF BRAND NAMES
Source: Council on Public Policy

To advocate for Food and Drug Administration authority to prohibit reuse of brand names of prescription and nonprescription drugs when any active component of the product is changed or after any other changes are made in the product that may affect its safe use.

This policy was reviewed in 2022 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
To avoid patient safety risks and provider error, FDA should not reuse brand names for drugs. In particular, recent examples of the reuse of product names or minor changes to product names in the nonprescription category (e.g., Zantac 360, Dramamine Drug-Free) have resulted in patient and provider confusion.

0720
STANDARDIZING PREFIXES AND SUFFIXES IN DRUG PRODUCT NAMES
Source: Council on Public Policy

To collaborate with others, including the United States Pharmacopeia and the Food and Drug Administration, in standardizing and defining the meaning of prefixes and suffixes for prescription and nonprescription drugs to prevent medication errors and ensure patient safety.

This policy was reviewed in 2022 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

0721
MEDICARE PRESCRIPTION DRUG BENEFIT

This policy was superseded by ASHP policy 0813.

0723

REMOVAL OF PROPOXYPHENE FROM THE MARKET

This policy was discontinued in 2012.

0724
ASHP STATEMENT ON THE ROLE OF HEALTH-SYSTEM PHARMACISTS IN PUBLIC HEALTH
Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Role of Health-System Pharmacists in Public Health.

This statement was superseded by ASHP policy 2119.

0725
ASHP STATEMENT ON PROFESSIONALISM

This statement was superseded by ASHP policy 2202.

0726
ASHP STATEMENT ON RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE

This policy was discontinued in 2025 by the ASHP Board of Directors on April 3, 2025, to ensure compliance with federal law.

2006 Policy Positions

0601
UNIVERSAL INFLUENZA VACCINATION

This policy was superseded by ASHP policy 2121.

0602
MINIMUM EFFECTIVE DOSES

This policy was superseded by ASHP policy 2114.

0603
MEDICATION MANAGEMENT FOR PATIENT ASSISTANCE PROGRAMS

This policy was superseded by ASHP policy 1521.

0604
MINIMIZING THE USE OF ABBREVIATIONS

This policy was superseded by ASHP policy 2132.

0605
PHARMACEUTICAL DISTRIBUTION SYSTEMS

This policy was superseded by ASHP policy 1016.

0608
INTERDISCIPLINARY HEALTH PROFESSIONS EDUCATION

This policy was superseded by ASHP policy 1014.

0610
PHARMACIST'S RIGHT OF CONSCIENCE AND PATIENT'S RIGHT OF ACCESS TO THERAPY

This policy was superseded by ASHP policy 2615.

0611
REDISTRIBUTION OF UNUSED MEDICATIONS

This policy was discontinued in 2021.

0613

FDA AUTHORITY TO PROHIBIT REUSE OF BRAND NAMES

This policy was superseded by ASHP policy 0719.

0614
SAFE DISPOSAL OF PATIENTS' HOME MEDICATIONS
Source: Council on Professional Affairs

To minimize the patient safety consequences and public health impact of inappropriate disposal of patients' home medications by working collaboratively with other interested organizations to (1) develop models for patient-oriented medication disposal programs that will minimize accidental poisoning, drug diversion, and potential environmental impact, (2) advocate that the pharmaceutical industry and regulatory bodies support the development and implementation of such models, and (3) educate health professionals, regulatory bodies, and the public regarding safe disposal of unused home medications.

This policy was reviewed in 2025 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Improper disposal of unused or expired medications poses significant risks to patient safety, public health, and the environment. Accidental ingestion, especially among children and older adults, as well as the diversion of controlled substances, are ongoing concerns tied to medications retained in patients' homes. Disposal of home medications in trash receptacles increases the possibility of accidental poisoning of children and animals and provides inappropriate access to controlled substances that could be used for illicit purposes. Additionally, flushing or discarding medications improperly can contribute to pharmaceutical contamination in water supplies and ecosystems.

Over the past several years, more options have become available for safely disposing and removing unused or expired medications from patient homes. Examples include medication take-back programs, permanent collection receptacles, mail-back programs, and medication deactivation bags. Despite increased patient awareness and availability of these options, standardized, patient-friendly, and affordable disposal programs remain limited. Collaborative efforts among healthcare organizations, regulatory agencies, and the pharmaceutical industry are essential to advance safe, sustainable, and widely adopted disposal solutions.

0615
INFLUENZA VACCINATION REQUIREMENTS TO ADVANCE PATIENT SAFETY AND PUBLIC HEALTH

This policy was superseded by ASHP policy 2138.

0617
ACCREDITATION OF COMPOUNDING FACILITIES

This policy was discontinued in 2016.

0619
INTEGRATED TEAM-BASED APPROACH FOR THE PHARMACY ENTERPRISE

This policy was superseded by ASHP policy 1618.

0620
PHARMACISTS' ROLE IN MEDICATION RECONCILIATION

This policy was superseded by ASHP policy 1117.

0621
STATEMENT ON THE PHARMACIST'S ROLE IN INFORMATICS

This policy was superseded by ASHP policy 1534.

2005 Policy Positions

0501
MANDATORY LABELING OF THE PRESENCE OF LATEX

This policy was discontinued in 2020.

0502
HEALTH CARE QUALITY STANDARDS AND PHARMACY SERVICES

This policy was superseded by ASHP policy 2021.

0503
CRITICAL-ACCESS, SMALL, AND RURAL HOSPITALS

This policy was superseded by ASHP policy 1022.

0504
PHARMACY STAFF FATIGUE AND MEDICATION ERRORS
Source: Council on Administrative Affairs

To encourage pharmacy managers to consider workload fatigue, length of shifts, and similar performance-altering factors when scheduling pharmacy staff, in order to ensure safe pharmacy practices; further,

To oppose state or federal laws or regulations that mandate or restrict work hours for pharmacy staff; further,

To support research on the effects of shift length, fatigue, and other factors on the safe practice of pharmacy.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Many studies have shown that excessively long shifts cause fatigue and can result in significant performance deficits, but other factors can contribute to fatigue. Studies suggest sleep deprivation and fatigue negatively impact the performance of medical residents and nurses, but little has been published regarding the effects of fatigue in the pharmacy workforce. Pharmacy staff fatigue may be attributed to not only the number of hours worked but also the work environment, workload, and other variables not attributable to the workplace (e.g., childcare issues, working a second job, stressful personal situations). Fatigue is a state of physical or mental exhaustion; whereas, burnout is a chronic condition resulting from prolonged stress and fatigue. Chronic exposure to such fatigue can accumulate over time, leading to burnout, which

is characterized by emotional exhaustion, detachment and a reduced sense of personal accomplishment. Although very little has been published on the effects of fatigue, sleep deprivation, or shift length on the performance of pharmacists and pharmacy technicians, and ultimately on patient safety, ASHP believes that pharmacy managers should consider fatigue-inducing factors when scheduling pharmacy staff. Since all these factors must be considered on a case-by-case basis, establishing a strict hour limit for pharmacy staff may not prevent the occurrence of an unsafe worker. ASHP recognizes the need for more research on the impact of work hours and the work environment on the performance of pharmacy staff.

0505
HEALTH-SYSTEM FACILITY DESIGN

This policy was superseded by ASHP policy 2008.

0506
ACCESSIBILITY AND AFFORDABILITY OF PHARMACEUTICALS

This policy was superseded by ASHP policy 1908.

0507
ELECTRONIC INFORMATION SYSTEMS

This policy was superseded by ASHP policy 2015.

0508
FINANCIAL MANAGEMENT SKILLS

This policy was superseded by ASHP policy 1207.

0509
DEVELOPING LEADERSHIP AND MANAGEMENT COMPETENCIES

This policy was superseded by ASHP policy 1518.

0510
HEALTH LITERACY AND COMMUNICATION AMONG HEALTH-SYSTEM PHARMACY PRACTITIONERS, PATIENTS, AND OTHER HEALTH CARE PROVIDERS
Source: Council on Educational Affairs

To foster effective communication (with appropriate attention to patients' levels of general and health literacy) among health-system pharmacy practitioners, patients, and other health care providers; further,

To develop programs to enable pharmacy students, residents, and health-system pharmacy practitioners to self-assess their levels of health literacy and general communication skills; further,

To develop methods with which pharmacy students, residents, and health-system pharmacy practitioners can assess the level of general and health literacy of patients; further,

To disseminate information about resources for students, residents, and health-system pharmacy practitioners to use in working with patients and others having specific communication needs.

This policy was reviewed in 2025 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.

Rationale

Only 12% of Americans have proficient health literacy skills according to the National Assessment of Adult Literacy. The growing diversity of our patient population in the U.S. demands appropriate attention to general and health literacy among health-system pharmacy practitioners, patients, and other healthcare providers to ensure equal access to accurate health information and usable health services. The Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health's Healthy People 2030 initiative defines health literacy in two ways: personal health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others; and organizational health literacy is the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Programs that support education and training around self-assessment of health literacy and general communication skills and methods for practitioner assessments of patient health literacy are needed to ensure full adoption and appropriate implementation. Barriers to health literacy include language barriers such as limited English proficiency and communication barriers such as those experienced by the deaf or hard of hearing community. Each of these barriers, along with disability, transportation, and cultural barriers require practice resources to accommodate patients with specific communication needs.

0511
PROFESSIONAL DEVELOPMENT

This policy was discontinued in 2010.

0512
FULL HEALTH INSURANCE COVERAGE

This policy was superseded by ASHP policy 1001.

0513
POSTMARKETING COMPARATIVE CLINICAL STUDIES

This policy was superseded by ASHP policy 1004.

0515
POSTMARKETING SAFETY STUDIES

This policy was superseded by ASHP policy 2025.

0516
MANDATORY REGISTRATION OF CLINICAL TRIALS
Source: Council on Legal and Public Affairs

To advocate disclosure of the most complete information on the safety and efficacy of drug products; further,

To advocate that the Department of Health and Human Services establish a mandatory registry for all Phase II, III, and IV clinical trials that are conducted on drugs intended for use in the United States; further,

To advocate that each clinical trial have a unique identifier; further,

To advocate that all data from registered clinical trials be posted electronically with unrestricted access, and that such posting occur (1) after Food and Drug Administration approval of the related new product but before marketing begins and (2) as soon as possible for trials completed after initial marketing.

This policy was reviewed in 2023 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
Incomplete disclosure of data on the safety and efficacy of drug products from clinical trials has negatively impacted patient safety and pharmacy practice. For example, in 2004 unpublished data and results regarding the efficacy and safety of antidepressants in pediatric patients prompted a national analysis of the potential effects of suppressing negative findings in clinical trials. That experience demonstrated that positive and negative data and results should be made available to healthcare providers so they can make the best decisions about medications for their patients.

In 2016, the Department of Health and Human Services issued a final rule that specifies requirements for registering certain clinical trials and submitting summary results information to ClinicalTrials.gov. The rule expands the legal requirements for submitting registration and results information for clinical trials involving U.S. Food and Drug Administration-regulated drug, biological and device products. Similarly, the National Institutes of Health has issued a

complementary policy for registering and submitting summary results information to ClinicalTrials.gov for all NIH-funded trials, including those not subject to the final rule. Requirements under the final rule apply to most interventional studies of drug, biological, and device products that are regulated by the FDA.

0517
ETHICAL USE OF PLACEBOS

This policy was superseded by ASHP policy 1116.

0518
FUNDING, EXPERTISE, AND OVERSIGHT OF STATE BOARDS OF PHARMACY

This policy was superseded by ASHP policy 1507.

0520
FEDERAL REVIEW OF ANTICOMPETITIVE PRACTICES BY DRUG PRODUCT MANUFACTURERS

This policy was superseded by ASHP policy 1818.

0521
OPPOSITION TO CREATION OF NEW CATEGORIES OF LICENSED PERSONNEL

This policy was discontinued in 2012.

0522
NEW AND EMERGING MEDICATION ORDERING AND DISTRIBUTION SYSTEMS

This policy was discontinued in 2012.

0523
ONLINE PHARMACY AND INTERNET PRESCRIBING

This policy was superseded by ASHP policy 1529.

0524
PRUDENT PURCHASING OF PHARMACEUTICALS

This policy was discontinued in 2010.

0525
MANDATORY TABLET SPLITTING FOR COST CONTAINMENT
Source: Council on Professional Affairs

To oppose mandatory tablet splitting for cost containment in ambulatory care; further,

To encourage pharmacists, when voluntary tablet splitting is considered, to collaborate with patients, caregivers, and other health care professionals to determine whether tablet splitting is appropriate on the basis of the patient's ability to split tablets and the suitability of the medication (e.g., whether it is scored or is an extended-release product); further,

To urge pharmacists to promote dosing accuracy and patient safety by ensuring that patients are educated on how to properly split tablets; further,

To encourage further research by the United States Pharmacopeia and the Food and Drug Administration on the impact of tablet splitting on product quality.

This policy was reviewed in 2023 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

0526
ASHP STATEMENT ON OVER-THE-COUNTER AVAILABILITY OF STATINS

This statement was superseded by ASHP policy 2225.

2004 Policy Positions

0401
PHARMACEUTICAL COUNTERFEITING

This policy was discontinued in 2019.

0402
READY-TO-USE PACKAGING FOR ALL SETTINGS

This policy was discontinued in 2026.

0403
SCOPE AND HOURS OF PHARMACY SERVICES

This policy was superseded by ASHP policy 1023.

0404
STANDARDIZATION, AUTOMATION, AND EXPANSION OF MANUFACTURER-SPONSORED PATIENT-ASSISTANCE PROGRAMS

This policy was superseded by ASHP policy 1806.

0405
ELECTRONIC INFORMATION SYSTEMS

This policy was superseded by ASHP policy 0507.

0406
WORKLOAD MONITORING AND REPORTING

This policy was superseded by ASHP policy 0901.

0408
CONTINUING PROFESSIONAL DEVELOPMENT

This policy was superseded by ASHP policy 0916.

0409
CULTURAL DIVERSITY AMONG HEALTH CARE PROVIDERS

This policy was superseded by ASHP policy 1414.

0413
IMPORTATION OF PHARMACEUTICALS

This policy was superseded by ASHP policy 2012.

0414
HOME INTRAVENOUS THERAPY BENEFIT

This policy was superseded by ASHP policy 1623.

0415
ASHP STATEMENT ON THE USE OF DIETARY SUPPLEMENTS
Source: Council on Professional Affairs
To approve the ASHP Statement on the Use of Dietary Supplements.

This statement was reviewed in 2022 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

2003 Policy Positions

0301
CONTINUITY OF CARE

This policy was superseded by ASHP policy 1208.

0302
DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS

This policy was discontinued in 2008.

0303
PHARMACY DRUG THEFT

This policy was discontinued in 2024.

0304
COMPLEMENTARY OR ALTERNATIVE SUBSTANCES

This policy was superseded by the ASHP Statement on the Use of Dietary Supplements dated June 20, 2004.

0305
EXPRESSION OF THERAPEUTIC PURPOSE OF PRESCRIBING

This policy was superseded by ASHP policy 2255.

0306
PAIN MANAGEMENT

This policy was superseded by ASHP policy 1106.

0307
PHARMACIST SUPPORT FOR DYING PATIENTS

This policy was superseded by ASHP policy 2333.

0308
MACHINE-READABLE CODING AND RELATED TECHNOLOGY

This policy was superseded by the ASHP Statement on Bar-Code-Enabled Medication Administration Technology dated June 10, 2008.

0310
TECHNICIAN-CHECKING-TECHNICIAN PROGRAMS
Source: Council on Administrative Affairs

To advocate technician-checking-technician programs (with appropriate quality control measures) in order to permit redirection of pharmacist resources to patient care activities; further,

To advocate state board of pharmacy approval of these programs.

This policy was reviewed in 2023 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Technician-checking-technician (tech-check-tech) programs create advanced roles for certified pharmacy technicians with appropriate training and education. These programs allow pharmacists' time to be redirected to additional clinical and cognitive functions, such as drug therapy management activities. Tech-check-tech programs, with appropriate quality control, are an acceptable alternative to pharmacists checking unit dose medication carts. Many state boards of pharmacy still require that pharmacists perform this activity and will consider exceptions to this requirement only upon specific request. Not all states allow technicians to perform final checks or allow them to do so only after obtaining a variance from the Board in limited situations. In 2022, 17 states allowed tech-check-tech programs with varying degrees of oversight (NABP 2022 Survey of Pharmacy Law, p. 60).

0313
PATIENT-CENTERED CARE

This policy was discontinued in 2013.

0315
PRACTICE SITES FOR COLLEGES OF PHARMACY

This policy was superseded by ASHP policy 1827.

0316
BIOLOGICAL DRUGS

This policy was superseded by ASHP policy 0809.

0318
ROLE OF LICENSING, CREDENTIALING, AND PRIVILEGING IN COLLABORATIVE DRUG THERAPY MANAGEMENT

This policy was superseded by ASHP policy 0905.

0319
DRUG PRODUCT SHORTAGES

This policy was superseded by ASHP policy 1118.

0320
RE-IMPORTATION OF PHARMACEUTICALS

This policy was superseded by ASHP policy 0413.

0323
LICENSURE FOR PHARMACY GRADUATES OF FOREIGN SCHOOLS

This policy was discontinued in 2023.

0324
REGULATION OF DIETARY SUPPLEMENTS

This policy was superseded by the ASHP Statement on the Use of Dietary Supplements dated June 20, 2004.

0325
PUBLIC FUNDING FOR PHARMACY RESIDENCY TRAINING
Source: Council on Legal and Public Affairs

To support legislation and regulation that ensures public funding for accredited pharmacy residency programs consistent with the needs of the public and the profession; further,

To oppose legislation or regulation involving reimbursement levels for graduate medical education that adversely affects pharmacy residencies at a rate disproportionate to other residency programs.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
Many organizations capitalize on pass-through funding to maintain the operation of postgraduate year 1 (PGY1) pharmacy practice residencies. Another source of reimbursement

for eligible PGY1 pharmacy residency programs is Medicare+Choice Nursing and Allied Health Education Program Payments. In recent years, Centers for Medicare & Medicaid Services (CMS) audits of pharmacy residency programs have resulted in significant cost disallowances, some over a number of years and in amounts that threaten program viability. Many of these cases involve arbitrary and inconsistent application of cost-reporting requirements as well as substandard and poorly organized audit processes.

ASHP has requested that CMS cease disallowances until program technical assistance (TA) has been provided and audit processes have been standardized. ASHP advocates strengthened auditor training and provision of TA specific to pharmacy residency programs, including a comprehensive overview of what CMS deems to be optimal cost accounting processes and procedures.

0326
ASHP STATEMENT ON THE ROLE OF HEALTH-SYSTEM PHARMACISTS IN EMERGENCY PREPAREDNESS

This policy was superseded by ASHP policy 2223.

2002 Policy Positions

0202
PERFORMANCE IMPROVEMENT

This policy was superseded by ASHP policy 2206.

0206
REIMBURSEMENT FOR UNLABELED USES OF FDA-APPROVED DRUG PRODUCTS
Source: Council on Administrative Affairs

To support third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses.

This policy was reviewed in 2022 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale
Off-label use of drug products includes any use of a drug product for a diagnosis, combination with other medications, dosage, frequency, route of administration, place in therapy, or patient population that is not specifically approved by the U.S. Food and Drug Administration (FDA) and contained in the drug labeling. Drug products' labeling often fails to represent the most current therapeutic information, because making changes to FDA labeling is a time-consuming and expensive process and medical knowledge is constantly expanding based on evolving evidence.

Once a drug is FDA-approved for a specific indication, it can legally be used for any indication, and off-label prescribing is common. Researchers have conservatively estimated that

it accounts for 10-20% of all prescriptions, but the practice is much more common in specific patient populations (e.g., children, geriatric patients, and patients with life-threatening or terminal conditions).

In many clinical situations, off-label use represents a therapeutic approach that has been extensively studied, is supported by the medical literature, and is most appropriate for the patient. Failure to recognize these circumstances or, more importantly, regarding such uses as unapproved or experimental, may restrict patient access to effective drug therapies. Some degree of flexibility must be maintained to optimize patient outcomes and allow for individualized care. While the ultimate responsibility for the safety and efficacy of off-label use resides with the prescriber, hospital and health-system pharmacy and therapeutics committees often develop policies and procedures for managing off-label medication use, with the goal of providing access to the most appropriate, effective treatment for each patient. Although a distinction must be made between evidence-based and inappropriate off-label use, the clinical judgment of healthcare practitioners and experts, as reflected in peer-reviewed publications, clinical practice guidelines, and approved compendia, provides better guidance than FDA labeling alone.

0207
PRODUCT REIMBURSEMENT AND PHARMACIST COMPENSATION

This policy was superseded by ASHP policy 1304.

0209
SUBSTANCE ABUSE AND CHEMICAL DEPENDENCY

This policy was discontinued in 2012.

0210
HEALTH LITERACY

This policy was superseded by ASHP policy 0510.

0211
IMAGE OF AND CAREER OPPORTUNITIES FOR PHARMACY TECHNICIANS

This policy was superseded by ASHP policy 1610.

0213
PHARMACISTS' ROLE IN IMMUNIZATION AND VACCINES

This policy was superseded by ASHP policy 1309.

0214
IMAGE OF AND CAREER OPPORTUNITIES FOR HEALTH-SYSTEM PHARMACISTS

This policy was superseded by ASHP policy 0703.

0215
EDUCATIONAL PROGRAM RESOURCES FOR AFFILIATED STATE SOCIETIES

This policy was discontinued in 2017.

0216
RESIDENCY PROGRAMS

This policy was superseded by ASHP policy 0704.

0217
"P.D." (PHARMACY DOCTOR) DESIGNATION FOR PHARMACISTS

This policy was discontinued in 2012.

0218
PHARMACIST RECRUITMENT AND RETENTION

Source: Council on Legal and Public Affairs

To support federal and state incentive programs for new pharmacy graduates to practice in underserved areas; further,

To provide information and educational programming on strategies used by employers for successful recruitment and retention of pharmacists and pharmacy technicians; further,

To conduct regular surveys on trends in the health-system pharmacy work force, including retention rates for pharmacists and pharmacy technicians.

This policy was reviewed in 2017 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

0220
INTERMEDIATE CATEGORY OF DRUGS

This policy was discontinued in 2017.

0222
GREATER ACCESS TO LESS EXPENSIVE GENERIC DRUGS

This policy was superseded by ASHP policy 1716.

0223
FEDERAL RESEARCH ON DIETARY SUPPLEMENT LABELING

This policy was superseded by the ASHP Statement on the Use of Dietary Supplements dated June 20, 2004.

0225
COMPOUNDING VERSUS MANUFACTURING

This policy was superseded by ASHP policy 0616.

0226
PROXY/ABSENTEE BALLOTING

This policy was discontinued in 2007.

0227
PHARMACIST'S RESPONSIBILITY FOR PATIENT SAFETY

This policy was discontinued in 2012.

0228
APPROPRIATE DOSING OF MEDICATIONS IN PATIENT POPULATIONS WITH UNIQUE NEEDS

This policy was discontinued in 2018.

0229
CLINICAL INVESTIGATIONS OF DRUGS USED IN ELDERLY AND PEDIATRIC PATIENTS

This policy was superseded by ASHP policy 1723.

0230
INSTITUTIONAL REVIEW BOARDS AND INVESTIGATIONAL USE OF DRUGS

This policy was superseded by ASHP policy 0711.

0231
PHARMACEUTICAL WASTE

This policy was superseded by ASHP policy 0903.

0232
PHARMACIST'S ROLE IN DRUG PROCUREMENT, DISTRIBUTION, SURVEILLANCE, AND CONTROL

This policy was superseded by ASHP policy 2222.

0233
ELECTRONIC HEALTH AND BUSINESS TECHNOLOGY AND SERVICES

This policy was superseded by ASHP policy 0712.

0234
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN HOSPICE AND PALLIATIVE CARE

This statement was superseded by ASHP Guidelines on Pharmacist's Role in Palliative and Hospice Care.

0235
ASHP STATEMENT ON THE ROLE OF HEALTH-SYSTEM PHARMACISTS IN EMERGENCY PREPAREDNESS
Source: ASHP Board of Directors
To approve the ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness.

This policy was superseded by ASHP policy 0326.

2001 Policy Positions

0101
PHARMACY BENEFITS FOR THE UNINSURED

This policy was superseded by ASHP policy 2109.

0102
MEDICATION FORMULARY SYSTEM MANAGEMENT

This policy was superseded by ASHP policy 1805.

0104
PATIENT SATISFACTION

This policy was superseded by ASHP policy 1616.

0105
COMPUTERIZED PROVIDER ORDER ENTRY
Source: Council on Administrative Affairs
To advocate the use of computerized entry of medication orders or prescriptions by the prescriber when (1) it is planned, implemented, and managed with pharmacists' involvement, (2) such orders are part of a single, shared database that is fully integrated with the pharmacy

information system and other key information system components, especially the patient's medication administration record, (3) such computerized order entry improves the safety, efficiency, and accuracy of the medication-use process, and (4) it includes provisions for the pharmacist to review and verify the order's appropriateness before medication administration, except in those instances when review would cause a medically unacceptable delay.

This policy was reviewed in 2025 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.

Rationale

Computerized provider order entry (CPOE) is the process of digitally entering and sending providers' medical orders and treatment instructions rather than delivery by paper, fax, or telephone. CPOE has become the standard of care within hospitals and health-systems for orders including medications, labs, and medical imaging. The use of CPOE has reduced medication errors, improved safety, accelerated order processing, and enhanced access to documentation. CPOE system design, implementation, and integration with other medical technologies must be considered to fully realize its benefits.

0107
NONACCREDITED PHARM.D. PROGRAMS

This policy was discontinued in 2011.

0108
NONTRADITIONAL PHARM.D. ACCESSIBILITY

This policy was discontinued in 2011.

0110
PROFESSIONAL SOCIALIZATION

This policy was superseded by ASHP policy 1113.

0117
PERIODIC REEXAMINATION OF ASHP'S ORGANIZATIONAL STRUCTURE AND GOVERNING PROCESS

This policy was discontinued in 2006.

0118
STATE AFFILIATE MEMBERSHIP AND ASHP APPOINTMENTS
Source: Council on Organizational Affairs

To give consideration to ASHP members who also hold membership in their state affiliate when making appointments to ASHP councils, committees, commissions, and other appointed bodies.

This policy was reviewed in 2022 by the Commission on Affiliate Relations and by the Board of Directors and was found to still be appropriate.

Rationale
Appointments to ASHP's councils, committees, commissions, and other appointed bodies are made by ASHP leaders according to their best judgment. State affiliate involvement is routinely considered in the appointment process. Although state affiliate membership is not the only criterion for appointment, a high percentage of individuals serving on ASHP's appointed bodies typically are leaders of their state affiliates.

2000 Policy Positions

0002
DRUG SHORTAGES
Source: Council on Administrative Affairs

To declare that pharmaceutical manufacturers, distributors, group purchasing organizations, and regulatory bodies, when making decisions that may create drug product shortages, should strive to prevent those decisions from compromising the quality and safety of patient care.

This policy was reviewed in 2023 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Drug product shortages continue to be a critical issue because of their frequency, duration, and widespread nature. Although the effects of drug product shortages on patient care and pharmacy services are complex and have not been comprehensively described, the negative effects include increases in (1) patient safety risks, (2) drug expenditures due to higher prices paid for noncontract or alternative product supplies, (3) physician dissatisfaction and patient dissatisfaction, and (4) staff time spent resolving shortage problems. Pharmacy managers are hampered in addressing shortages by the lack of any advance notice of shortages from manufacturers, group purchasing organizations (GPOs), distributors, or the Food and Drug Administration (FDA); limited information regarding the estimated duration of shortages; and limited information on the reasons behind the shortages. Further, managers lack immediate information on what options are available (i.e., alternative sources of products or appropriate

therapeutic alternatives) to ameliorate the problem on both a short- and long-term basis. In addition, the concerted effort to decrease inventories across the drug supply chain leave little buffer when drug product shortages occur.

Drug shortages occur for a variety of reasons, including manufacturer noncompliance with FDA's Current Good Manufacturing Practices, natural disasters that damage production plants, shortages of raw materials, increases in unlabeled uses, consolidation within the industry, predetermined production quotas, and market shifts driven by large purchasers and payers. A significant factor affecting product supply is business-related decisions made by the key players in the drug supply chain. These decisions, and the limited information pharmacists are able to retrieve regarding shortages, has harmed the trust between pharmacists and the pharmaceutical supply industry. ASHP believes that these key players, including pharmaceutical manufacturers, GPOs, distributors, and regulatory bodies must consider the impact that their decisions affecting supply and demand of a product have on the quality or safety of patient care.

0005
RESIDENCY TRAINING FOR PHARMACISTS WHO PROVIDE DIRECT PATIENT CARE

This policy was superseded by ASHP policy 2027.

0006
PHARMACIST CREDENTIALING

This policy was superseded by ASHP policy 1415.

0010
DISPENSING BY NONPHARMACISTS AND NONPRESCRIBERS

This policy was superseded by ASHP policy 2022.

0011
STATUTORY PROTECTION FOR MEDICATION-ERROR REPORTING

This policy was superseded by ASHP policy 1505.

0012
FDA'S PUBLIC HEALTH MISSION

This policy was superseded by ASHP policy 2620.

0013
PATIENT'S RIGHT TO CHOOSE

This policy was superseded by ASHP policy 2508.

0016
PHARMACOGENOMICS

This policy was superseded by ASHP policy 1104.

0018
INLINE FILTERS

This policy was discontinued in 2005.

0020
DRUG NAMES, LABELING, AND PACKAGING ASSOCIATED WITH MEDICATION ERRORS

This policy was superseded by ASHP policy 2044.

0021
MEDICATION ERRORS AND RISK MANAGEMENT

This policy was discontinued in 2020.

0023
ASHP STATEMENT ON REPORTING MEDICAL ERRORS

This statement was discontinued in 2026.

1999 Policy Positions

9901
FOSTERING PHARMACY LEADERSHIP

This policy was discontinued in 2014.

9902
COMPLIANCE WITH GOVERNMENTAL PAYMENT POLICIES

This policy was superseded by ASHP policy 1205.

9903
OPTIMIZING THE MEDICATION-USE PROCESS

This policy was discontinued in 2024.

9904
EMERGENCY PREPAREDNESS

This policy was superseded by the ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness dated June 1, 2003.

9905
DIVERSIFYING PHARMACEUTICAL SERVICES

This policy was discontinued in 2004.

9908
PHARMACISTS' ROLE IN DRUG PROCUREMENT, DISTRIBUTION, AND CONTROL

This policy was superseded by ASHP policy 0232.

9915
ASHP POSITION ON ASSISTED SUICIDE

This policy was superseded by ASHP policy 1704.

9916
PHARMACIST DECISION-MAKING ON ASSISTED SUICIDE
Source: Council on Legal and Public Affairs
To approve the ASHP Statement on Pharmacist Decision-making on Assisted Suicide.

This statement was reviewed in 2014 by the Council on Pharmacy Practice and by the ASHP Board of Directors and was found to still be appropriate.

9917
CONFIDENTIALITY OF PATIENT HEALTH CARE INFORMATION

This statement was superseded by the ASHP Statement on Confidentiality of Patient Health Care Information dated June 10, 2008.

9919
MANAGEMENT OF BLOOD PRODUCTS AND DERIVATIVES

This policy was discontinued in 2014.

9920
TELEPHARMACY

This policy was discontinued in 2019.

9921
PHARMACIST VALIDATION OF INFORMATION RELATED TO MEDICATIONS

This policy was discontinued in 2019.

9922
PHARMACIST'S ROLE IN PRIMARY CARE

This statement was superseded by ASHP policy 2226.

1998 Policy Positions

9801
COLLABORATIVE DRUG THERAPY MANAGEMENT ACTIVITIES

This policy was discontinued in 2018.

9803
MEDICATION FORMULARY SYSTEM MANAGEMENT

This policy was superseded by ASHP policy 0102.

9804
MULTIDISCIPLINARY ACTION PLANS FOR PATIENT CARE

This policy was discontinued in 2013.

9805
MEDICATION MISADVENTURES

This policy was discontinued in 2019.

9806
ELECTRONIC ENTRY OF MEDICATION ORDERS

This policy was superseded by ASHP policy 0105.

9808
DEFINING AND MEASURING THE QUALITY OF CLINICAL SERVICES

This policy was superseded by ASHP policy 0202.

9810
RELATIONSHIP BETWEEN PRACTICE SITES AND EDUCATIONAL INSTITUTIONS

This policy was superseded by ASHP policy 0315.

9811
PUBLIC FUNDING FOR PHARMACY RESIDENCY TRAINING

This policy was superseded by ASHP policy 0325.

9812
COLLABORATIVE DRUG THERAPY MANAGEMENT

This policy was superseded by ASHP policy 1217.

9813
REGULATION OF AUTOMATED DRUG DISTRIBUTION SYSTEMS
Source: Council on Legal and Public Affairs

To work with the Drug Enforcement Administration and other agencies to seek regulatory and policy changes to accommodate automated drug distribution in health systems.

This policy was reviewed in 2024 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.

Rationale
In 2021, ASHP published guidelines on the safe use of automated dispensing cabinets, including requirements for controlled storage, secure operations, and technology infrastructure including interfaces. Those guidelines contain recommendations regarding diversion surveillance, monitoring, and detection guidance. In the same year, the National Association of Boards of Pharmacy (NABP) published Model State Pharmacy Act and Model Rules concerning automated pharmacy systems. NABP provides guidance on system documentation, oversight, security systems, record/data keeping, and pharmacist-in-charge responsibilities. In 2020, the DEA revised its Pharmacist's Manual to assist pharmacists in understanding of the Federal Controlled Substances Act. The council recognized the policy reflects automated systems for drug distribution and the regulatory jurisdiction of additional federal and state agencies beyond the Drug Enforcement Administration.

9819
ROLE OF PHARMACISTS AND BUSINESS LEADERS IN HEALTH CARE SERVICES AND POLICIES

This policy was discontinued in 2018.

9820
MEDICATION ADMINISTRATION BY PHARMACISTS

This policy was superseded by ASHP policy 2321.

9821
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN CLINICAL PHARMACOKINETIC MONITORING
Source: Council on Professional Affairs
To approve the ASHP Statement on the Pharmacist's Role in Clinical Pharmacokinetic Monitoring.

This statement was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

9822
ASHP STATEMENT ON THE PHARMACIST'S ROLE IN INFECTION CONTROL
Source: Council on Professional Affairs
To approve the ASHP Statement on the Pharmacist's Role in Infection Control.

This policy was superseded by ASHP policy 0922.

1997 Policy Positions

9702
DRUG SAMPLES

This policy was superseded by ASHP policy 2210.

9703
MANUFACTURER-SPONSORED PATIENT-ASSISTANCE PROGRAMS

This policy was superseded by ASHP policy 1420.

9705
PHARMACIST EDUCATION OF CONSUMERS

This policy was discontinued in 2002.

9707
PEDIATRIC DOSAGE FORMS

This policy was superseded by ASHP policy 2244.

9711
INTERVENTIONS TO REDUCE HIGH-RISK BEHAVIORS IN INTRAVENOUS DRUG USERS

This policy was superseded by ASHP policy 2215.

1996 Policy Positions

9601
STANDARDIZATION OF MEDICATION FORMULARY SYSTEMS

This policy was superseded by ASHP policy 2016.

9607
CODE OF ETHICS
Source: Council on Legal and Public Affairs

To endorse the Code of Ethics for Pharmacists.

The endorsement of this document was reviewed in 2018 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

9608
USE OF COLOR TO IDENTIFY DRUG PRODUCTS
Source: Council on Professional Affairs

To support the reading of drug product labels as the most important means of identifying drug products; further,

To oppose reliance on color by health professionals and others to identify drug products; further,

To oppose actions by manufacturers of drug products and others to promulgate reliance on color to identify drug products.

This policy was reviewed in 2024 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Rationale
Using color to transmit information about a drug product (e.g., the drug's identity, strength, route of administration, therapeutic class, or other characteristic) is a potentially unsafe practice. ASHP discourages dependence on such color coding and encourages the reading of

drug product labels. Although color may be useful to differentiate drug products, there is an important distinction between use of color for differentiation and reliance on or promulgation of color as an information-carrying code. The safety of using color as a code is scientifically untested, and approximately 7% of males cannot distinguish certain colors. In addition, an industry-wide standardization of colors or their use is unlikely to occur. Therefore, pharmacists, drug product manufacturers, and others should refrain from encouraging reliance on color as a means of identifying drug products or communicating other information about drug products, and patients should be educated not to rely on color to identify drug products. Further, ASHP encourages manufacturers, drug packagers and repackagers, outsourcing pharmacies, and others to thoughtfully select color and other labeling and packaging characteristics to avoid look-alike and other types of medication errors (ASHP policy 2044).

9609
HUMAN FACTORS CONCEPTS

This policy was discontinued in 2020.

9613
THE EXPANDED ROLE OF PHARMACY TECHNICIANS

This policy was discontinued in 2002.

9614
DUES AUTHORITY

This policy was discontinued in 2001.

1995 Policy Positions

9502
ASHP CONTINUING-EDUCATION ACTIVITIES AND NONTRADITIONAL PHARM.D. PROGRAMS

This policy was discontinued in 2002.

9503
MODEL CONTINUING EDUCATION REGULATIONS

This policy was discontinued in 1998.

9504
ASHP STATEMENT ON THE PHARMACIST'S RESPONSIBILITY FOR DISTRIBUTION AND CONTROL OF DRUG PRODUCTS
Source: Council on Professional Affairs
To approve the ASHP Statement on the Pharmacist's Responsibility for Distribution and Control of Drug Products.

This statement supersedes a previous version dated June 1, 1992, and ASHP policy 9210.

This statement was reviewed in 2005 by the Council on Professional Affairs and by the Board of Directors and was found to still be appropriate.

9505
ASHP STATEMENT ON THE ROLE OF THE PHARMACIST IN PATIENT-FOCUSED CARE

This statement was discontinued in 2002.

1994 Policy Positions

9401
PATIENT-FOCUSED CARE

This policy was discontinued in 2005.

9407
PRIMARY AND PREVENTIVE CARE

This policy was discontinued in 2017.

9409
NABP MODEL PHARMACY PRACTICE ACT LANGUAGE ON THE RESPONSIBILITY OF THE PHARMACIST FOR OVERALL MEDICATION DISTRIBUTION SYSTEMS

This policy was discontinued in 2004.

9411
NAME CHANGE

This policy was discontinued in 2026.

1993 Policy Positions

9303
HEALTH-CARE REFORM

This policy was discontinued in 2018.

9304
ASHP STATEMENT ON PHARMACEUTICAL CARE
Source: Council on Professional Affairs
To approve the ASHP Statement on Pharmaceutical Care.

This statement was reviewed in 1998 by the Council on Professional Affairs and by the Board of Directors and was found to still be appropriate.

9306
ASHP STATEMENT ON THE PHARMACIST'S ROLE WITH RESPECT TO DRUG DELIVERY SYSTEMS AND ADMINISTRATION DEVICES
Source: Council on Professional Affairs
To approve the ASHP Statement on the Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices.

This statement supersedes a previous version dated June 5, 1989, and ASHP policy 8904.

9307
DRUG DISTRIBUTION SYSTEMS IN ORGANIZED HEALTH-CARE SYSTEMS

This policy was discontinued in 2002.

9309
EXPIRATION DATING OF PHARMACEUTICAL PRODUCTS

This policy was superseded by ASHP policy 1712.

9310
RECOGNITION OF ONCOLOGY PHARMACY PRACTICE AS A SPECIALTY

This policy was discontinued in 2000.

1992 Policy Positions

9201
HUMAN IMMUNODEFICIENCY VIRUS (HIV) POSITIVE EMPLOYEES

This policy was discontinued in 2008.

9202
NEEDLE-FREE DRUG PREPARATION AND ADMINISTRATION SYSTEMS

This policy was discontinued in 2007.

9204
ELECTRONIC COMMUNICATION OF MEDICAL INFORMATION

This policy was discontinued in 2002.

9205
AUTOMATED SYSTEMS

This policy was discontinued in 2012.

9206
MEDICATION-ERROR REPORTING

This policy was discontinued in 2000.

9207
AVERSIVE FLAVORING

This policy was discontinued in 1998.

9208
ASHP STATEMENT ON THE USE OF MEDICATIONS FOR UNLABELED USES
Source: Council on Professional Affairs

To approve the ASHP Statement on the Use of Medications for Unlabeled Uses.

9209
ASHP STATEMENT ON THE PHARMACY AND THERAPEUTICS COMMITTEE

This policy was superseded by the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System dated June 10, 2008.

9211
TAMPER-EVIDENT PACKAGING ON TOPICAL PRODUCTS

This policy was superseded by ASHP policy 2221.

1991 Policy Positions

9103
DRUG TESTING

This policy was superseded by ASHP policy 1717.

9106
MEDICAL DEVICES

This policy was superseded by ASHP policy 1820.

9108
EMPLOYEE TESTING
Source: Council on Legal and Public Affairs

This policy was discontinued in 2025.

9111
ASHP STATEMENT ON PHARMACEUTICAL RESEARCH IN ORGANIZED HEALTH-CARE SETTINGS
Source: Council on Professional Affairs
To approve the ASHP Statement on Pharmaceutical Research in Organized Health-Care Settings.

This policy supersedes the ASHP Statement on Institutional Pharmacy Research and ASHP policy 8517.

9118
STATEMENT OF PRINCIPLE FOR PHARMACISTS' RELATIONSHIP WITH INDUSTRY

This policy was discontinued in 1999.

9121
LIMITED AUTHORITY TO ADJUST THE DUES RATE

This policy was superseded by ASHP policy 9614.

9122
RECOGNITION OF PSYCHOPHARMACY PRACTICE AS A SPECIALTY

This policy was discontinued in 2000.

1990 Policy Positions

9001
REIMBURSEMENT FOR UNLABELED USES OF FDA-APPROVED DRUG PRODUCTS

This policy was superseded by ASHP policy 0206.

9002
ASHP STATEMENT ON CONTINUING EDUCATION

This statement was discontinued in 2014.

9004
HOME INTRAVENOUS THERAPY

This policy was superseded by ASHP policy 0414.

9005
GENERIC DRUG PRODUCTS

This policy was discontinued in 2007.

9006
NONDISCRIMINATORY PHARMACEUTICAL CARE

This policy was discontinued in 2017.

9007
DRUG NAMES, LABELING, AND PACKAGING

This policy was superseded by ASHP policy 0020.

9008
STANDARDIZED PROTOCOL FOR INFORMATION EXCHANGE BETWEEN HOSPITALS

This policy was discontinued in 1998.

9009
STUDENT MEMBERSHIP DUES

This policy was discontinued in 2000.

9010
GENERIC PHARMACEUTICAL TESTING

This policy was superseded by ASHP policy 1803.

9011
DRUG NOMENCLATURE

This policy was discontinued in 2024.

1989 Policy Positions

8903
POLITICAL ACTION COMMITTEE (PAC)

This policy was discontinued in 1998.

8907
ASHP STATEMENT ON UNIT DOSE DRUG DISTRIBUTION
Source: Council on Professional Affairs
To approve the ASHP Statement on Unit Dose Drug Distribution.

This statement supersedes a previous version dated June 8, 1981.

1988 Policy Positions

8802
EDUCATIONAL PROGRAM RESOURCES FOR AFFILIATED STATE CHAPTERS

This policy was superseded by ASHP policy 0215.

8804
EMPLOYEE DRUG TESTING

This policy was discontinued in 1998.

8808
HUMAN IMMUNODEFICIENCY VIRUS INFECTIONS

This policy was discontinued in 2007.

8809
COUNCIL ON THERAPEUTICS

This policy was discontinued in 2002.

8810
PROMOTION OF PHARMACISTS' PROFESSIONAL IMAGE

This policy was discontinued in 2001.

8812
RECOGNITION OF NUTRITIONAL SUPPORT PHARMACY PRACTICE AS A SPECIALTY

This policy was discontinued in 2000.

1987 Policy Positions

8701
PHARMACISTS' ROLE IN DRUG PROCUREMENT PROCESS

This policy was superseded by ASHP policy 9908.

8704
NATIONAL MANPOWER DATA SYSTEM

This policy was discontinued in 2002.

8705
ASSESSMENT SURVEY OF CONTINUING EDUCATION NEEDS

This policy was discontinued in 2002.

8706
STAFF DEVELOPMENT PROGRAMS AND RESOURCES

This policy was superseded by ASHP policy 0112.

8707
VACCINE AVAILABILITY

This policy was discontinued in 2000.

8708
THERAPEUTIC INTERCHANGE

This policy was discontinued in 2024.

8709
CODES ON SOLID DOSAGE FORMS OF PRESCRIPTION DRUG PRODUCTS

This policy was discontinued in 2017.

8711
CLINICAL INVESTIGATION OF DRUGS USED IN ELDERLY AND PEDIATRIC PATIENTS

This policy was superseded by ASHP policy 0229.

8712
THE PHARMACEUTICAL INDUSTRY AND DESIGN OF INVESTIGATIONAL STUDIES IN INSTITUTIONS

This policy was discontinued in 2000.

1986 Policy Positions

8607
PHARMACY CRIME

This policy was discontinued in 2002.

8610
PHARMACY TECHNICIANS

This policy was discontinued in 2012.

8612
INTERNATIONAL SYSTEM OF UNITS

This policy was discontinued in 2014.

8613
ELIMINATION OF APOTHECARY SYSTEM

This policy was discontinued in 2021.

8614
MEDICATION ERRORS AND RISK MANAGEMENT

This policy was superseded by ASHP policy 0021.

8619
NONTRADITIONAL PHARMACY PRACTICE SETTINGS

This policy was discontinued in 2000.

1985 Policy Positions

8504
STATEMENT ON THIRD-PARTY COMPENSATION FOR CLINICAL SERVICES BY PHARMACISTS

This statement was discontinued in 2005.

8506
INTERNSHIP, EXTERNSHIP, AND CLERKSHIP

This policy was discontinued in 2002.

8507
CAREER COUNSELING

This policy was superseded by ASHP policy 2216.

8508
EXTERNAL DEGREE PROGRAMS AND INITIATIVES FOR HELPING PRACTITIONERS UPGRADE SKILLS

This policy was discontinued in 2007.

8510
ORGAN TRANSPLANT LEGISLATION

This policy was discontinued in 2002.

8511
PHARMACIST DISPENSING OF CERTAIN DRUGS

This policy was superseded by ASHP policy 0220.

8512
FDA REVIEW OF DRUG PRODUCTS FOR SAFETY AND EFFICACY

This policy was discontinued in 2002.

8514
NATIONAL DRUG CODE

This policy was discontinued in 2002.

8515
CONTROLLED SUBSTANCES REGULATIONS

This policy was superseded by ASHP policy 9813.

8516
SINGLE UNIT PACKAGES

This policy was discontinued in 2000.

8517
STATEMENT ON INSTITUTIONAL PHARMACY RESEARCH

This statement was superseded by the ASHP Statement on Pharmaceutical Research in Organized Health-Care Settings and ASHP policy 9111.

8519

HOSPITAL PHARMACY MANAGEMENT INFORMATION SYSTEM (HPMIS)

This policy was discontinued in 1999.

8520
BULK RESALE OF DRUG PRODUCTS

This policy was discontinued in 2000.

1984 Policy Positions

8402
HEALTH-CARE FINANCING: DEPARTMENTAL STRATEGIES

This policy was discontinued in 1999.

8406
PATIENT EDUCATION

This policy was discontinued in 1998.

8407
ASHP PRACTICE STANDARDS AS AN INTEGRAL PART OF EDUCATIONAL PROCESS

This policy was superseded by ASHP policy 0705.

8408
DRUG PRICE COMPETITION ACT—POST-1962 ABBREVIATED NEW DRUG APPLICATION LEGISLATION

This policy was discontinued in 2002.

8409
VETERANS ADMINISTRATION PERSONNEL LEGISLATION

This policy was discontinued in 1998.

8410
USE OF DRUGS IN CAPITAL PUNISHMENT

This policy was superseded by ASHP policy 1531.

8411

DISSOLUTION OF COUNCIL ON EDUCATIONAL AFFAIRS

This policy was discontinued in 2001.

8412
AFFILIATED STATE CHAPTER MEMBERSHIP AND ASHP APPOINTMENTS

This policy was superseded by ASHP policy 0118.

1983 Policy Positions

8302
MEDICAID COST-CONTAINMENT OPTIONS

This policy was discontinued in 1998.

8303
MATERIALS MANAGEMENT

This policy was discontinued in 2000.

8305
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This policy was discontinued in 1999.

8310
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This policy was discontinued in 2018.

8311
ASHP PLANNING PROCESS AND ASHP LONG-TERM GOALS

This policy was discontinued in 2003.

8312
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This policy was discontinued in 2000.

1982 Policy Positions

8201
PLAN OF ACTION FOR DEALING WITH PHARMACY REIMBURSEMENT MATTERS

This policy was discontinued in 2002.

8205
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This policy was discontinued in 2006.

8207
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This policy was discontinued in 2000.

8210
CONTINGENCY PLAN TO ASSIST STATE CHAPTERS' ADJUSTMENTS TO FEDERAL BUDGET REFORMS

This policy was discontinued in 1998.

8211
PATENT TERM RESTORATION

This policy was discontinued in 1998.

8212
HOME HEALTH CARE

This policy was discontinued in 2004.

8213
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This policy was discontinued in 1998.

8214
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This policy was discontinued in 2002.

8216
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This policy was discontinued in 2007.

8219
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This policy was discontinued in 2002.

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