

# ASHP POLICY POSITIONS

## 1982–2022

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### Introduction

*ASHP Policy Positions 1982–2022* is a catalog of professional policy positions adopted by the ASHP House of Delegates, organized from the most current year, 2022, 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 national professional organization whose nearly 55,000 members include pharmacists, pharmacy technicians, and pharmacy students who provide patient care services in hospitals, health systems, and ambulatory clinics. For more than 75 years, the Society has been on the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists help people make the best use of medicines, visit ASHP’s website, [www.ashp.org](http://www.ashp.org), or its consumer website, [www.safemedication.com](http://www.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. The Society 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.

All ASHP policy positions are published annually in this document, and practice-related policy positions are compiled in *Best Practices: Positions and Guidance Documents of ASHP*.

American Society of Health-System Pharmacists®

4500 East West Highway

Bethesda, Maryland 20814

<https://www.ashp.org/pharmacy-practice/policy-positions-and-guidelines>

## Practice-Related Positions Listed by Topic

### Automation and Information Technology

- 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
- 1418 - Risk Assessment of Health Information Technology
- 1302 - Interoperability of Patient-Care Technologies
- 1212 - Clinical Decision Support Systems
- 1020 - Role of Pharmacists in Safe Technology Implementation
- 0712 - Electronic Health and Business Technology and Services
- 0105 - Computerized Provider Order Entry
- 9813 - Regulation of Automated Drug Distribution Systems

### Drug Distribution and Control

- 2222 - Pharmacist's Role in Medication Procurement, Distribution, Surveillance, and Control
- 2145 - Reduction Of Unused Prescription Drug Products
- 2042 - Controlled Substances Diversion Prevention
- 0303 - Pharmacy Drug Theft
- 9903 - Optimizing the Medication-Use Process

### Preparation and Handling

- 2139 - Safe and Effective Extemporaneous Compounding
- 2024 - Safety and Efficacy of Compounded Topical Formulations
- 1903 - Compounded Sterile Preparation Verification
- 1813 - Use of Closed-System Transfer Devices to Reduce Drug Waste
- 0903 - Pharmaceutical Waste
- 0614 - Safe Disposal of Patients' Home Medications

### Distribution

- 2022 - Dispensing by Nonpharmacists and Nonprescribers
- 1913 - Pharmaceutical Distribution Systems
- 0310 - Technician-Checking-Technician Programs

### Education and Training

- 2201 - State-Specific Requirements for Pharmacist and Pharmacy Technician Continuing Education
- 2203 - Preceptor Skills and Abilities
- 2216 - Career Counseling
- 2230 - Advancing Diversity, Equity, and Inclusion in Education and Training
- 2231 - Cultural Competency

- 2104 - Fostering Leadership Development
- 2105 - Interprofessional Education and Training
- 2106 - Pharmacy Education and Training Models
- 2107 - Pharmacy Internships
- 2117 - Education and Training in Telehealth
- 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
- 1825 - Clinician Well-being and Resilience
- 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
- 1203 - Qualifications of Pharmacy Technicians in Advanced Roles
- 1108 - Quality of Pharmacy Education and Expansion of Colleges of Pharmacy
- 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
- 0917 - Pharmacy Residency Training
- 0704 - Residency Programs
- 0510 - Communication Among Health-System Pharmacy Practitioners, Patients, and Other Health Care Providers
- 0323 - Licensure for Pharmacy Graduates of Foreign Schools
- 0325 - Public Funding for Pharmacy Residency Training

## Ethics

- 2036 - Racial and Discriminatory Inequities
- 1704 - Medical Aid In Dying
- 1531 - Pharmacist Role in Capital Punishment
- 1403 - Pharmacist's Role on Ethics Committees
- 1116 - Ethical Use of Placebos in Clinical Practice
- 0610 - Pharmacist's Right of Conscience and Patient's Right of Access to Therapy
- 0013 - Patient's Right to Choose

## Formulary Management (Medication-Use Policy Development)

- 2113 - Pharmacogenomics
- 2016 - Medication Formulary System Management
- 1802 - Gene Therapy
- 1820 - Medical Devices

0817 - Generic Substitution of Narrow Therapeutic Index Drugs

8708 - Therapeutic Interchange

### Government, Law, and Regulation

2239 - Drug Pricing Proposals

2101 - Direct-to-Consumer Clinical Genetic Tests

2111 - Pharmacist Involvement in the Strategic National Stockpile

2112 - Medication Price-Gouging Laws

2114 - FDA Requirement for Dose-Response Information

2115 - Medical Cannabis

2116 - Nonprescription Availability of Oseltamivir

2118 - Supply Chain Resilience During Disasters and Public Health Emergencies

2141 - Pharmacist Engagement in and Payment for Telehealth

2142 - Pharmacy Services in a State of Emergency

2144 - Agricultural Use of Hormone and Prohormone Therapy

2004 - Evaluation of Abuse-Deterrent Drug Mechanisms

2005 - Quality Consumer Medication Information

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

2021 - Funding, Expertise, and Oversight of State Boards of Pharmacy

2023 - New Categories of Licensed Pharmacy Personnel

2025 - Postmarketing Studies

2026 - Gabapentin as a Controlled Substance

2030 - Interstate Pharmacist Licensure

2037 - Support of the World Health Organization

2040 - Premarketing Comparative Clinical Studies

2043 - Drug Product Supply Chain Integrity

1904 - Notification of Drug Product Price Increases

1905 - Mitigating Drug Product Shortages

1906 - Emergency Supplies of Drug Products

1908 - 340B Drug Pricing Program Sustainability

1909 - Pharmacist Authority to Provide Medication-Assisted Treatment

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

1816 - Biosimilar Medications

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

1621 - Timely Board of Pharmacy Licensing

- 1501 - Pharmacist Participation in Health Policy Development
- 1502 - Pharmacist Recognition as a Healthcare Provider
- 1508 - Support for FDA Expanded Access (Compassionate Use) Program
- 1405 - Automatic Stop Orders
- 1406 - Federal and State Regulation of Compounding
- 1408 - State Prescription Drug Monitoring Programs
- 1410 - Access to Oral Contraceptives Through an Intermediate Category of Drug Products
- 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
- 1315 - DEA Scheduling of Controlled Substances
- 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 Registry of Clinical Trials
- 0012 - FDA's Public Health Mission

## Medication Safety

- 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

- 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

- 2236 - Pharmacist Prescribing in Interprofessional Patient Care
- 2238 - Patient Disability Accommodations
- 2242 - Use of Intravenous Drug Products for Inhalation
- 2248 - Health-System Use of Drug Products Provided by Outside Sources
- 2249 - Screening for Social Determinants of Health
- 2251 - Qualifications and Competencies Required To Prescribe Medications
- 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)
- 2134 - Patient Access to Pharmacist Care within Provider Networks
- 2137 - Documentation of Pharmacist Patient Care
- 2006 - Pharmacist's Leadership Role in Anticoagulation Therapy Management
- 2008 - Health-System Facility Design
- 2031 - Continuity of Care in Insurance Payer Networks
- 2033 - Health-System Use of Administration Devices Supplied Directly to Patients
- 2039 - Complementary, Alternative, and Integrative Medicine Products
- 1902 - Safe Administration of Hazardous Drugs
- 1809 - Health Insurance Policy Design
- 1811 - Use of International System of Units for Patient- and Medication-related Measurements
- 1822 - Rational Use of Medications
- 1823 - Responsible Medication-related Clinical Testing and Monitoring
- 1824 - Use of Biomarkers in Clinical Practice
- 1721 - Clinical Significance of Accurate And Timely Height And Weight Measurements
- 1504 - Patient Adherence Programs as Part of Health Insurance Coverage
- 1523 - Pharmacist's Role in Population Health Management
- 1525 - Standardization of Doses
- 1401 - Standardization of Oral Liquid Medication Concentrations
- 1419 - Documentation of Patient-Care Services in the Permanent Health Record
- 1306 - Standardization of Intravenous Drug Concentrations
- 1313 - Drug-Containing Devices
- 1107 - Patient-Reported Outcomes Tools
- 1114 - Pharmacist Accountability for Patient Outcomes
- 1005 - Medication Therapy Management
- 1023 - Scope and Hours of Pharmacy Services
- 0502 - Health Care Quality Standards and Pharmacy Services
- 0525 - Mandatory Tablet Splitting for Cost Containment
- 9820 - Medication Administration by Pharmacists

### Specific Practice Areas

- 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
- 2229 - Pharmacist's Role in Respiratory Pathogen Testing and Treatment
- 2240 - Post-Intensive Care Syndrome
- 2245 - Substance Use Disorder
- 2247 - Pharmacy Workforce's Role in Vaccination
- 2250 - Access to Reproductive Health Services
- 2254 - Pain Management
- 2102 - Use of Antimicrobials in Surgical Wounds and Procedures
- 2125 - Tobacco, Tobacco Products, and Electronic Nicotine Delivery Systems
- 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 by Medically Underserved Populations
- 2035 - Role of the Pharmacy Workforce in Violence Prevention
- 2041 - Safety of Intranasal Route as an Alternative Route of Administration
- 1901 - Suicide Awareness and Prevention
- 1910 - Therapeutic Use of Cannabidiol
- 1831 - Safe and Effective Use of IV Promethazine
- 1718 - Therapeutic And Psychosocial Considerations of Transgender Patients
- 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
- 1305 - Education About Performance-Enhancing Substances
- 1214 - Pharmacist's Role in Accountable Care Organizations
- 0902 - Pharmacist's Role in Providing Care for an Aging Population
- 0908 - Pharmacist Role in the Health Care (Medical) Home



0912 - Safe and Effective Use of Heparin in Neonatal Patients

0307 - Pharmacist Support for Dying Patients

## Pharmaceutical Industry

### Drug Products, Labeling, and Packaging

2221 - Tamper-Evident Packaging on Multidose Products

2244 - Pediatric Dosage Forms

2253 - Unit Dose Packaging Availability

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

1615 - Protecting Workers from Exposure to Hazardous Drugs

1535 - Nonproprietary Naming of Biological Products

0920 - Standardized Clinical Drug Nomenclature

0720 - Standardizing Prefixes and Suffixes in Drug Product Names

0402 - Ready-To-Use Packaging for All Settings

0002 - Drug Shortages

9608 - Use of Color to Identify Drug Products

9011 - Drug Nomenclature

### 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

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

1914 - Safe Medication Preparation, Compounding, and Administration in All Sites of Care

1915 - Pharmacy Department Business Partnerships

1810 - Pharmacy Accreditations, Certifications, and Licenses

1522 - Disposition of Illicit Substances

1417 - Integration of Pharmacy Services in Multifacility Health Systems

0901 - Workload Monitoring and Reporting

0918 - Pharmacist Leadership of the Pharmacy Department

0504 - Pharmacy Staff Fatigue and Medication Errors

### [Compensation and Reimbursement](#)

2232 - Revenue Cycle Management and Reimbursement and Pharmacist Compensation for Drug Product Dispensing

2233 - Value-Based Purchasing

2020 - Care-Commensurate Reimbursement

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](#)

2209 - Drug Testing as Part of Diversion Prevention Programs

2217 - Workforce Diversity

2234 - Financial Management Skills

2237 - Universal Vaccination for Vaccine-Preventable Diseases in the Healthcare Workforce

2103 - Professional Development as a Retention Tool

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

1828 - Promoting the Image of Pharmacists and Pharmacy Technicians

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

9108 - Employee Testing

### [Practice Settings](#)

2219 - Hospital-at-Home Care

2010 - Use of Two Patient Identifiers in the Outpatient Setting

1623 - Home Intravenous Therapy

### [Research](#)

2207 - Institutional Review Boards and Investigational Use of Drugs

2243 - Enrollment of Underrepresented Populations in Clinical Trials

1920 - Research on Drug Use in Obese Patients

1804 - Drug Dosing in Conditions that Modify Pharmacokinetics or Pharmacodynamics

## ASHP Statements, Endorsements, and Governance Positions

### Approval of ASHP Statements

- 2202 - Professionalism
- 2215 - Pharmacy Technician's Role in Pharmacy Informatics
- 2223 - Role of the Pharmacy Workforce in Emergency Preparedness
- 2225 - Pharmacist Prescribing of Statins
- 2226 - Role of Pharmacists in Primary Care
- 2227 - 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
- 2038 - ASHP Statement on the Use of Artificial Intelligence in Pharmacy
- 1919 - ASHP Statement on the Role of the Medication Safety Leader
- 1830 - ASHP Statement on Advocacy as a Professional Obligation
- 1532 - Roles and Responsibilities of the Pharmacy Executive
- 1533 - Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance
- 1534 - Pharmacist's Role in Clinical Informatics
- 1537 - Roles of Pharmacy Technicians
- 1421 - Pharmacist's Role in Clinical Pharmacogenomics
- 1226 - Role of the Medication Safety Leader
- 1227 - Pharmacist's Role in Medication Reconciliation
- 1228 - Use of Social Media by Pharmacy Professionals
- 1123 - Leadership as a Professional Obligation
- 1025 - Bar-Code Verification During Inventory, Preparation, and Dispensing of Medications
- 0922 - Pharmacist's Role in Antimicrobial Stewardship and Infection Prevention and Control
- 0923 - Health-System Pharmacist's Role in National Health Care Quality Initiatives
- 0818 - Bar-Code-Enabled Medication Administration
- 0820 - Standards-Based Pharmacy Practice in Hospitals and Health Systems
- 0821 - Pharmacy Services to the Emergency Department
- 0822 - Pharmacy and Therapeutics Committee and the Formulary System
- 0823 - Confidentiality of Patient Health Care Information
- 0824 - Criteria for an Intermediate Category of Drug Products
- 0724 - Role of Health-System Pharmacists in Public Health
- 0726 - Racial and Ethnic Disparities in Health Care
- 0415 - Use of Dietary Supplements
- 0234 - Pharmacist's Role in Hospice and Palliative Care
- 0235 - Role of Health-System Pharmacists in Emergency Preparedness
- 0023 - Reporting Medical Errors
- 9916 - Pharmacist Decision-Making on Assisted Suicide
- 9821 - Pharmacist's Role in Clinical Pharmacokinetic Monitoring
- 9504 - Pharmacist's Responsibility for Distribution and Control of Drug Products
- 9505 - Role of the Pharmacist in Patient-Focused Care
- 9304 - Pharmaceutical Care

9306 - Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices

9208 - Use of Medications for Unlabeled Uses

9111 - Pharmaceutical Research in Organized Health-Care Settings

8907 - Unit Dose Drug Distribution

8504 - Third-Party Compensation for Clinical Services by Pharmacists

#### [ASHP Endorsements](#)

9607 - Code of Ethics

#### [ASHP Governance](#)

0118 - State Affiliate Membership and ASHP Appointments

9411 - Name Change

## 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 1302, [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 mu<sub>2</sub> 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 equitable and inclusive student-centered career counseling approaches; further,

To urge colleges of pharmacy to develop an assessment process to evaluate the equity and inclusivity of their career counseling.

*This policy supersedes ASHP policy 8507.*

**Rationale**

To ensure students are exposed to the increasing diversity of postgraduate opportunities and ensure their success in obtaining those opportunities, a structured student-centered career counseling approach must be taken. ACPE Standards 14.4 (Advising) and 19.5 (Faculty/Staff Development) address career counseling but fail to address current concerns about equity and inclusivity in career counseling. Promoting a more equitable and inclusive student-centered career counseling approach will ideally result in a more diverse pharmacy workforce that is nimble and able to provide patient care services in more underserved communities and nontraditional care settings.

**2217****WORKFORCE DIVERSITY**

*Source: Council on Education and Workforce Development*

To affirm that a diverse and inclusive workforce contributes to improved health equity and health outcomes; further,

To advocate for the development and retention of a workforce whose background,

perspectives, and experiences reflect the diverse patients for whom care is provided; further,

To advocate that institutions incorporate diversity, equity, and inclusion initiatives into daily practices and strategic plans.

*This policy supersedes ASHP policy 1705.*

### **Rationale**

As the U.S. becomes more heterogeneous, the pharmacy workforce should reflect and respond to this increasingly diverse patient base. An inclusive pharmacy workforce is best able to positively impact the health and wellness of patients for whom care is provided. According to the Institute of Medicine, increasing diversity among healthcare providers is associated with improved access to care for racial and ethnic minority patients, greater patient choice and satisfaction, and better educational experiences for health professions students (Smedley BD, Butler AS, Bristow LR, eds. In the nation's compelling interest: ensuring diversity in the health-care workforce. Washington, DC: National Academies Press; 2004). Diversity in the pharmacy workforce includes, but is not limited to, the categories of sexual identity and gender expression, age, national origin, socioeconomic origin, ethnicity, culture, gender, race, religion, and physical, sensory, or mental disability. A diverse pharmacy workforce will provide the best care for all patients. Recognizing the positive impact of diversity, equity, and inclusion (DEI) on patient outcomes, it is important for the pharmacy workforce to incorporate DEI initiatives in strategic plans, communications, and hiring and retention practices across the pharmacy enterprise.

## **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](https://www.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 services 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

*Source: Council on Therapeutics*

To advocate that state board of pharmacy regulations include respiratory pathogen testing and associated prescribing or dispensing under pharmacists' scope of practice; further,

To support the development of specific and structured criteria for pharmacist prescribing, dosing, and dispensing of antimicrobials for treatment of respiratory infections; further,

To advocate for laws and regulations that would allow pharmacists to dispense antimicrobials when clinically indicated or refer patients, as appropriate, based on point-of-care testing; further,

To support the diagnosis and tracking of reportable diseases through pharmacist-driven testing and reporting to appropriate public health agencies prior to dispensing of antimicrobials; further,

To advocate for reimbursement for pharmacists' patient care services involved in respiratory pathogen testing and treatment; further,

To promote training and education of the pharmacy workforce to competently engage in respiratory pathogen testing and treatment when clinically indicated.

### ***Rationale***

There is currently a patchwork of state 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. 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 prescribers. 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).

Furthermore, a 2018 study found that 69% of pharmacists are willing to perform point of care testing (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.

Finally, 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 human immunodeficiency virus, but also showed an increased willingness to perform and recommend the tests, which could expand access.

## **2230**

### **ADVANCING DIVERSITY, EQUITY, AND INCLUSION IN EDUCATION AND TRAINING**

*Source: Council on Education and Workforce Development*

To advocate that health systems and organizations cultivate training and education partnerships that advance diversity, equity, and inclusion; further,

To advocate that all members of the pharmacy workforce actively participate in the equitable training and education of people from marginalized populations.

### ***Rationale***

People from marginalized populations, including Black, Indigenous, and People of Color (BIPOC) and others, can experience disparities when receiving or accessing healthcare. Implicit biases exist against underrepresented minorities among many healthcare providers, which can

perpetuate medication nonadherence, decrease trust in healthcare, and ultimately increase morbidity and mortality (Hall WJ, Chapman MV, Lee KM, et al. Implicit racial/ethnic bias among health care professionals and its influence on health care outcomes: a systematic review. *Am J Public Health*. 2015; 105:e60-e76).

ASHP created the Task Force on Racial Diversity, Equity, and Inclusion in June 2020. One of its three focus areas was education and training, which resulted in two key recommendations (13 and 16). The first of these recommendations encourages hospitals and health systems to include statements and/or integrate expectations into their departments' planning and operations for the equitable training of underrepresented minorities. Further, the Task Force recommended hospitals and health systems partner with knowledgeable organizations to help educate and train the pharmacy workforce on how to support future underrepresented minority pharmacy workforce members (e.g., training on implicit bias, cultural competency, and fostering an inclusive climate)([Report of the ASHP Task Force on Racial Diversity, Equity, and Inclusion](#). *Am J Health-Syst Pharm*. 2021; 78:903–906). Organizations are encouraged to partner with their respective offices of diversity, equity, and inclusion (DEI) as well as local or national organizations to support these education and training efforts (e.g., National Association for Equity, Diversity, and Inclusion [NAEDI] and Government Alliance on Race and Equity [GARE]). By advancing DEI in the education and training of the pharmacy workforce, all members of the pharmacy workforce can positively impact patient care.

## **2231**

### **CULTURAL COMPETENCY**

*Source: Council on Education and Workforce Development*

To foster the ongoing development of cultural humility and competency within the pharmacy workforce; further,

To educate the pharmacy workforce to interact with patients and caregivers in a manner that demonstrates respect for and responsiveness to personal and social identities; further,

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

*This policy supersedes ASHP policy 1613.*

### **Rationale**

The United States is rapidly becoming a more diverse nation. Culture influences a patient's belief and behavior toward health and illness. Cultural humility and competence can significantly affect clinical outcomes. Research has shown that overlooking cultural beliefs may lead to negative health consequences. According to the National Center for Cultural Competency, there are numerous examples of benefits derived from the impact of 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 client levels" of



healthcare that encourages provider cultural competence while recognizing that "[p]atients and families bring their own values, perceptions, and expectations to healthcare encounters which also influence the creation or destruction of cultural congruence." The [Report of the ASHP Ad Hoc Committee on Ethnic Diversity and Cultural Competence](#) and the [ASHP Statement on Racial and Ethnic Disparities in Health Care](#) support ways to raise awareness of the importance of cultural competence in the provision of patient care so that optimal therapeutic outcomes are achieved in diverse populations.

When considering holistic approaches to patient care, clinicians should recognize and respond effectively to all personal and social identities, including but not limited to the categories of sexual identity and gender expression, age, national origin, socioeconomic origin, ethnicity, culture, gender, race, religion or spirituality, and physical, sensory, or mental disability. 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.

## **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 policy 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 programs 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 policy 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**

*Source: Council on Pharmacy Practice*

To advocate that healthcare delivery organizations 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 for comprehensive medication management that includes autonomous prescribing authority for pharmacists as part of optimal interprofessional care; further,

To advocate that all pharmacists on the interprofessional team have a National Provider Identifier (NPI); further,

To advocate that payers recognize pharmacist NPIs.

*This policy supersedes ASHP policy 1213.*

### **Rationale**

Pharmacists are highly trained medication experts skilled in providing comprehensive medication management (CMM) services across the continuum of care. Nearly all states include pharmacist prescribing authority within their state practice acts, although those acts differ in how pharmacist prescribing authority is described, terminology used, and the degree of prescribing autonomy (i.e., autonomous or collaborative). Regulations at the state level are critical to ensuring that pharmacists can seamlessly provide CMM services within the interprofessional team and to the top of their skills and abilities. Pharmacists are a core healthcare team member, 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. A 2010 comprehensive systematic review of 298 studies of U.S. pharmacists' effect as a member of the patient care team found positive results on therapeutic and safety metrics (Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. *Med Care*. 2010; 48:923-33).

Autonomous prescribing allows pharmacists to be fully optimized as a part of the interprofessional healthcare team and ensures that their skills are used to the fullest potential to allow them to be responsible and accountable and fully execute CMM treatment plans. Pharmacist prescribing is implicit to interprofessional care delivery, but the form and manner of pharmacist prescribing varies among health systems and organizations. Independent and autonomous drug 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 autonomous prescribing 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, prescribing 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.

Many health systems authorize pharmacists to manage drug therapy by enacting pharmacy and therapeutics committee policies that require use of medical staff protocols and physician oversight for pharmacist-initiated orders. While this model works effectively for specific scenarios (e.g., management of population-specific patients), it does not allow the pharmacist to fully function and fulfill the CMM needs of their patients. Depending on the patient, medication, and degree of trust with the pharmacist, physicians often delegate therapeutic decision-making and medication treatment planning to pharmacists, based on the trust relationship developed through the interprofessional team and shared experiences in successfully dealing with challenging clinical situations, rather than through formal collaborative practice agreements. Common examples of pharmacist prescribing include independently managing symptoms and adverse events in oncology patients, identifying and resolving drug-induced disease or problems, managing anticoagulant therapy for patients whose clinical status falls outside specified parameters, and responding to general directives to simply “fix the problem” when medication therapy is indicated. Further, there are settings of care and pharmacy practice models that allow for autonomous and accountable prescribing authority by pharmacist practitioners as core component of CMM, without the need for collaborative practice authority for specific patients or populations. Pharmacist autonomous prescribing 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.

Pharmacists who prescribe must be recognized by payers and reimbursed for performing these advanced practice services. All pharmacist prescribers on the interprofessional team must possess a National Provider Identifier (NPI) number to monitor the care provided as well as reimburse for services rendered. 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 the pharmacists function as a part of the interprofessional team. Finally, interdisciplinary health professional training programs should incorporate the concept of pharmacist prescribing in a standard way to ensure



consistency amongst pharmacists practicing in similar practice settings and with similar levels of responsibilities.

## 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 (Schumacher S et al. Increasing influenza vaccination coverage in healthcare workers: a review on campaign strategies and their effect. *Infection*. 2021; 49: 387–99. <https://doi.org/10.1007/s15010-020-01555-9>). 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 is not well defined, nor are ways to prevent and treat this disorder well researched. It is recognized that patients with PICS require a multidimensional, 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 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

*Source: Council on Therapeutics*

To encourage healthcare organizations to develop an interdisciplinary team that includes pharmacists and respiratory therapists to provide institutional guidance; safety recommendations regarding preparation, dispensing, delivery, and exposure; and electronic

health record support for prescribing and administration of intravenous drug products for inhalational use; further,

To advocate for further research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for inhalational administration, devices for administration, and the effects of excipients; further,

To foster the development of educational resources on the safety and efficacy of inhalational administration of drug products not approved for that route and devices for administration; further,

To encourage manufacturers to develop ready-to-use inhalational formulations when evidence supports such use.

### ***Rationale***

Practitioners have been increasingly seeking out novel delivery mechanisms for drugs to patients who require a more localized application. This approach has more frequently been seen through the nebulization of antibiotics and antifungals that are formulated for intravenous (IV) use as a part of an effort to treat an invasive pulmonary infection in critically ill patients. Nebulization of IV morphine has also been used to provide relief in chronic obstructive pulmonary disease exacerbations, dyspnea in cancer patients, and pain management in trauma patients. Data for these treatment efforts is limited to small patient populations, and the information on the pharmacokinetics, safety, and efficacy of drugs administered by this method remain insufficient. Furthermore, the number of drug products that are formulated exclusively for the purpose of aerosolization is limited, and the degree of pulmonary penetration depends on the properties of antimicrobial formulations, including size, viscosity, surface tension, osmolality, tonicity, and pH. Drug stability, safety for both the patient receiving and the person administering the drug, and the methods of preparation and delivery also bear consideration. The mechanism of nebulization also introduces uncertainty. Because pneumatic nebulizers and ultrasonic nebulizers have different particle size tolerance and deliverability capabilities, susceptibility for contamination may vary, depending on the device used.

Nebulized drugs also present a potential risk to healthcare providers, who may be exposed to drug particles that are expelled through the device when administering the drug. Therefore, an interdisciplinary team that includes representatives from pharmacy and respiratory therapy (as it is often a respiratory therapist who administers the drug in an inpatient setting) is needed to ensure that occupational exposure is minimized, that patients are placed in rooms with proper ventilation, and that, if necessary, caregivers are provided with appropriate masks during administration.

There is evidence that certain drugs delivered by nebulization have a beneficial role in management of patient disease. It is important to recognize that 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 in order to improve patient tolerability. Due to this variability and potential source for sterile compounding and potential administration errors, where there is evidence that supports the

use of compounded nebulized drugs, manufacturers should be encouraged to create a commercially available formulation for delivery via nebulizer.

**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 in 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 in underrepresented 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 patients, fetuses, neonates, children, members of racial or ethnic minority groups, the elderly, and transgender individuals 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, particularly those of color; 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 the inclusion of 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.*

### **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, social determinants of

health, and ways to provide trauma-informed and culturally sensitive care to patients. 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**

*Source: Council on Pharmacy Practice*

To affirm that the pharmacy workforce has a role in improving public health and increasing patient access to vaccinations by promoting and administering appropriate vaccinations to patients and employees in all settings; further,

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

To advocate that states grant pharmacists and appropriately supervised student pharmacists the authority to initiate and administer all adult and pediatric vaccinations; further,

To advocate that states grant appropriately supervised pharmacy technicians the authority to prepare and administer all adult and pediatric vaccinations; further,

To advocate for the inclusion of pharmacist-provided vaccination training in college of pharmacy curricula and pharmacy technician-provided vaccination training in technician training programs; further,

To advocate that members of the pharmacy workforce who have completed a training and certification program acceptable to state boards of pharmacy and meeting the standards established by the Centers for Disease Control and Prevention may provide such vaccinations; further,

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

To advocate that state and federal health authorities require all vaccination providers to report their documentation to these centralized databases, if available; further,

To encourage the pharmacy workforce to educate all patients, their caregivers, parents, guardians, and healthcare providers to promote vaccine confidence and convey the importance of vaccinations for disease prevention; further,

To encourage the pharmacy workforce to seek opportunities for involvement in disease prevention through community vaccination programs; further,

To foster education, training, and the development of resources to assist the pharmacy workforce and other healthcare professionals in building vaccine confidence; further,

To advocate for adequate staffing, resources, and equipment for the pharmacy workforce to support vaccination efforts to ensure patient safety; further,

To advocate for appropriate reimbursement for vaccination services rendered; 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 and equitably distributed supply of vaccines.

*This policy supersedes ASHP policies 1309 and 2122.*

### **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 vulnerable 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 pharmacist vaccination authority.

Although all states permit pharmacist administration of some vaccines, state laws differ in the range of vaccines pharmacists 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 pediatric vaccinations. 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 pharmacist-provided vaccinations be conducted within a collaborative drug therapy management agreement) would encourage standardization of pharmacy vaccination practice within and among states, as would permitting appropriately supervised pharmacy technicians to prepare and administer vaccinations. ASHP also advocates for appropriate reimbursement for all vaccination services.

Only pharmacists, student pharmacists, and pharmacy technicians who undergo appropriate training and certification should be authorized by state boards to provide vaccinations. To ensure their consistency and quality, those training and certification programs should meet Centers for Disease Control and Prevention standards.

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 and health equity 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. Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines, and is influenced by factors such as complacency, convenience, and confidence. Vaccine-hesitant patients, healthcare providers, and caregivers have been found to be responsive to vaccine information, consider vaccination, and are not opposed to all vaccines, and therefore would benefit from counseling.

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, and to ensure that vaccines supplies are equitably distributed to promote public health by reducing disparities in vaccine access.

## **2248**

### **HEALTH-SYSTEM USE OF DRUG PRODUCTS PROVIDED BY OUTSIDE SOURCES**

*Source: Council on Pharmacy Management*

To support care models in which drug products are procured and/or prepared for administration by the pharmacy and are obtained from a licensed, verified source to ensure drug product and patient safety and continuity of care; further,

To encourage hospitals and health systems not to permit administration of drug products supplied to the hospital, clinic, or other healthcare setting by the patient, caregiver, or pharmacy contracted by a healthcare insurance payer or pharmacy benefit manager; further,

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of drug products; further,

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 2032.*

### **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 patient 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). ASHP supports care models in which drug products are procured and/or prepared for administration by the pharmacy and are obtained from a licensed, verified source and encourages hospitals and health systems not to permit administration of drug products supplied by the patient, caregiver, or a pharmacy contracted by a healthcare insurance payer or pharmacy benefit manager.

Healthcare insurance and pharmacy benefit management (PBM) models should ensure fair reimbursement and payment for drug product preparation and administration and in the provision of direct patient care services for drug products supplied to patients. 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.

## **2249**

### **SCREENING FOR SOCIAL DETERMINANTS OF HEALTH**

*Source: Council on Pharmacy Management*

To encourage social determinants of health (SDoH) screening and data collection using standardized codes during the provision of pharmacy patient care services; further,

To promote the integration of SDoH data into the design and delivery of clinical pharmacy services, including the creation of targeted interventions and leveraging the use of clinical decision support to improve patient outcomes; further,

To encourage the use of SDoH data in reporting and evaluating the effectiveness of pharmacist patient care; further,

To encourage the use of SDoH data to identify opportunities to reduce healthcare disparities and improve healthcare access and equity; further,

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

To advocate for the funding of community resources related to improving patient access to medications, and the integration of these resources into health-system care delivery models; further,

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

### ***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 the quality of life for individuals and communities. SDoH have been found to account for 80-90% of modifiable contributors to health outcomes. The CDC recognizes five distinct SDoH domains: [Economic Stability](#), [Education Access and Quality](#), [Healthcare Access and Quality](#), [Neighborhood and Built Environment](#), and [Social and Community Context](#). 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. 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 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 clinical practice (e.g., consults, medication reconciliation, patient assistance programs) to improve health outcomes. Patient screenings and data collection to ascertain SDoH should use 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. The 2020-2025 Federal Health IT Strategic plan includes strategies such as increasing standardization of SDoH data, integrating all captured SDoH data into electronic health records, strengthening health IT infrastructure through secure exchange of data and interprofessional collaboration, and leveraging data to improve related health outcomes. 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. Most vendors use the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) framework, which is a standardized patient risk assessment tool as well as a repository of resources to act on SDoH data. Vendors develop screening tools that are largely customizable to the needs of each customer organization or health system. In many situations, there is a need for patients to be referred to community-based organizations or external programs to address SDoH during transitions of care. 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. Additional 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 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. 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.

## **2250**

### **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 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.

### **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.)

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 patients 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 patient 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 patient. Under some state laws, pregnant patients 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.

## 2251

### QUALIFICATIONS AND COMPETENCIES REQUIRED TO PRESCRIBE MEDICATIONS

*Source: Council on Education and Workforce Development*

To affirm that prescribing is a collaborative process that includes patient assessment, understanding of the patient's diagnoses, evaluation and selection of available treatment options, monitoring to achieve therapeutic outcomes, patient education, and adherence to safe and cost-effective prescribing practices; further,

To affirm that safe prescribing of medications, performed independently or collaboratively, requires competent professionals who complement each others' strengths at each step.

*This policy supersedes ASHP policy 1202.*

#### **Rationale**

Debate about health care providers' evolving scopes of practice, focused primarily on prescribing privileges, has raised the question of what training and competencies should be required of current or potential prescribers. The increasing complexity of medication use,

growing diversity of professionals authorized to prescribe, and continuing high incidence of adverse drug events call for the development of standards for prescribing and further development of associated competencies and training requirements.

**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.

*Note: 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**

*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 the Food and Drug Administration to support this goal in the interest of public health and healthcare worker and patient safety.

*Note: This policy supersedes ASHP policy 1801.*

**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. 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 that reduce medication waste.

**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.

*Note: 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.

*Note: 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 Institute 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**

*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, and (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; 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 1103.*

#### **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 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.

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 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 ordered by the healthcare team from a CLIA-certified laboratory.

## **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.

**Rationale**

The addition of antimicrobials to irrigation solutions during surgical procedures in an effort to prevent surgical site infections has been a long-standing surgical practice. Antibiotics are the most common additives to surgical irrigation fluids, but recent data has shown no clinical benefit compared with saline irrigation, likely due to the mechanism of antibiotics needing a longer exposure time than is allowed during irrigation. 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 OR nurses were the individuals most often reported to be doing the mixing.

The results of numerous surveys of surgeons has indicated that the practice of using topical antibiotics intraoperatively, in both irrigation fluids and powders, is widespread. This practice stemmed from the belief that applying antibiotics locally would minimize toxicity and resistance. However, newer data suggest that there is a potential for toxicities and systemic exposure leading to resistance associated with these practices. Because of this, the 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. Complicating the picture is that neither the Joint Commission nor the Centers for Medicare and Medicaid Services have 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.

**2103****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.

*This policy supersedes ASHP policy 0112.*

### **Rationale**

Workforce development can take many forms, including formal education, informal mentoring, participation in certification programs, career ladder implementation, and expanded experiences. The need for job growth and career advancement is an important motivator for job satisfaction among those entering the workforce, such as 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, that are not taught in education and training programs and nurture the workforce to provide continuous succession planning.

## **2104**

### **FOSTERING LEADERSHIP DEVELOPMENT**

*Source: Council on Education and Workforce Development*

To work with healthcare organization leadership to foster opportunities, allocate time, and provide resources for members of the pharmacy workforce to move into leadership roles; further,

To encourage leaders to seek out and mentor members of the pharmacy workforce in developing administrative, managerial, and leadership skills; further,

To encourage members of the pharmacy workforce to obtain the skills necessary to pursue administrative, managerial, and leadership roles; further,

To encourage colleges of pharmacy and ASHP state affiliates to collaborate in fostering student leadership skills through development of co-curricular leadership opportunities, leadership conferences, and other leadership promotion programs; further,

To reaffirm that residency programs should develop leadership skills through mentoring, training, and leadership opportunities; further,

To foster leadership skills for members of the pharmacy workforce, including skills for pharmacists to use on a daily basis in their roles as leaders in patient care.

*This policy supersedes ASHP policy 1611.*

**Rationale**

In their 2013 report, *Is there still a pharmacy leadership crisis? A seven-year follow-up assessment* (*Am J Health-Syst Pharm.* 2013; 70:443–7), White and Enright anticipated a high rate in turnover of pharmacy directors and middle managers over the coming decade. Healthcare organizations must address this ongoing challenge if there are to be a sufficient number of new directors and managers to fill those positions. Factors that may contribute to a shortage of potential new leaders and managers include:

- New graduates frequently accept clinical positions or positions in drug distribution. After a few years, they may have a desire to assume managerial positions in health-system pharmacies, but training programs may not be convenient for them, and they may not have the resources to obtain training.
- Health-system pharmacy management positions do not turnover often. Prospective managers view those positions as unavailable for the near future, so there is little incentive to obtain training to be ready to move into those positions.
- Job satisfaction among pharmacy managers appears low to prospective managers.
- Frequent turnover in organizational administrative positions (above pharmacy) is frustrating to pharmacy directors, because they continually need to inform new administrators about the organization's medication-use strengths and weaknesses and the pharmacy department's roles, strategic plans, and priorities for sustaining quality and making improvements. In those turnover circumstances, diligently achieved pharmacy service improvements can sometimes be eroded and reversed. The ensuing frustration can induce pharmacy directors to depart voluntarily from management positions and make those positions unattractive to others.
- Flattening of organizational structures in healthcare organizations has eliminated numerous managerial positions in pharmacies, leaving fewer pharmacists to serve as mentors for prospective managers. Without positive role models, it is difficult for pharmacists to gain good management experience.
- Pharmacy management positions that combine clinical and management responsibilities sometimes allow little time for clinical work.
- Many pharmacists, even those in managerial positions, have no training in personnel administration. Skills such as conflict resolution and negotiation are rarely taught in pharmacy curricula but are very important in leadership positions.
- In some healthcare organizations, managers receive raises predicated on overall organizational or departmental performance. However, the compensation of some staff may be based on individual performance. These differing bases can lead to instances in which the compensation of those supervised is higher than that of their managers. When that occurs, it can be a disincentive to individuals considering management positions.

Leadership and managerial potential in today's student pharmacists, pharmacy technicians, and new graduates is as high as it has ever been, but more effort is needed to nurture that potential and develop leadership and management skills in practice. Colleges of pharmacy, state associations, residency programs, pharmacy technician training programs, and practitioners

themselves need to foster the development of leadership and management skills. ASHP can help foster leadership competencies at all levels of practice through actions such as providing education about leadership and management roles, developing web-based resources, and facilitating networking among leaders, managers, and those aspiring to such roles.

Leadership continues to be a critical area for development, as leadership is a necessary competency in the provision of patient care. There are multiple avenues available to pharmacists for leadership development and ASHP should take the lead in fostering this effort.

## **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.*

### ***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.

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 counterproductive and devastating 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.*

#### ***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.

**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.*

**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, measureable 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.*

### **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 the federal Health Resources and Services Administration 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.

#### ***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.

At the outset of the pandemic, hospitals and health systems struggled to make requests to the SNS for both medications and supplies. Because there was not a clear mechanism for making requests, with the process varying among states, 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 huge amounts of time to making SNS requests in the midst of an emergency – and there should be a mechanism for quickly checking on the status of SNS requests to avoid additional wasted time.

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 at any time, rather than predicated action on a triggering event, such as a disaster or shortage.

**2113****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 effort to implement appropriate pharmacogenomics services and to determine appropriate dissemination of actionable genetic 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 encourage pharmacy workforce education on the use of pharmacogenomics and its application to therapeutic decision-making.

*This policy supersedes ASHP policy 1104.*

**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.

With the advent of widely available pharmacogenomic tests, many are also marketed to the public, which 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.

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.

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.

**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**

*Source: Council on Therapeutics*

To support expanded access to oseltamivir through a proposed intermediate category of drug products, as described by ASHP policy, that would be available from all pharmacists and licensed healthcare professionals (including pharmacists) who are authorized to prescribe medications, rather than nonprescription designation; further,

To support diagnosis and tracking of influenza through pharmacist-driven influenza point-of-care testing and reporting to the appropriate public health agencies prior to oseltamivir dispensing; further,

To support interoperable documentation of oseltamivir dispensing and associated testing accessible by all members of the healthcare team in outpatient and inpatient settings; further,

To advocate that specific and structured criteria be established for prescribing, dosing, and dispensing of oseltamivir for treatment and prophylaxis by pharmacists; further,

To advocate that pharmacist-provided counseling for oseltamivir and patient education on influenza be required for dispensing; further,

To continue to promote influenza vaccination by pharmacists, despite oseltamivir availability; further,

To advocate that the proposed reclassification of oseltamivir be accompanied by coverage changes by third-party payers to ensure that patient access is not compromised and that pharmacists are reimbursed for the clinical services provided.



**Rationale**

Oseltamivir (Tamiflu) is a neuraminidase inhibitor used for the treatment and chemoprophylaxis of influenza. In July 2019, manufacturer Sanofi signed a deal with Roche Pharmaceuticals to obtain exclusive nonprescription rights to Tamiflu. ASHP would support the availability of oseltamivir as an intermediate category of drug products, as described in the ASHP Statement on Criteria for an Intermediate Category of Drug Products. This designation would facilitate appropriate use of oseltamivir after patient assessment and professional consultation by a pharmacist or other licensed healthcare professional who is authorized to prescribe medications.

There are several perceived advantages and disadvantages of the nonprescription designation for oseltamivir. Potential benefits include quicker and improved oseltamivir access for patients, public health value by reducing exposure of sick individuals at provider visits, unlikely development of oseltamivir 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 efficacy (an approximate reduction in symptom duration of one day), adverse effects (e.g., nausea, vomiting, headache, neuropsychiatric effects), reduction of influenza vaccination rates because of oseltamivir 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, public health considerations must also be a part of this expanded access. With availability over or behind the counter, patients may bypass visiting their primary care providers to obtain oseltamivir, 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 intent to expand patient access to oseltamivir, ASHP advocates that the proposed reclassification should not result in increased costs to patients and 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, oseltamivir dosing, counseling, and documentation of the care provided in the pharmacy and medical record. Pharmacists should be compensated for these clinical and patient care services.

**2117****EDUCATION AND TRAINING IN TELEHEALTH**

*Source: Council on Education and Workforce Development*

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

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

To promote the incorporation of students and residents into virtual modalities of care and interdisciplinary collaboration; further,

To foster documentation and dissemination of best practices and outcomes achieved by the pharmacy workforce as a result of telehealth services.

### ***Rationale***

Continuous development of information technology is rapidly redefining the provision of healthcare. The expansion of telehealth services creates opportunity to improve access to telepharmacy and telemedicine for patients unable to access health services in traditional modalities. Lack of access to healthcare remains critical for many individuals for a variety of reasons including geographic issues (i.e. rural communities), lack of transportation, physical or fiscal challenges. The provision of medical care using telehealth allows patients to have access when they need it at the time they need it.

To ensure that telepharmacy becomes a strong component of telehealth, training and education must be developed that supports the pharmacy workforce in their delivery of optimal patient care. Expanded access for the pharmacy workforce as well as interoperability and information integrity between organizations where patients may receive care is crucial. Additionally, student learners must have appropriate access levels with oversight to the electronic health record to ensure development of the skills needed for this type of care. Research supporting improved outcomes while maintaining security for patients' health information is needed to foster continued development.

## **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.

**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 through 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**

*Source: Council on Therapeutics*

To discourage the use of tobacco, tobacco products, and electronic nicotine delivery systems due to their long-term adverse health effects; further,

To oppose the distribution and sale of tobacco, tobacco products, and electronic nicotine delivery systems by pharmacies or facilities that contain a pharmacy; further,

To advocate for tobacco-free environments in hospitals and health systems; further,

To promote legislation that supports pharmacist prescriptive authority for tobacco-cessation medications; further,

To promote the pharmacist's interprofessional role in tobacco-cessation counseling and comprehensive medication management; further,

To join with other interested organizations in statements and expressions of opposition to the use of tobacco, tobacco products, and electronic nicotine delivery systems; further,

To educate the public and patients on the risks of nicotine consumption through traditional and electronic delivery systems.

*This policy supersedes ASHP policy 1625.*

### ***Rationale***

Pharmacists, as healthcare providers, have long discouraged the use of tobacco and tobacco products as a threat to public health. Electronic nicotine delivery systems (e.g., vaporizers, vape

pens, hookah pens, and electronic cigarettes and pipes) are relatively new and unregulated delivery systems for nicotine. The contents of these systems include flavorings, propylene glycol, glycerin, and other unknown ingredients, and the long-term effects of their use have not been studied. Given these uncertainties, pharmacists should discourage their use as well. In addition, ASHP opposes the distribution or sale of tobacco, tobacco products, and electronic 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.

Furthermore, 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.

## 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***

As outlined in the ASHP Statement on Racial and Ethnic Disparities in Health Care, race and ethnicity are social constructs with a cultural rather than a scientific basis. 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.

### **Rationale**

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 in particular 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.*

**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.*

### **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 that addresses the *Pharmacy Technician Training and Certification*, which advocates for the education, training, and certification for new pharmacy technicians. This covers a need for the on-going professional development and career advancement for pharmacy technicians.

### **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**

*Source: Council on Pharmacy Management*

To advocate for laws and regulations that require healthcare payer provider networks to include pharmacists providing patient care services within their scope of practice when such services are covered benefits; further,

To advocate 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; further,

To acknowledge that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality and viability of healthcare services provided; further,

To advocate for laws and regulations that would help ensure the same level of patient care within a payer network by requiring healthcare payers to (1) disclose to participating providers and those applying to participate the criteria used to include, retain, or exclude providers; (2) ensure that those criteria are standardized across all network providers; and (3) collect data on how well providers meet those criteria and report that data to providers; further,

To advocate for comparative, transparent sharing of performance and quality measure data based on those criteria.

*This policy supersedes ASHP policy 1808.*

### **Rationale**

As hospitals and healthcare organizations have become more engaged in developing ambulatory care services, pharmacists providing patient care services within those settings increasingly find themselves excluded from healthcare payer networks. Vertical integration of the healthcare value chain has given payers more control over healthcare costs and has better positioned them to link directly with providers and negotiate value-based contracts. 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), but when creating provider networks, payers should consider including pharmacists providing patient care services, within their scope of practice, when such services are covered benefits. To ensure equal treatment for healthcare providers, payers should be required to disclose to participating providers and those applying to participate in a provider network the criteria used to include, retain, or exclude providers. When pharmacists obtain provider status, the infrastructure required to implement direct, independent patient care and billing for provider-based services needs to be in place and accessible. Although a possible risk of payer transparency is a reduction in market competition, comparative, transparent sharing of performance and quality measure data, based on standardized criteria, reveals the level of patient care provided and demonstrates to payers and providers where their performance and quality fall in comparison to others. Ensuring that pharmacists have the opportunity to engage and have access to payers and payer networks improves coordination of care and patient access to pharmacists' care.

### **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.

#### ***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 (FDA. Medical Devices. Available at: <https://www.fda.gov/medical-devices>. Accessed August 20, 2020).

Pharmacists are experts in initiating and managing a patient’s comprehensive

medication management (CMM) plan. A CMM is an individualized care plan that helps patients achieve specific goals of therapy. The patient-centered medical home: integrating comprehensive medication management to optimize patient outcomes resource guide, 2nd ed. [www.pcpcc.org/sites/default/files/media/medmanagement.pdf](http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf)). 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.

ASHP has long advocated for the role pharmacists have in helping patients obtain and properly use drug delivery systems and devices. The ASHP Statement on the Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices states: Pharmacists bear a substantial responsibility for ensuring optimal clinical outcomes from drug therapy and are suited by education, training, clinical expertise, and practice activities to assume responsibility for the professional supervision of drug delivery systems and administration devices. As a natural extension of efforts to optimize drug use, pharmacists should participate in organizational and clinical decisions with regard to these systems and devices.

Extension of those responsibilities to medication-related medical supplies and equipment, DME, and medical devices is a natural progression in pharmacist patient care. There are many actions that pharmacists can implement to help improve patient outcomes in regards to medical supplies and equipment, DME, and medical devices. 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. Furthermore, 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.

Additionally, pharmacists 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. Pharmacists 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 pharmacist can use data provided from the devices to help make necessary changes to the patient's medication plan. Pharmacists' expertise should be leveraged to help patients procure and manage their medical supplies and equipment, DME, and medical devices to provide all-encompassing comprehensive medication management.

## **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](http://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](http://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 improving 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**

*Source: Council on Pharmacy Practice*

To affirm that extemporaneous 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 the principle that medications should not be extemporaneously compounded when drug products are commercially and readily available in the form necessary to meet patient needs; 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, where those exist; 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 and equipment that meet technical and professional standards to ensure the quality of compounded medications; further,

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

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

*This policy supersedes ASHP policy 0616.*

**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. 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 and other healthcare professionals about the potential risks associated with the use of extemporaneously compounded preparations.

**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**

*Source: Council on Public Policy*

To advocate for pharmacists' provision of telehealth services in all sites of care; further,

To advocate that reimbursement for pharmacists' provision of telehealth services be commensurate with the complexity and duration of service and consistent with other healthcare providers.

**Rationale**

During the COVID-19 public health emergency, hospitals, health systems, and clinics quickly pivoted to providing patient services via telehealth. The Centers for Medicare & Medicaid Services, commercial payers, and state policymakers have indicated that they would like to maintain telehealth services post-pandemic. Because pharmacists are not Medicare-eligible, it has been a struggle to ensure that they can be reimbursed for services provided via telehealth. In particular, it is vital that services be reimbursed at a level commensurate with the complexity and duration of the service and consistent with other healthcare providers, to ensure that patients can maintain access to services.

**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.

**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.*

**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.

Hormone therapies for agricultural purposes 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 needs to 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.*

**Rationale**

According to the [Centers for Disease Control and Prevention](#) (CDC), almost 5% of the U.S. population over 12 years old used prescription pain relievers for nonmedical reasons in 2010, resulting in 15,000 overdose deaths. A major source of diversion is unused prescription drug products, such as those left over after a patient has gained relief from temporary pain. Although prescribers and other healthcare providers have long been aware of the dangers of unused prescription drug products, incentives for overprescribing remain. The desire to minimize office visits, concern about undertreatment of pain, and prohibitions against partial fills and refills of controlled substances contribute to overprescribing. In addition to the risk of misuse, abuse, and diversion, research reveals that as many as 10 million prescriptions go unused every year, resulting in up to \$5 billion in wasted medication (Lenzer J. *BMJ* 2014; 349:g7677). There is clearly a need for concentrated effort to minimize medication waste from unused prescription drug products.

ASHP recognizes the need for research on best practices to ensure appropriate quantities of drug products are prescribed, reconciled, and dispensed, which will include study of the effectiveness of partial fills or refills of prescription drug products, among other solutions. ASHP has concerns about quantity and duration limits, because rigid restrictions on treatment options may result in adverse patient outcomes.

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 through appropriate pain management practices 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.*

#### **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. ASHP supports efforts to prohibit 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.*

### **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 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. 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.

## 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.*

### **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 currently state laws 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.

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.

There may be false patient perception that oral anticancer agents are less dangerous than IV chemotherapy, furthering 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.*

#### **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

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

To advocate that the FDA engage a single third-party author to provide editorial control of 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 unalterable content, format, and distribution of CMI.

*This policy supersedes ASHP policy 1513.*

### **Rationale**

ASHP supports the intent of efforts to improve the quality, consistency, and simplicity of consumer medication information (CMI). The Food and Drug Administration (FDA) defines CMI (previously called *patient medication information*, or PMI) as “written information about prescription drugs developed by organizations or individuals other than a drug’s manufacturer

that is intended for distribution to consumers at the time of drug dispensing.” CMI is not reviewed or approved by the FDA or a drug’s manufacturer.

In the 1970s, the FDA began evaluating the usefulness of patient labeling, and in 1996, [Public Law 104-180](#) defined PMI “usefulness” as being “scientifically accurate, unbiased in content and tone, sufficiently specific and comprehensive, presented in an understandable and legible format that is readily comprehensible to consumers, timely and up-to-date, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm.” In 2002, the National Association of Boards of Pharmacy conducted a study on the usefulness of PMI and that found that 89% of patients in the study received some form of written PMI but that only about 50% of the PMI met the definition of usefulness.

In 2006, the FDA published [guidance](#) on useful written CMI. However, because CMI improvement efforts were largely based on consensus of expert opinion, rather than quantitative and well-documented evidence, and because subsequent studies were conducted using expert-based focus groups and other study designs that do not reflect typical patients and under flawed methodology, ASHP encourages the development of evidence-based models for CMI that are designed to support desired outcomes (e.g., better medication use, improved patient safety). In addition, research to validate the effectiveness of any new CMI models under real-use conditions by actual patients, including establishment of a universal literacy level for CMI, should be encouraged. Evidence to establish the essential CMI content needed for the safe and effective use of medications by patients remains to be determined.

Although drug information publishers have made significant progress in improving the quality of CMI, this content is often truncated or provided in illegible formats to accommodate size restrictions or marketing information on patient drug information leaflets that are stapled to prescription packaging.

Because of the FDA’s long history of failure to ensure the consistency, currency, and accuracy of the professional labeling on which CMI would be based; the potential for inclusion of biased or promotional information; and the resulting patient confusion and possible harm, ASHP strongly opposes any proposal for manufacturer-authored CMI that would not be subject to FDA review. Approximately 85% of professional labeling has not been reviewed or updated since 1992 to reflect FDA’s current standard for the Physician Labeling Rule (PLR) format. In addition, numerous inconsistencies and inaccuracies in such labeling continue. Given these limitations, the majority of information on which CMI would be based under such a regime would not be likely to “enhance the safe and effective use of prescription drug products and in turn reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information,” which is the main goal of the FDA requirements.

ASHP further advocates that state legislatures and regulatory agencies require that all dispensers distribute CMI according to FDA-established standards and be held accountable if CMI content or format is modified in a manner that results in nonconformance to the standards.

Creation and maintenance of CMI by a single third-party author (subject to FDA-contracted standards and quality assurance metrics) would provide clear, concise, unbiased, evidence-based CMI that is both timely and consistent for the same drug and for relevant information within the same drug class. Such coordination of the medication information

database would allow for consistency in style and content, as well as more frequently updated content.

Due to the evolution of how information is consumed and accessed and in light of the 2009 [Health Information Technology for Economic and Clinical Health \(HITECH\) Act](#), ASHP also advocates that CMI also be consumable across multiple platforms, including electronic platforms, as more individuals use online medical records to better manage their health and healthcare needs. The Department of Health and Human Services has reported a steady increase in the proportion of individuals who reported having been offered access to their online medical record, with approximately three-quarters of individuals reporting having access to a current list of medications within their online medical record.

## 2006

### PHARMACIST'S LEADERSHIP ROLE IN ANTICOAGULATION THERAPY MANAGEMENT

*Source: Council on Therapeutics*

To advocate that pharmacists provide leadership in caring for patients receiving drug products for anticoagulant therapy management; further,

To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving drug products for anticoagulation therapy management; further,

To encourage pharmacists who participate in anticoagulation therapy management to educate patients, caregivers, prescribers, and other members of the interprofessional healthcare team about anticoagulant drug product uses, drug interactions, reversal therapies and strategies, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

*This policy supersedes ASHP policy 1703.*

#### **Rationale**

As medication experts, pharmacists are well positioned to play a key role in implementation, maintenance, monitoring, management of complications, risk assessment, and assurance of continuity of care for patients receiving medications for management of anticoagulation therapy. Inappropriate medication-related management of anticoagulants creates unnecessary preventable harm.

Since 2008, The Joint Commission National Patient Safety Goals for hospitals have included a requirement for reducing the likelihood of harm associated with anticoagulant therapy. Healthcare facilities were instructed to assign leadership for ensuring compliance with this requirement, standardize therapeutic practices and protocols, establish monitoring procedures and a drug–food interaction program, individualize care for each patient receiving these treatments, and provide education on the appropriate management of these patients. In 2019, the related elements of performance [were revised](#) to address a rise in adverse drug events associated with direct oral anticoagulants (DOACs).

**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.*

**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 than 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. 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 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. 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 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.*

#### **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.

#### ***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**

*Source: Council on Pharmacy Practice*

To encourage the use of two identifiers to confirm patient identity when transferring filled prescriptions to the possession of the patient or patient's agent for outpatient use.

*This policy supersedes ASHP policy 1024.*

**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.*

**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. When possible, pharmacists should be included as providers in medical staff bylaws.

**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.*

**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, or 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.

#### ***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 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.*

**Rationale**

For the past two decades, the U.S. health system has been racing to take advantage of the potential that digital health information offers for improved patient care. Each institution and practice has 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, even within departments.

In 2004, an executive order created the Office of the National Coordinator for Health Information Technology (ONC). ONC is the primary federal entity charged with coordination of nationwide efforts to implement and advance health information technology and the electronic exchange of health information. 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.

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.” ONC 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 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 sharing of health information, 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. Pharmacists have 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 have the ability to share relevant patient care data securely across care settings is a critical step 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.*

**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 Statement 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.

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.

#### ***Rationale***

Firearm-related injury is a leading cause of death in the U.S. Over 39,000 people succumbed to death by firearm-related injuries in 2017 (60% by suicide, 37% from homicide, 1% unintentional, and 1% related to legal intervention), which translates to 12.2 deaths per 100,000 population. For perspective, there were 14.9 drug overdose deaths involving any opioid and 11.9 motor vehicle traffic deaths per 100,000 population. Over 67,000 people receive medical care in an emergency department or are hospitalized (approximately 46% and 54%, respectively) as a result of a firearm-related injury inflicted by assault, self-harm, or unintentional action. According to the [American College of Surgeons](#), in 2016 a firearm was involved in 51% of suicides and 75% of homicides, and while there has been 22% decrease in traffic-related deaths since 1999, there has been a 17% increase in firearm-related intentional injury death rates over the same period.

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 (HVIPs), screening and treatment for post-traumatic stress disorder, and case management aimed at preventing firearm-related violence and injury recidivism.

In February 2019, the American College of Surgeons hosted a [summit](#) of 44 major medical and injury prevention organizations and the American Bar Association with the goal of



building consensus around ways to address the growing problem of firearm injury and death in the U.S. The participants arrived at the following consensus positions.

1. Firearm injury in the US is a public health crisis.
2. A comprehensive public health and medical approach is required to reduce death and disability from firearm injury.
3. Research is needed to better understand the root causes of violence, identify people at risk, and determine the most effective strategies for firearm injury prevention.
4. Federal and philanthropic research funding must be provided to match the burden of disease.
5. Engaging firearm owners and populations at risk is critical in developing programs and policies for firearm injury prevention.
6. Healthcare providers should be encouraged to counsel patients and families about firearm safety and safe storage. Educational and research efforts are needed to support appropriate culturally competent messaging.
7. Screening for the risk of depression, suicide, intimate partner violence, and interpersonal violence should be conducted across all healthcare settings and in certain high-risk populations (such as those with dementia). Comprehensive resources and interventions are needed to support patients and families identified as high risk for firearm injury and who have access to a firearm.
8. Hospitals and healthcare systems must genuinely engage the community in addressing the social determinants of disease, which contribute to structural violence in underserved communities.
9. Our professional organizations commit to working together and continuing to meet to ensure these statements lead to constructive actions that improve the health and well-being of our fellow Americans.

ASHP recognizes that these consensus positions provide one example of a comprehensive public health and medical approach to reducing death and disability from firearm injury and that 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.*

**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. Healthcare should be affordable, but also sufficient to ensure patient access to services.

**2020****CARE-COMMENSURATE REIMBURSEMENT**

*Source: Council on Public Policy*

To advocate that reimbursement for healthcare services be commensurate with the level of care provided, based on the needs of the patient.

**Rationale**

As a means to reduce costs for federal programs, the Centers for Medicare & Medicaid Services (CMS) has been aggressively expanding efforts to reduce reimbursement at certain sites of care. Specifically, CMS has cut reimbursement for care services provided at hospital outpatient departments to match the rate paid physicians' offices. CMS refers to this policy as "site-neutral payment." On the basis of site neutrality, CMS also extended cuts to hospital reimbursement for drugs purchased under the 340B drug discount program to hospital outpatient departments. Private payers have also sought to impose site-neutral payment policies.

Reimbursement for services should reflect unique factors associated with a site of care. Hospital outpatient departments are held to higher quality standards with more oversight than what is often required for alternate sites of care. In addition to the Medicare Conditions of Participation, hospital outpatient departments must meet accreditation, United States Pharmacopeia (USP), and even Food and Drug Administration requirements. These standards result in high-quality patient care, but at a higher cost than what can be accomplished without the oversight.

Patients may also derive benefits from receiving care at a hospital outpatient department. Hospital care delivery models are crafted to ensure that patients receive the highest quality care possible. For hospitals that belong to an accountable care organization or are otherwise part of an integrated network, seeing patients at the outpatient department allows providers to better coordinate care, resulting in improved patient outcomes. Care provided in this setting is often highly complex and complementary to acute care that the patient receives from the hospital. Drastic cuts to hospital outpatient reimbursement could endanger the long-term viability of these care delivery models – if services are cut or outpatient departments are closed, patient access will suffer.

**2021****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 other state and federal agencies whose mission it is to protect the public health; further,

To advocate representation on state boards of pharmacy and related agencies by pharmacists and pharmacy technicians; further,

To advocate that hospitals and health systems are adequately represented on state boards of pharmacy; further,

To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies including funding for the training of state board of pharmacy inspectors and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the pharmaceutical supply chain, and protection of the public; further,

To advocate that inspections be performed only by individuals with demonstrated competency in the applicable area of practice.

*This policy supersedes ASHP policy 1507.*

### **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 add 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.

## **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.*

### **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 9903.

## 2023

### NEW CATEGORIES OF LICENSED PHARMACY PERSONNEL

*Source: Council on Public Policy*

To oppose the creation of new categories of licensed pharmacy personnel.

#### ***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. In effect, this would create another midlevel provider in the pharmacy. Not only would this create confusion regarding terminology and job roles, it would undermine ASHP’s work to professionalize the technician role. 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.

#### ***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 nontopical 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 located 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.

**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.*

**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.

#### ***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 programs (PDMPs). 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.

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 (h) 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. 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.*

**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 make the most effective interventions when selecting, modifying, and monitoring patients' drug therapy regimens.

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. An increasing number of pharmacy graduates are completing one or two years of residency training after graduating in order to bolster their clinical skills and develop clinical judgement, which is acquired only through experience and reflection on that experience.

The number of PGY1 residencies continues to grow with the number of available residencies in the U.S. is now nearly 2600 programs. The growth in the number of pharmacy school graduates has begun to plateau while PGY1 residency positions has grown 11% in the last three years.

**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.

**Rationale**

Pharmacy leadership should be directly involved in the selection of the health system's pharmacy benefit manager (PBM) servicing their employee's 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 BY 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.

#### ***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 subset within an established geographic area. MUPs may face economic, cultural, or linguistic barriers to healthcare; examples include low-income, Medicaid-eligible, homeless, migrant or seasonal worker, or Native American populations. Many federal programs use different types of shortage designations to determine eligibility. The Health Center Program and Physician J-1 Visa Waiver Program, for example, use both MUA and MUP, whereas the CMS Rural Health Clinic Program only uses MUA. Trends within the healthcare industry are also increasing the number of MUPs. 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.

Increasing hospital closures are not a recent phenomenon – rural areas have been closing hospitals for decades. For instance, 140 rural hospitals closed between 1985 and 1988 after the implementation of Medicare’s Inpatient Prospective Payment System. This payment model led to large Medicare losses and increased financial distress for many rural hospitals, ultimately resulting in numerous hospital closings.

Today, many rural hospitals are facing a similar fate. Nationally, 430 rural hospitals 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.

Since 2010, 99 hospitals in rural areas and MUAs in the U.S. have closed. Between 2013 and 2017 alone, 64 rural hospitals closed, which is more than twice as many as the previous 5-year period. Hospital closures disproportionately affected rural hospitals in the South (64% of rural hospital closures) and are more prevalent in states that did not expand Medicaid coverage. It is estimated that hundreds more hospitals are at risk of closing; therefore, the impact of these closures on access to and continuity of care should be assessed.

Although hospital closures in rural areas have numerous consequences, reduced access to care for the populations served is the most obvious one. An analysis by the Medicare Payment Advisory Commission determined that one third of hospitals that have closed since 2013 are more than 20 miles from the next closest hospital. An issue brief published by The Kaiser Commission on Medicaid and the Uninsured found a major impact of hospital closure to be loss of access to emergency care in the community; more specifically, a lack of access for people with acute mental health or addiction treatment needs was found.

Other consequences of rural hospital closures are focused around accessibility of physicians and other healthcare providers. Regardless of hospital closures, rural communities commonly struggle to recruit and retain healthcare providers. Retention of these providers becomes increasingly difficult when a hospital closes due to providers relocating to an alternative hospital or clinic location. As a result, communities are often left without vital healthcare providers and exacerbated gaps in access to specialty care. For instance, specialists who visited the local hospital on a regular basis become unavailable to residents in the area after the hospital closes, or residents lose their access point for referrals to subspecialists. In addition, once hospitals close other resources dwindle, such as home health, pharmacy, hospice, and emergency medical services care, thus leading to hospital deserts and a dramatic decrease in access to and continuity of care for residents.

With the number of hospital deserts increasing, 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.

It is important to note that not all rural hospital closures lead to a complete depletion in access to care for residents. There has been some success with transitions to community-based primary care following a hospital closure. In this scenario local residents still have access to primary care services, but not necessarily critical services, such as those necessary for cardiac arrest or stroke. Currently there is no systematic approach to determine which services are critical to provide locally or virtually, and not every hospital closing can be smoothly

transitioned into a primary care facility to address residents' healthcare needs.

## 2030

### INTERSTATE PHARMACIST LICENSURE

*Source: Council on Pharmacy Management*

To advocate for interstate pharmacist licensure to expand the mobility of pharmacists and their ability to practice.

#### **Rationale**

Rapid changes in technology have increasingly allowed healthcare to be delivered at a distance, and the growth of health systems and the consolidation and closing of hospitals in rural areas have created a demand for practitioner mobility across state lines. The century-old state-by-state licensure model of pharmacy has not kept pace with these changes, creating barriers to care. The nursing profession has addressed this challenge by creating the [enhanced Nurse Licensure Compact \(NLC\)](#). Under the NLC, registered nurses and licensed practical/vocational nurses who meet uniform standards are granted one multistate license that provides the privilege to practice in their home state and any other NLC state. This licensing model protects the interests of the state in ensuring the qualifications of its healthcare providers while fostering provider mobility and distance healthcare, increasing access to care. This licensing model has demonstrated its value by growing to include 25 states over 20 years. In addition, the NLC reduces the cost and administrative burden of licensure to both healthcare organizations and providers.

## 2031

### CONTINUITY OF CARE IN INSURANCE PAYER NETWORKS

*Source: Council on Pharmacy Management*

To oppose provider 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.

#### **Rationale**

As hospitals and healthcare organizations have become more engaged in developing ambulatory care services, pharmacies (e.g., specialty, outpatient infusion) and pharmacists working in those settings increasingly 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), but when creating provider networks, payers should also consider the potential impacts on a patient's care and choice. Patients generally choose pharmacies that are most convenient for them. When providers or 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 (EHR) integration, proximity and relationship to providers, and in some cases onsite clinical pharmacy specialists. This clinically superior environment, coupled with health systems' ability to measure

and meet outcome-based metrics, allows them to easily show their performance against other pharmacies. Therefore, giving payer network access to integrated health-system pharmacies could improve care coordination and quality-based care, and reduce overall cost.

**2032****HEALTH-SYSTEM USE OF MEDICATIONS SUPPLIED TO HOSPITALS BY PATIENTS, CAREGIVERS, OR SPECIALTY PHARMACIES**

*This policy was superseded by ASHP policy 2248.*

**2033****HEALTH-SYSTEM USE OF ADMINISTRATION DEVICES SUPPLIED DIRECTLY TO PATIENTS**

*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.*

**Rationale**

The potential exists for serious patient safety and liability issues for healthcare staff when the use of patients' own infusion 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, complemented by expedient methods to gain familiarity and competency demonstration with a device. 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.

***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 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*

To acknowledge that racism, discrimination, and inequities exist in healthcare and society; further,

To assert that racism, or any form of discrimination or injustice, has no value in society and cannot be tolerated; further,

To fervently commit to creating a just and inclusive healthcare system and society.

#### ***Rationale***

ASHP and its members have long been committed to eliminating [racial and ethnic disparities in healthcare](#) and recognize the need to further strengthen that commitment following the recent killings of George Floyd, Ahmaud Arbery, and Breonna Taylor. ASHP has pledged to take actionable steps through the creation of a Board of Directors–appointed Task Force on Racial Diversity, Equity, and Inclusion. The Task Force is charged with taking inventory of ASHP’s efforts in the areas of racial diversity, equity, and inclusion as they relate to issues facing Black



Americans, and for making related recommendations on new or enhanced efforts ASHP may undertake. ASHP further seeks to help eliminate racism, discrimination, and inequities that impact other minority and underrepresented populations and to help improve diversity, equity, and inclusion in healthcare and society.

**2037****SUPPORT OF THE WORLD HEALTH ORGANIZATION**

*Source: House of Delegates*

To strongly support the mission and work of the World Health Organization in its role in public health preparedness, prevention, and control to improve the health and well-being of people globally.

***Rationale***

In an age of global travel between and among countries, the efforts to prevent, control, treat, and eradicate diseases and conditions that decrease health and well-being of all peoples are critical to all countries, independent of factors such as income and education. Addressing new vectors of disease transmission and behavioral conditions related to lifestyles and environmental conditions continue to provide challenges that need to be addressed. Agencies such as World Health Organization that provide evidence-based warnings, guidelines, education, research, and advocacy, and that collect data to help countries prepare their public health infrastructure, are critical in providing all peoples with the tools and resources needed to address critical health issues globally.

**2038****ASHP STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE IN PHARMACY**

*Source: Section of Pharmacy Informatics and Technology*

To approve the ASHP Statement on the Use of Artificial Intelligence in Pharmacy.

**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.*

### **Rationale**

The terms *complementary*, *alternative*, and *integrative* are sometimes used interchangeably to describe healthcare approaches that are not part of conventional medical care. When a non-mainstream practice is used together 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 so pharmacists and other healthcare practitioners have the knowledge and information they need to safely treat and advise patients.

## **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.*

### **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 those in which the drug is used off label, represent adverse events that may take multiple years to emerge, or other adverse events that are relatively rare. Postmarketing studies provide the best opportunity to identify such events. 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 and Patient-Centered Outcomes Research Institute. 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*

To encourage the development of institutional guidance and advocate for further research

on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for intranasal administration; further,

To foster the development of educational resources on the safety of intranasal administration of drugs not approved for that route; further,

To encourage manufacturers to develop intranasal formulations in ready-to-use devices.

*This policy supersedes ASHP policy 1601.*

### **Rationale**

Intranasal administration can be used for systemic drug delivery and is the delivery route of choice in specific circumstances. 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 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. Certain rescue medications such as naloxone can also be administered intranasally and may be preferred for intravenous drug users. Vaccines are also commonly administered via the intranasal route.

Because many of these drugs are not approved for intranasal administration, there are varying degrees of evidence for use in specific cases. There is also varying evidence regarding the degree of systemic absorption of intranasally administered drugs that are not formulated for that route. A large number of characteristics may affect systemic distribution from the intranasal route, such as the presence of preservatives and viscosity of the agents. Given the interest in and potential benefits of intranasal administration, further research on the pharmacokinetics and pharmacodynamics of that route is needed.

In recent years, intranasal administration has become a part of routine practice, but a pre-made, ready-to-administer device has not been developed. Medication is often administered through an ancillary device such as an atomizer to optimize delivery, but these devices are not always available and have been on backorder in the past. By encouraging manufactures to develop intranasal formulations in ready-to-use devices, patient-specific doses could be administered, allowing patients or caregivers to administer medications in a less-invasive or labor-intensive method.

## **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.*

### **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) [2019 National Drug Threat Assessment Summary](#), controlled substances are responsible for the most drug-involved overdose deaths and are the second most commonly abused substances in the United States. Traffickers continue to manufacture and distribute counterfeit controlled substances, often containing fentanyl and other opioids, along with non-opioid illicit drugs in attempts to expand their customer base and increase profits.

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.

## 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.*

### **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) sets forth new definitions and requirements related to drug product tracing. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, which will identify and trace certain prescription drug products as they are distributed in the United States. Implementation of this new electronic, interoperable system, over a 10-year period, 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.

## 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.*

#### **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, 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 pharmacists, 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**

*Source: Council on Education and Workforce Development, Council on Pharmacy Management, Council on Pharmacy Practice, Council on Public Policy, and Council on Therapeutics*

To support the goal of zero suicides; further,

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

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

To recognize that pharmacists, as key providers on the patient care team, are integral to suicide awareness and prevention 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 provide education that assists the pharmacy workforce in their continuing professional development efforts related to suicide awareness and prevention; further,

To support the inclusion of suicide awareness and prevention principles throughout pharmacy curricula and postgraduate educational and training programs; further,

To encourage efforts that support universal education and training of healthcare providers in suicide awareness and prevention; further,

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

To enhance awareness of local, state, and national suicide awareness and prevention resources, including the National Suicide Prevention Lifeline funded by the Substance Abuse and Mental Health Services Administration; further,

To foster education and research on suicide awareness and prevention.

#### ***Rationale***

The high and increasing number of suicides in the U.S. has created a call for national action. The U.S. Surgeon General and the National Action Alliance for Suicide Prevention, in the 2012 [National Strategy for 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.

The responsibility for healthcare professionals to become involved in suicide prevention 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, when viewed as the collective efforts of government, public and private organizations, and care providers to reduce the incidence of suicide, 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 and prevention 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. Clinical pharmacy specialists trained in behavioral health could also be incorporated into behavioral health programs to serve as a resource to the healthcare 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 1825, Clinician Well-Being and Resilience.

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 and prevention efforts. Further, ASHP advocates inclusion of suicide awareness and prevention in college of pharmacy curricula and postgraduate educational and training programs, through a multimodal approach. ASHP also advocates universal suicide awareness and prevention training for healthcare providers, including pharmacists, via mandatory state education requirements and other means. Adequate government and private-sector funding of suicide awareness and prevention efforts will be required to promote the success of suicide awareness and prevention efforts. ASHP joins other organizations in supporting efforts to promote awareness of local, state, and national suicide awareness and prevention resources, including the [National Suicide Prevention Lifeline](https://suicidepreventionlifeline.org/) (1-800-273-TALK [8255]), with the ultimate goal of making the Lifeline number as memorable as the 911 emergency hotline. The Lifeline, accessible via phone and chat (<https://suicidepreventionlifeline.org/>), is a national network of 150 local crisis centers that provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. Finally, ASHP urges research on suicide awareness and prevention, including research on patient assessment tools, the role of genomic testing in drug approval and patient care, and practice models and strategies to identify and manage patients at risk for suicide.

## 1902

### SAFE ADMINISTRATION OF HAZARDOUS DRUGS

*Source: Council on Pharmacy Practice*

To advocate that all healthcare settings proactively conduct an interprofessional assessment of risk for exposure to hazardous drugs (HDs) during administration, including when closed-system transfer devices (CSTDs) cannot be used; further,

To advocate for pharmacist involvement in the development of policies, procedures, and operational assessments regarding administration of HDs, including when CSTDs cannot be used; further,

To encourage device and pharmaceutical manufacturers and the Food and Drug Administration to foster development of CSTD-compatible, ready-to-administer HD products.

#### ***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. These procedures are becoming more common. 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. 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.

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. ASHP encourages all healthcare settings to conduct an interprofessional, proactive assessment of the risk of such procedures to assess the potential exposure risks for healthcare providers and identify mitigating measures. Given their depth of knowledge regarding the handling of HDs, pharmacists should be involved in the development of policies, procedures, and operational assessments regarding administration of HDs in such circumstances. To reduce the risks to healthcare providers, ASHP encourages device and pharmaceutical manufacturers and the Food and Drug Administration to foster the development of CSTD-compatible, ready-to-administer HD drug products. The goal would be that CSTDs be utilized for all routes of administration of HD products as a best practice. However, when such use is not possible, an assessment of risk could 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 could also address any specialized training for staff in procedural areas, or the availability of a HD-specialized trained staff member to assist in the administration of the drug (e.g., a “chemo nurse”).

### 1903

#### **COMPOUNDED STERILE PREPARATION VERIFICATION**

*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.*

#### **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 2017 ASHP survey showed that 64% of hospitals did not use any technology for sterile product preparation activities. Only 26.9% of health systems surveyed employed barcode verification in their IV medication preparation and verification process. The survey found that 12.8% 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, with only 27% of respondents to the 2017 survey indicating their departments use barcode scanning to verify the ingredients in CSPs. 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.

##### ***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.

### ***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).

FDASIA requires that drug product manufacturers submit a notification of a production disruption to FDA. Manufacturers should also be required to provide in these notices a specific reason for the shortage and an estimated timeline for resolution. This information would be helpful not only to those affected but also in the federal evaluation of the risks posed by drug product shortages. 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 those manufacturers.

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

*Source: Council on Public Policy*

To advocate for states to allow any pharmacist, during a declared emergency, to dispense without a prescription an emergency supply of a drug product in quantities that meet the needs of patients.

#### ***Rationale***

Many states allow pharmacists to provide emergency supplies of prescription drug products during or in the immediate aftermath of a declared emergency. States such as Florida allow this practice for up to 72 hours after an emergency has been declared (i.e., a patient can obtain a 72-hour supply during an emergency or disaster). However, the long duration of events like hurricanes demonstrates the need to expand the 72-hour window. Hurricanes, for example, typically generate an emergency declaration prior to the storm, and the impact can last until days after the storm, when flood waters crest. Several states, including California and Texas, allow pharmacists to adequately provide prescription drug products, excluding controlled substances, during disasters, emergencies, or catastrophic events. In California, pharmacists are empowered to use their professional judgment when determining the appropriate quantity of an emergency fill. In these situations, patients without a prescription may use an empty pill bottle or other documentation to demonstrate their need for a drug product. In addition, states sometimes require appropriate follow-up by the pharmacist with the patient's prescriber and supporting documentation of the provision of care under an emergency declaration. American Medical Association policy H-120.933, Emergency Prescription Drug Refills, calls for emergency refills beyond the 72-hour period, excluding controlled substances.

**1907****CREDENTIALING AND PRIVILEGING BY REGULATORS, PAYERS, AND PROVIDERS FOR COLLABORATIVE PRACTICE**

*Source: Council on Public Policy*

*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.*



**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**

*Source: Council on Public Policy*

To advocate for the role of the pharmacist in medication-assisted treatment (MAT) for opioid use disorder, 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 for opioid use disorder; further,

To foster additional research on clinical outcomes of pharmacist-driven MAT; further,

To advocate for the removal of barriers for all providers to be able to provide MAT to patients.

**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 some states allow pharmacists to prescribe controlled substances under collaborative practice agreements, pharmacists are not eligible to obtain a waiver under the Drug Addiction Treatment Act of 2000 to prescribe buprenorphine or other drugs for opioid use disorder. Having such prescribing authority would allow pharmacists to fully exercise their expertise and expand the pool of MAT providers. ASHP advocates the removal of barriers for all providers to be able to provide MAT to patients and encourages additional research on the clinical outcomes of pharmacist-driven MAT.

## 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.

#### ***Rationale***

In June 2018, the Food and Drug Administration (FDA) approved Epidiolex, an oral solution containing cannabidiol (CBD), for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is the first prescription formulation of 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 placed Epidiolex in schedule V of the Controlled Substances Act (CSA), the least restrictive schedule of the Act.

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, FDA is currently considering a two-pronged approach that would:

- 1) regulate products that make therapeutic claims as new drugs, evaluating them for both safety and efficacy (e.g., Epidiolex); and

- 2) allow the continued marketing of CBD-containing products that do not make therapeutic claims, with limited regulation for safety (e.g., as dietary supplements).

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.*

### **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 by the year 2022; 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.*

### **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.

The target date of 2022 was included to provide a goal for requiring that all new pharmacy technicians in hospitals and health systems complete a pharmacy technician education and training program accredited by ASHP and ACPE. The date is in line with the initiatives and timeline of the Stakeholder Advisory Committee (the Committee). This Committee continues to advance the recommendations of the Pharmacy Technician Stakeholder Consensus Conference ([Toward uniform standards for pharmacy technicians: Summary of the 2017 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. The Committee uses the recommendations and consensus statements to guide their work. Two of these statements are as follows:

2.1 The profession of pharmacy should move urgently towards the development and adoption of national standards for pharmacy technician education.

2.2 The profession of pharmacy should set a target for implementation of the national standard for pharmacy technician education at 3 to 5 years after adoption of the standard.

The accreditation standard for the education and training of pharmacy technicians was revised and approved by both the ASHP and ACPE Boards in June of 2018. Consistent with recommendation 2.2, 2022 is a reasonable target to require accredited training for new pharmacy technicians as it is four years from the time new standard was developed. The new standard was developed based on a job analysis of more than 44,000 pharmacy technicians in the U.S. The group developing the standard included educators; representatives from community, hospital, and chain pharmacy practice; and members of the Pharmacy Technician Accreditation Commission. More than 500 public comments were received and evaluated for inclusion in the revised standard before it was sent to the Boards of ASHP and ACPE for approval. The revised standard is divided into entry level and advanced, as recommended at the Pharmacy Technician Stakeholder Consensus Conference. This differentiation allows practice settings to have different education and training requirements based on the needs of the position. Additionally, boards of pharmacy can develop requirements based on entry-level competencies as a minimum standard and the advanced level can be an added credential that can be pursued based on employer requirements.

The Committee is currently working with the National Association of Boards of Pharmacy (NABP) to modify the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. At the NABP national meeting in May 2019, a resolution was passed to convene a task force of stakeholders to evaluate and make recommendations to NABP regarding the education requirements, practice responsibilities, and competence assessments for pharmacy technicians.

Additionally, work is being done at the state level with individual boards of pharmacy to evaluate requirements for accredited education and training for new pharmacy technicians. This activity follows consensus statement 5.2: The level of urgency for achieving state-to-state consistency in regulation of pharmacy technicians' scope of practice, education, certification, and licensure or regulation is high.

At the state level, advocacy will include several specific issues for boards of pharmacy to include as they consider regulations for technicians:

- There should be clear distinctions between pharmacy technicians and student pharmacists. Technician requirements should not be applied to student pharmacists.
- There should be a provision for a “technician in training” that would allow a technician who is enrolled in an accredited education and training program to be eligible to work in a pharmacy as long they complete the program in some prescribed amount of time (e.g., 12-18 months).

### 1913

#### PHARMACEUTICAL DISTRIBUTION SYSTEMS

*Source: Council on Pharmacy Management*

To support drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,

To oppose manufacturers, distributors, and wholesalers restricting or making availability of drug products contingent on how those products are used; 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 Verified-Accredited Wholesale Distributors program; and (5) uses information systems that are interoperable with common types of pharmacy systems.

*This policy supersedes ASHP policy 1707.*

#### **Rationale**

Wholesalers and distributors have traditionally contracted with hospitals and health systems for basic drug 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, and the need to manage drug 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 pharmaceuticals. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient.

Additionally, some wholesalers have required that pharmacies ensure certain drugs 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 drug 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; should 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 [Verified-Accredited Wholesale Distributors \(VAWD\) program](#); and use information systems that are interoperable with common types of pharmacy systems. VAWD accreditation requires a rigorous criteria compliance review to ensure that a wholesale distribution facility operates legitimately, is licensed in good standing, and employs security and best practices for safe prescription drug distribution from manufacturers to pharmacies. As of 2018, 23 states had recognized VAWD accreditation.

## 1914

### **SAFE MEDICATION PREPARATION, COMPOUNDING, 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 preparation, compounding, and administration to ensure safety and quality.

#### ***Rationale***

As pharmacy costs become increasingly relevant in managing the overall cost of healthcare, third-party payers have increased their attention to sites of care, increasing the pressure to manage this trend. Integrated pharmacy benefit models are working to funnel patients to lower-cost settings and deliver more comprehensive care by leveraging big data.

Consolidation in the pharmacy benefit management sector has resulted in just three major companies. To protect and further grow their margins and fend off disruptive entrants, the big three are reinventing themselves within vertically integrated conglomerates, allowing them to tap into other parts of the healthcare value chain. Patients are increasingly receiving care at nonhospital sites of care, where they can receive the care they need at a lower cost, rather than through traditional venues, such as hospital outpatient infusion centers. In addition to these alternative sites being less expensive for payers and purchasers, patients who seek care from alternative sites often have lower out-of-pocket costs and may perceive these sites as more convenient than traditional sites of care (e.g., emergency departments, hospital-based clinics). This trend has led to lower hospital outpatient revenues. Vertical integration of the healthcare value chain has given payers more control over healthcare costs and has better positioned them to link directly with providers and negotiate value-based contracts. Vertically integrated systems may allow payers to steer patients toward lower cost-of-care options (e.g., providers, pharmacies). In the [ASHP Foundation Pharmacy Forecast 2018](#), 44% of panelists predicted at least 25% of health systems will discontinue or abandon plans to begin drug dispensing services (e.g., distribution of specialty or infusion products) because of insufficient financial margins.

One of the challenges that confronts health systems is the level of infrastructure investment required to adequately address regulatory and accreditation requirements focused

on quality and safety (e.g., United States Pharmacopeia Chapters 797 and 800, state boards of pharmacy regulations, and the standards of accreditors such as The Joint Commission and Det Norske Veritas Healthcare). Physician offices, dialysis centers, stand-alone cancer care centers, freestanding neighborhood hospitals, and other nonhospital sites of care are commonly devoid of this same level of regulatory and accreditation scrutiny.

## 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.*

### **Rationale**

Hospitals 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.*

**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. There has been no reduction between 2003 and 2013 in the percentage of respondents who were aware of a medication error during the year in which disrespectful behavior played a role.

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. 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 Bureau of Labor Statistics and National Crime Victimization Survey, more assaults occur in the healthcare and social services industries than in any other industry. For healthcare workers, assaults comprise 10-11% of workplace injuries involving days away from work, compared with 3% of injuries of all private sector employees. Further, it has been identified that workplace violence can harm a person's intrinsic sense of self-worth and confidence, which can result in physical symptoms including headaches, anxiety, and depression. The American Nurses Association and the American Medical Association have taken positions concerning violence against healthcare workers and are actively promoting 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. These organizational efforts will help with compliance with The Joint Commission leadership standard on disruptive behavior (LD.03.01.01), which suggests that healthcare organizations should “educate all team members – both physicians and non-physician staff – on appropriate professional behavior defined by the organization's code of conduct. The code and education should emphasize respect. Include training in basic business etiquette (particularly phone skills) and people skills.”

## 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.

#### ***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 (Pharm.D.) or Doctor of Philosophy (Ph.D.) 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 (B.S.Pharm.) to obtain licensure and practice pharmacy, which indicates that all state legislatures or regulators have concluded that pharmacists with a B.S.Pharm. degree can practice pharmacy safely and effectively. In the U.S., the B.S.Pharm. degree was awarded until 2005; in 2006, the Pharm.D. degree became the only entry-level degree awarded. A 2014 survey of the pharmacy workforce found that only 40% of pharmacists had earned a Pharm.D. The minimum educational requirements set by OPM would automatically disqualify 60% 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 effectively, efficiently, and responsibly fulfill their roles. 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**

Source: *Council on Therapeutics*

To encourage drug product manufacturers to conduct and publish pharmacokinetic and pharmacodynamic research in obese patients to facilitate safe and effective dosing of medications in this patient population, especially for medications most likely to be affected by obesity; further,

To encourage manufacturers to include in the Food and Drug Administration (FDA)–approved labeling detailed information on characteristics of individuals enrolled in drug dosing studies; further,

To advocate that the FDA develop guidance for the design and reporting of studies that support dosing recommendations in obese patients; further,

To advocate for increased enrollment and outcomes reporting of obese patients in clinical trials of medications; further,

To encourage independent research on the clinical significance of obesity on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

To recognize that pharmacists are medication therapy experts who should provide guidance on appropriate drug dosing for obese patients.

*This policy supersedes ASHP policy 1515.*

**Rationale**

Given the growing rate of obesity in the United States, ASHP is concerned about the uncertainty surrounding how obesity affects drug dosing, effectiveness, and safety, especially for medications most likely to be affected by obesity (defined as body mass index of  $>30 \text{ kg/m}^2$ ). The FDA does not require that studies of obese patient populations be performed, despite the growing proportion of obese patients in United States. Obese patients are subject to variable pharmacokinetic effects of oral, parenteral, and topical therapeutic agents.

Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies of obese patients, especially for drugs for which obesity is expected to have a significant clinical impact (e.g., antimicrobials, highly lipophilic drugs). If these voluntary studies are not completed, then manufacturers should include in the FDA-approved labeling complete information on the population enrolled in dosing studies and the methods used to determine dosing so that clinicians can assess the extent to which that population reflects patients being treated.

ASHP advocates that the FDA develop guidance for voluntary drug dosing studies of obese patients that would define study design and reporting with the intent of standardizing this research to the extent possible. The need for this guidance is supported by the complexity of drug dosing for obese patients, which varies based on drug and patient characteristics. A paucity of research in this population is noted, similar to the lack of preapproval studies in geriatric and pediatric patients. Such studies could help standardize research methods and promote comparative effectiveness research. ASHP also encourages independent clinical and practice-based research to further define clinical use of drugs in the treatment of obese patients, as well as clinician reporting of patient experience in articles and clinical registries.

ASHP also believes that pharmacists are uniquely positioned to review and apply this literature to make dosing recommendations based the most appropriate weight classification for obese patients, including ideal body weight, adjusted body weight, or total body weight.

## 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.*

### **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. 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. 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

### 1801

#### UNIT DOSE PACKAGING AVAILABILITY

*This policy was superseded by ASHP policy 2253.*

### 1802

#### GENE THERAPY

*Source: Council on Pharmacy Management*

To assert that health-system decisions on the selection, use, and management of gene therapy agents should be managed as part of the medication formulary system in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; and (2) such decisions must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; further,

To advocate that gene therapy be documented in the permanent patient health record; further,

To advocate that documentation of gene therapy in the permanent patient health record accommodate documentation by all healthcare team members, including pharmacists.

*This policy supersedes ASHP policy 0103.*

#### **Rationale**

The first biologics license agreement for a gene therapy product was submitted to the Food and Drug Administration in May 2017. Gene therapy is an emerging area of medicine, and pharmacists should take a leadership role in managing these therapies and associated devices under the medication formulary systems in their institutions.

As described in more detail in the [ASHP Statement 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. It is important that gene therapy be documented in the permanent patient health record to ensure accurate and complete documentation of the care provided to patients and to validate the impact of therapies on patient outcomes and that all healthcare providers involved in providing gene therapy, including pharmacists, be able to document the patient care provided.

### 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.*

### **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. 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**

*Source: Council on Therapeutics*

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

To collaborate with stakeholders in enhancing aggregation and publication of and access to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug dosing within these patient populations.

*This policy supersedes ASHP policy 1720.*

### **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.

In addition, 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. Given the complex dose adjustments and variety of conditions, education of pharmacists and other healthcare professionals is critically important to appropriately treat patients.

## 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.*

**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. 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.

**1807****REIMBURSEMENT AND PHARMACIST COMPENSATION FOR DRUG PRODUCT DISPENSING**

*This policy was superseded by ASHP policy 2232.*

**1808****PATIENT ACCESS TO PHARMACIST CARE WITHIN PROVIDER NETWORKS**

*This policy was superseded by ASHP policy 2134.*

**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.*

### **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**

*Source: Council on Pharmacy Management*

To advocate that healthcare accreditation, certification, and licensing organizations include providers and patients in their accreditation and standards development processes; further,

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 encourage hospitals and health systems to include pharmacy practice leaders in decisions about seeking recognition by specific accreditation, certification, and licensing organizations; further,

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

*This policy supersedes ASHP policy 1303.*

### **Rationale**

Pharmacy leaders have years of experience managing the demands and challenges of ensuring that pharmacy services meet the standards of accreditation organizations. Until recently, 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). Healthcare organizations with ambulatory care services (e.g., home infusion, specialty pharmacy, and durable medical equipment) have had to manage the additional accreditation process for these business units. Until recently, the number of accreditation standards pharmacy leaders needed to be knowledgeable about was limited. Three recent phenomena 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, creating the 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 must 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.

**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.

### ***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.

### ***Rationale***

A [20 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.

**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.

**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.

#### ***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**

*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 regarding biosimilar interchangeability prior to finalization of FDA guidance; 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 support the development of FDA guidance documents on biosimilar use, with input from healthcare practitioners; 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 about biosimilar medications and their appropriate use within hospitals and health systems; further,

To advocate and encourage pharmacist evaluation and the application of the formulary system before biosimilar medications are used in hospitals and health systems.

*This policy supersedes ASHP policy 1509.*

### **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-szsz, infliximab-abda, infliximab-dyyb) have followed.

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 2017, 35 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).

ASHP recognizes FDA's authority to determine biosimilar interchangeability, and in cases where 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.

**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.

**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 considered 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.

*This policy supersedes ASHP policy 0814.*

**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.

**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.*

**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.*

**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, 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.

**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.*

### **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.

**1823****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 pharmacist accountability and engagement in interprofessional efforts to promote the judicious use of clinical testing and monitoring; 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.

***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, entails the risk of generating false-positive results, leads to overloading of diagnostic services, wastes valuable healthcare resources, and is associated with other inefficiencies in healthcare delivery, undermining the quality of health services. One strategy for reducing unnecessary testing is use of interoperable health information technology services and health information exchanges.

[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.

## 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.

### **Rationale**

The National Institutes of Health Biomarkers Definitions Working Group [defined a biomarker](#) as “a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.” 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. As [defined by the FDA](#), 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.” The FDA classifies biomarkers in the following 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

*Source: Council on Education and Workforce Development*

To affirm that 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 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 encourage individuals to embrace well-being and resilience as a personal responsibility that should be supported by organizational culture; further,

To encourage the development of programs aimed at prevention, recognition, and treatment of burnout, and to support participation in these programs; further,

To encourage education and research on stress, burnout, and well-being; further,

To collaborate with other professions and stakeholders to identify effective preventive and treatment strategies at an individual, organizational, and system level.

### ***Rationale***

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. More than half of U.S. physicians show symptoms of burnout, which is nearly twice as high as other U.S. workers, even after controlling for work hours and other factors. Between 2011 and 2014, the prevalence of burnout increased by 9% among physicians while remaining stable in other U.S. workers. The American Foundation for Suicide Prevention reports that 300-400 physicians commit suicide each year, approximately one per day, double that of the general population. Nurses show a similarly high prevalence of burnout and depression. A 2007 study reported that 22-35% of nurses had a high degree of emotional exhaustion. A survey at Duke University Hospital found that 20% of pharmacists were at risk for burnout. And although less is known about other members of the healthcare team, data suggest a similar prevalence of burnout among pharmacy technicians, nurse practitioners, and physician assistants.

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. In May 2018, a New York City medical student and resident committed suicide within a

week of each other. One review estimates that nearly 29% of medical residents suffer from depression or depressive symptoms, well above the 16% estimated prevalence in the general population. One study has shown that pharmacy residents exhibit high levels of perceived stress, especially those who work more than 60 hours per week, and perceived stress is highly correlated to negative effects.

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) assess and understand the underlying causes of clinician burnout and suicide, and (2) advance evidence-based solutions that reverse the trends in clinician stress, burnout, and suicide. Clinician burnout is a concern because, in addition to clinician suffering, clinician burnout has been associated with increased rates of medical errors, healthcare-associated infection, and patient mortality. Clinician burnout also decreases patient satisfaction and healthcare workforce productivity. Students in the health professions are also susceptible to burnout.

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 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. Pharmacists, along with other healthcare professionals and administrators, have a role in researching and solving the problem. To be successful, interventional programs must promote prevention, recognition, and treatment of burnout, and healthcare organizations must foster a culture that supports not just participation in these programs but a sense of personal responsibility for developing and maintaining resilience. Providing patient care is meaningful and purposeful work. A healthcare organization with a resilient workforce will provide the best healthcare outcomes.

## 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.

**Rationale**

Persons 18-25 years of age have the highest prevalence of prescription drug misuse among all age groups. Moreover, there is growing evidence that prescription drug misuse has been increasing among U.S. college students, and it is second to marijuana as the most common form of substance abuse. Pharmacy professionals and students are entrusted with 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. Thus, an assessment of a student pharmacist'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 student pharmacists, 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. 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.*

**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**

*Source: Council on Education and Workforce Development*

To promote the professional image of pharmacists and pharmacy technicians who work in all settings of health systems to the general public, public policymakers, payers, other healthcare professionals, and healthcare organization decision-makers.

*This policy supersedes ASHP policy 0703.*

**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](#), is an ongoing priority for ASHP. In addition, 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. The recruitment of pharmacists and pharmacy technicians begins 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.

**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**

*Source: Council on Therapeutics*

To advocate that intravenous promethazine be used only when medically necessary.

*This policy supersedes ASHP policy 1105.*

**Rationale**

In its [2018-2019 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; removal of injectable promethazine from all computerized medication order screens and from all order sets and protocols. This recommendation was a change from previous ones in which ISMP promoted safe use by raising awareness about risks associated with IV promethazine administration. However, sporadic and significant patient harm continues to occur.

Promethazine is a known vesicant that can cause tissue damage and necrosis when extravasation occurs during intravenous (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. Because promethazine has demonstrated effectiveness for some indications, its use may be warranted in some clinical circumstances, despite its risks. Healthcare organizations should restrict its use to these indications. Processes to limit the potential for patient harm when IV promethazine is used include but are not limited to use of therapeutic alternatives; use of alternate routes and modalities of administration; restrictions on use; and basing use on a patient-specific evaluation of its risks and benefits, including potential adverse effects.

## 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.*

#### ***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 its 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 0610, [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 0307), and hospice and palliative care.

*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.*

## **1705**

### **WORKFORCE DIVERSITY**

*This policy was superseded by ASHP policy 2217.*

## **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.



**1707****PHARMACEUTICAL DISTRIBUTION SYSTEMS**

*This policy was superseded by ASHP policy 1913.*

**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 policies 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.*

**1718****THERAPEUTIC AND PSYCHOSOCIAL CONSIDERATIONS OF TRANSGENDER PATIENTS**

*Source: Council on Therapeutics*

To support medication and disease management of transgender patients as a part of care unique to this population; further,

To advocate that transgender patients have access to pharmacist care to ensure safe and effective medication use; further,

To promote research on, education about, and development and implementation of

therapeutic and biopsychosocial best practices in the care of transgender patients; further,

To encourage structured documentation of both a patient’s birth sex and self-identified gender in electronic health records.

### ***Rationale***

The transgender population is a small population that has unique healthcare and biopsychosocial needs. There are [guidelines](#) to help practitioners caring for the patients identify these needs and recommendations for practitioners to consider.

Patients electing to transition from their birth sex to their self-identified gender may have surgeries and take higher doses of hormones to change their physical appearance to reflect their self-identified sex. These patients have significant requirements for therapeutic drug monitoring, as certain lab values may appear out of normal limits but are clinically appropriate for the transgender patient, and the risk of drug-drug interactions may be higher because medications may be taken at a higher than normal doses. These patients may be more at risk for adverse effects, including thyroid disorders, and may more frequently require anticoagulation and management of diabetes as a result of medication therapy. Other unique needs of these patients include cardiovascular and thrombotic risk assessment, screening for certain types of cancers should they elect to keep their gonadal organs, and other associated primary care screenings associated with their birth sex. Considerations for transgender patients who wish to have children will add the complexity of fertility as well as attention to use of teratogenic medications to their needs. Because of the unique and complex healthcare needs of transgender patients, it is essential that they have adequate access to appropriate care, including pharmacist care. To help ensure appropriate assessment and treatment, patients’ birth sex and self-identified gender should be documented in a structured way in electronic health records. This documentation also helps healthcare providers address another of the unique biopsychosocial needs of transgender patients; like other healthcare providers, pharmacists should address transgender patients by their self-identified gender.

### **1719**

#### **PHARMACIST’S LEADERSHIP ROLE IN GLYCEMIC CONTROL**

*This policy was discontinued in 2022.*

### **1720**

#### **DRUG DOSING IN CONDITIONS THAT MODIFY PHARMACOKINETICS OR PHARMACODYNAMICS**

*This policy was superseded by ASHP policy 1804.*

### **1721**

#### **CLINICAL SIGNIFICANCE OF ACCURATE AND TIMELY HEIGHT AND WEIGHT MEASUREMENTS**

*Source: Council on Therapeutics*

To encourage pharmacists 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 encourage drug product manufacturers to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,

To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes.

*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**

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 (FDA) 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.

**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

### 1601

#### SAFETY OF INTRANASAL ROUTE AS AN ALTERNATIVE ROUTE OF ADMINISTRATION

*This policy was superseded by ASHP policy 2041.*

### 1602

#### DRUG PRODUCT SUPPLY CHAIN INTEGRITY

*This policy was superseded by ASHP policy 2042.*

### 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.*

## **1611**

### **DEVELOPING LEADERSHIP COMPETENCIES**

*This policy was superseded by ASHP policy 2104.*

**1612****INTERPROFESSIONAL EDUCATION AND TRAINING**

*This policy was superseded by ASHP policy 2105.*

**1613****CULTURAL COMPETENCY**

*This policy was superseded by ASHP policy 2231.*

**1614****CONTROLLED SUBSTANCE DIVERSION AND PATIENT ACCESS**

*This policy was superseded by ASHP policy 2042.*

**1615****PROTECTING WORKERS FROM EXPOSURE TO HAZARDOUS DRUGS**

*Source: Council on Pharmacy Management*

To advocate that pharmaceutical manufacturers eliminate surface contamination on packages and vials of hazardous drugs; further,

To inform pharmacists and other personnel of the potential presence of surface contamination on the packages and vials of hazardous drugs; further,

To advocate that the Food and Drug Administration require standardized labeling and package design for hazardous drugs that would alert handlers to the potential presence of surface contamination; further,

To encourage healthcare organizations, wholesalers, and other trading partners in the drug supply chain to adhere to published standards and regulations, such as ASHP guidelines and United States Pharmacopeia Chapter 800, to protect workers from undue exposure to hazardous drugs.

*This policy was reviewed in 2021 by the Council on Pharmacy Management and Workforce Development and by the Board of Directors and was found to still be appropriate.*

***Rationale***

The outer surfaces of vials of hazardous drugs have been shown to be contaminated with hazardous substances, and pharmacy and other personnel handling those vials may unknowingly be exposed. ASHP advocates that individuals involved in drug distribution, receiving, and inventory control adhere to safe handling guidelines, including ASHP guidelines and United States Pharmacopeia Chapter 800, to avoid undue exposure to hazardous substances but recognizes the limits of these best practices. Pharmaceutical manufacturers



have a responsibility to provide vials that are devoid of surface contamination due to inadequate vial-cleaning procedures, and can reduce contamination by using decontamination equipment and protective sleeves during the manufacturing process.

The purpose of United States Pharmacopeia (USP) Chapter 800 is to establish standards for protecting personnel and the environment when handling hazardous drugs. Each year, approximately 8 million U.S. healthcare workers are potentially exposed to hazardous drugs, according to the Centers for Disease Control and Prevention. USP Chapter 800 includes definitions, processes, and worker responsibilities that enhance understanding of risk and limit exposure. To support workers in protecting their patients, themselves, and the environment, the FDA and manufacturers will need to develop new production and processing standards to mitigate exposures, including labeling and package design that alerts handlers to the possibility of contamination.

**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**

*Source: Council on Public Policy*

To advocate that the National Association of Boards of Pharmacy (NABP) collaborate with boards of pharmacy to streamline the licensure process through standardization and improve the timeliness of application approval; further,

To advocate that NABP collaborate with boards of pharmacy and third-party vendors to streamline the licensure transfer or reciprocity process; further,

To advocate that boards of pharmacy grant licensed pharmacists in good standing temporary licensure, permitting them to engage in practice, while their application for licensure transfer or reciprocity is being processed.

*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**

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.

## 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 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.”<sup>1</sup>

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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<sup>2,3,4,5</sup> 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.

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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](http://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.

**1625****TOBACCO, TOBACCO PRODUCTS, AND ELECTRONIC NICOTINE DELIVERY SYSTEMS**

*This policy was superseded by ASHP policy 2125.*

**1626****ASHP STATEMENT ON TELEPHARMACY**

*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 2020 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 pharmacists 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 hospital and ambulatory care pharmacist input into 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 pharmacists being unable to practice at the top of their licenses.

### 1502

#### PHARMACIST RECOGNITION AS A HEALTHCARE PROVIDER

*Source: Council on Public Policy*

To advocate for changes in federal (e.g., Social Security Act), state, and third-party payment programs to define pharmacists as healthcare providers; further,

To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-quality care that is cost effective, resulting in improved patient outcomes; further,

To recognize that pharmacists, as healthcare providers, improve access to patient care and bridge existing gaps in healthcare; further,

To collaborate with key stakeholders to describe the covered direct patient-care services provided by pharmacists; further,

To advocate for sustainable compensation and standardized billing processes used by payers for pharmacist services by all available payment programs.

*This policy was reviewed in 2020 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

### **Rationale**

Recognition of pharmacists as healthcare providers is emerging and 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.

### **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*

To advocate for the pharmacist's role in patient medication adherence programs that are part of health insurance plans; further,

To advocate those programs that (1) maintain the direct patient pharmacist relationship; (2) are based on the pharmacist's knowledge of the patient's medical history, indication for the prescribed medication, and expected therapeutic outcome; (3) use a communication method desired by the patient; (4) are consistent with federal and state regulations for patient confidentiality; and (5) permit dispensing of partial fills or overfills of prescription medications in order to synchronize medication refills and aid in medication adherence.

*This policy was reviewed in 2020 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

### **Rationale**

Current payment rules for Medicare Part D plans require a prorated cost-sharing rate for prescriptions dispensed with less than a 30-day supply. This is allowed to avoid waste in the event that a prescription is modified in response to an adverse reaction. Aligning or synchronizing a medication to all of a patient's chronic medications has been proven to improve adherence. Although Medicare has adopted a policy allowing for a daily cost-sharing rate, other payers have not followed suit. ASHP advocates for similar changes in state law and regulation,



since such a change would allow for broader synchronization and improved adherence for patients covered by Medicaid and private third-party payers.

**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.*

**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**

*Source: Council on Public Policy*

To advocate that the Food and Drug Administration (FDA) Expanded Access (Compassionate Use) Program be the sole 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.

### ***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.

## **1509**

### **APPROVAL OF BIOSIMILAR MEDICATIONS**

*This policy was superseded by ASHP policy 1816.*

## **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.*

**1515****RESEARCH ON DRUG USE IN OBESE PATIENTS**

*This policy was superseded by ASHP policy 1920.*

**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 2020 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

***Rationale***

Ensuring patients' medication histories are accurate and continuity of medication therapies is a critical role for pharmacists to monitor and document as patients 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.

***Rationale***

Hospitals and health systems often treat patients that have in their possession illicit substances (e.g., Schedule I drugs, or other 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.

*This policy was reviewed in 2020 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**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 2020 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 2020 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 system 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 2020 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. ASHP National Survey data show that approximately 40% of hospitals have pharmacist participation in cardiopulmonary resuscitation (CPR) 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).



**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 2020 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 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. Education of consumers will be required to ensure that online pharmacies are used wisely, and use of online pharmacies should involve appropriate pharmacist counseling.

**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 2020 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.

An international joint working group composed of the [International Organization for Standardization \(ISO\)](#), [Association for the Advancement of Medical Instrumentation \(AAMI\)](#), FDA, manufacturers, clinicians, and other regulators recently initiated development of [new ISO connector standards](#) for medical devices for intravascular/hypodermic, limb cuff, enteral, neuraxial, and breathing systems/pressurized medical gas applications. Urethral standards are also planned, but not yet initiated. The new ISO standards are voluntary and intended to facilitate global standardization of medical devices. The FDA has announced that it will only approve or clear an enteral device with a new small-bore connector if it meets the ISO standard or equivalent alternative method. (Small-bore [less than 8.5 mm diameter] connectors are used to link or join devices, accessories, and components for intravascular/hypodermic, neuraxial [epidural, intrathecal, spinal], urinary, enteral, and breathing system/medical gas delivery of medications.) Subsequently, the first ISO standard for enteral device connectors ([ANSI/AAMI/ISO 80369-1](#)) has been adopted industrywide. New connectors will be phased in, beginning fourth quarter 2014. The Joint Commission recently published Sentinel Event Alert #53, [Managing risk and transition during transition to new ISO tubing connector standards](#). The alert provides 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.

In addition, the following statements were issued from the 2008 Global Conference on the Future of Hospital Pharmacy in Basel, Switzerland:

Pharmacists should ensure that strategies and policies are implemented to prevent

wrong route errors, including, for example, labeling of intravenous tubing near insertion site to prevent misconnections, and use of enteral feeding catheters that cannot be connected with intravenous or other parenteral lines.

Oral syringes that are distinctly different from hypodermic syringes should be used to prevent injection of enteral or oral medicines, especially in pediatric patients.

### 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 2020 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.

That increased scrutiny comes at a time when pharmacists are rapidly expanding their roles on the patient care team and are being recognized as patient care providers. This proposed policy developed by the ASHP Council on Pharmacy Practice recognizes that one's beliefs about capital punishment are a personal, individual decision but opposes pharmacist participation in capital punishment because it is contrary to their role as healthcare providers. Given the ethical questions about pharmacist participation in capital punishment, pharmacists should not be punished for their refusal to participate.

**1532****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*.

*This statement was superseded by ASHP policy 2143.*

**1533****ASHP STATEMENT ON THE PHARMACIST'S ROLE IN SUBSTANCE ABUSE PREVENTION, EDUCATION, AND ASSISTANCE**

*Source: Council on Pharmacy Practice*

To approve the *ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance*.

*This statement supersedes a previous version dated June 2, 2013.*

**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*

To advocate that originator biological products, related biological products, and biosimilar products share the same global nonproprietary name as defined by the United States Adopted Name Council, the World Health Organization Programme on International Nonproprietary Names, and United States Pharmacopeial Convention; further,

To oppose unique nonproprietary naming for originator biological products, related biological products, and biosimilar products.

*This policy was reviewed in 2020 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

### **Rationale**

As biosimilar products obtain approval for use in patients in the U.S., discussion continues among stakeholders over what type of naming process should be applied. A number of stakeholder groups have adopted policy regarding biologic and biosimilar naming, including FDA, National Council for Prescription Drug Programs, (NCPDP), United States Pharmacopoeia (USP), United States Adopted Name (USAN) Council, World Health Organization (WHO), American Medical Association (AMA), and other national pharmacy groups.

The recognized authorities for applying standardized principles of drug and biologic naming include the WHO Programme on International Nonproprietary Names (INN), USAN Council, and USP. These authorities have developed a harmonized biosimilar naming approach based on applying a shared nonproprietary name for originator biological products, related biological products, and biosimilar products. Under their authority, these products essentially share the same nonproprietary name (e.g., “filgrastim” for Neupogen, Zarxio, and Granix), but can be individually identified through their unique National Drug Code (NDC), other unique codified identifiers, and trade names. Thus, well-accepted and widely used existing mechanisms for distinguishing individual products obviate the need for deviation from these existing authoritative approaches by adding a prefix or suffix to the nonproprietary name. Other national pharmacy organizations (e.g., American Pharmacists Association [APhA], Academy of Managed Care Pharmacists [AMCP], National Association of Chain Drug Stores [NACDS], and National Community Pharmacists Association [NCPA]) as well as NCPDP support application of the identical nonproprietary name to these products.

FDA has proposed a nonproprietary naming process that deviates from the existing standardized approach that has been applied by international authorities such as INN and USAN. Under FDA’s proposal, a unique, randomly generated suffix composed of four lowercase letters, or a suffix relating to the license holder of the product (which could change over time), would be applied to originator biological products, related biological products, and biosimilar products.

In its [proposed rule](#) for the biologics to which this naming method would initially be applied, FDA has recommended changing the official names for biologics with globally adopted INNs and USANs as outlined below.

<b>INN/USAN Name</b>	<b>Proposed FDA Name(s)</b>	<b>Former FDA Placeholder Name</b>
filgrastim	filgrastim-bflm filgrastim-vkzt filgrastim-jcwp	filgrastim-sndz tbo-filgrastim
epoetin alfa	epoetin alfa-cgkn	
pegfilgrastim	pegfilgrastim- ljfd	
infliximab	infliximab-hjmt	

These would be just the first name changes that FDA would implement. The proposed plan would then retrospectively change the names of a broad group of existing products to include

unique, randomly generated, four-letter suffixes. Such a naming regime would require extensive education and reprogramming present a risk for medication errors.

Although FDA’s proposed naming process differs from the internationally recognized naming processes supported by WHO, USAN, NCPDP, USP, and others, it appears similar to WHO’s current proposal for four-consonant biological qualifiers that can be employed by countries not having other effective means of tracking specific drug products (e.g., with NDCs or other codified identifiers). Thus, it would result in the existence of two different four-letter modifications of the INN for the same product—the one assigned independently by FDA and the one assigned by WHO. For example, under this scenario, FDA would assign the nonproprietary name “epoetin alfa-cgkn” to the product INN would maintain under the long-established nonproprietary name “epoetin alfa,” but the FDA guidance would allow a qualified name such as “epoetin alfa-xktz.”

FDA cites safety concerns and the ability to track these products precisely to the patients receiving them as justifications for the proposed naming standard. However, stakeholders such as NCPDP have recently commented in opposition to FDA’s proposed naming standard, arguing that FDA’s random, no-vowel suffix could create confusion among clinicians and a potential safety issue if unrecognizable names are used.

#### **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

*Source: Council on Pharmacy Practice*

To advocate for the development of nationally standardized drug concentrations for oral liquid medications; further,

To encourage all health care providers and organizations to standardize concentrations of oral liquid medications; further,

To promote effective instruction of patients and caregivers on how to properly measure and administer oral liquid medications.

*This policy was reviewed in 2019 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. Many oral liquid medications are available in more than one concentration from manufacturers, and unique pharmacy-compounded formulations also result in a wide variety of concentrations. Standardization at a national level would reduce variability when patients are discharged and have prescriptions filled at pharmacies in the community. Standardization of concentrations within a hospital or health system would reduce the potential for errors in those settings. Standard doses would reduce the potential for error, reduce waste, and improve efficiency. Improved instruction of patients and caregivers would improve proper administration in the home, safely delivering the prescribed dosage of medication.

### 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 2019 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. Most hospitals outsource the preparation of injectable and oral radiopharmaceuticals to external suppliers. Because of the unique nature of these drugs and their narrow scope of use, the pharmacy department is often not involved with their acquisition, handling, or disposal. 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**

*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 encourage pharmacists serving on ethics committees to seek advanced training in health care ethics.

*This policy was reviewed in 2019 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**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. The number of ethical issues involving medications is expected to increase, given many new and unique drug products coming into the market. 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.

**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 2019 by the Council on Therapeutics 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 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.

**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 2019 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**

*Source: Council on Public Policy*

To advocate for mandatory, uniform 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 the design of these programs should balance the need for appropriate therapeutic management with safeguards against fraud, misuse, abuse, and diversion; further,

To advocate that such programs be structured as part of electronic health records and exchanges to allow prescribers, pharmacists, and other practitioners to proactively monitor data for appropriate assessment; further,

To advocate for full interstate integration to allow for access by prescribers, pharmacists, and other qualified designees across state lines; further,

To advocate for federal and state funding to establish and administer these programs; further,

To promote research, education, and implementation of best practices in prescription drug monitoring programs.

*This policy was reviewed in 2019 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**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. Some PDMPs do not update information in real time. When updating lags reporting by days (or even weeks), program effectiveness is compromised. Moreover, relevant information is sometimes not required, and not all dispensing sites are required to participate, which impacts the ability of practitioners to make relevant clinical decisions. PDMPs need to be fully integrated across state lines so information from other jurisdictions is available to practitioners and prescribers to assist them in balancing the goals of discouraging prescription drug abuse while providing appropriate therapeutic management. It is also important to ensure the integration and interoperability of these programs with the evolving use of electronic health records and information exchanges so that prescription monitoring programs can be an educational tool for prescribers and practitioners. 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. Such research and education would serve to raise awareness about how to best address the growing public health issue of prescription drug abuse and misuse.

**1409****APPROVAL OF BIOSIMILAR MEDICATIONS**

*This policy was superseded by ASHP policy 1816.*

**1410****ACCESS TO ORAL CONTRACEPTIVES THROUGH AN INTERMEDIATE CATEGORY OF DRUG PRODUCTS**

*Source: Council on Therapeutics*

To advocate that oral contraceptives be provided only under conditions that ensure safe use, including the availability of counseling to ensure appropriate self-screening and product selection; further,

To support expanded access to these products through a proposed intermediate category of drug products, as described by ASHP policy, that would be available from all pharmacists and licensed health care professionals (including pharmacists) who are authorized to prescribe medications; further,

To advocate that the proposed reclassification of these products be accompanied by coverage changes by third-party payers to ensure that patient access is not compromised and that pharmacists are reimbursed for the clinical services provided.

*This policy was reviewed in 2019 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**Rationale**

There have been repeated calls to make oral contraceptive products more widely available, with the intent of expanding access to women's reproductive health therapies and reducing unintended pregnancies. These proposals have merit, but ASHP believes that there are important differences in safety and effectiveness profiles for drug products within this class that necessitate the availability of a pharmacist or other health care professional to provide patient guidance. ASHP supports the availability of these products via an intermediate category of drug products, as the [ASHP Statement on Criteria for an Intermediate Category of Drug Products](#), which would facilitate appropriate use of these therapies after patient assessment and professional consultation by a pharmacist or other licensed health care professional who is authorized to prescribe medications. Patient screening and product selection would be improved through pharmacist-provided counseling that assists patients in identifying absolute and relative contraindications (e.g., hypertension, heart or kidney disease) and assessing other patient-specific factors (e.g., adherence practices). This process would guide the determination of whether a progestin-only or combination oral contraceptive product would be more 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 oral contraceptives because it would place the pharmacist in a gatekeeping role, not the clinical one that is necessary to ensure safe and effective use of these therapies.

Given the intent to expand access to these therapies, ASHP advocates that the proposed reclassification should not result in increased costs to women. Modifications to national, regional, and local drug coverage decisions may be needed to ensure that payer policies do not unintentionally restrict or prevent access. In addition, ASHP believes that the reclassification would result in increased workload and potential liability associated with pharmacist provision of this care, which includes patient screening, product selection, counseling, therapeutic monitoring, and documentation of the care provided in the pharmacy and medical record. Therefore, ASHP advocates that pharmacists should be compensated for these and other patient-care services as described in ASHP policy 1502, [Pharmacist Recognition as a Health Care Provider](#).

**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 2020 by the Council on Public Policy 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. 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.

#### ***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.*

**1414****CULTURAL COMPETENCY AND CULTURAL DIVERSITY**

*This policy was superseded by ASHP policy 1613.*

**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 2019 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](#), February 2011.) To ensure the quality of post-licensure credentialing programs, they should be required to adhere to the guiding principles developed by CCP.

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:** documented evidence of professional qualifications.

**Credentialing:** (1) the process of granting a credential, and (2) the process by which an organization obtains, verifies, and accesses 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 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**Rationale**

Data from a 2011 American Hospital Association annual survey of hospitals indicate that at the time of the survey, 4432 of 5724 hospitals were part of either a system or a network, reflecting the evolution of the health care enterprise from single hospitals to integrated systems and networks. Multiple hospitals organized and owned by the same system have been in the United States marketplace for decades, but the rapidly changing marketplace in the past 2–3 years seems to foreshadow 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 non-hospital 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. The pharmacy enterprise of the future will be more sophisticated and corporate in its nature. Pharmacy leaders both at the local hospital and at the corporate level have to more so than ever look at their pharmacy services in the context of the overall 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. Further challenging health system pharmacy leaders are coordinating pharmacy services across larger geographical regions.

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 market place. Especially as merged systems extend beyond local and regional markets, health care 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 health care 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.

*This policy was reviewed in 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

#### **1418**

#### **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; further,

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

*This policy was reviewed in 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

#### **Rationale**

The adoption of HIT in hospitals has been increasing at a quickening pace. The ASHP National Survey – 2012 reports the adoption of the following: full paperless electronic health record (EHR) (18.6%), computerized provider order entry with clinical decision support (CPOE with CDS) (54.4%), bar-coded medication administration (BCMA) (65.5%), and smart pumps (77%).

The adoption of HIT has undoubtedly been spurred by the American Recovery and Reinvestment Act (ARRA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions under Meaningful Use (MU) of the EHR. Hospitals have been incentivized to implement EHRs that meet the MU criteria by increased reimbursement through Medicare and/or Medicaid payments. Due to the strict guidelines and the rush to meet incentive payments, many providers are questioning whether some HIT is being implemented too quickly.

The implementation of HIT within the medication-use process has been proven to prevent and decrease errors, improve quality, and prevent waste. A key premise of the Office of the National Coordinator for Health Information Technology (ONC) report “Health Information Technology Patient Safety Action & Surveillance Plan” (July 2013) is that HIT, when fully integrated into health care delivery organizations, facilitates substantial improvements in health care quality and safety as compared to paper records. 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 starting to see reports of these 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 pharmacists and others 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. 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 need to recognize vendors’ accountability for the safety of their products as implemented.

## **1419**

### **DOCUMENTATION OF PATIENT-CARE SERVICES IN THE PERMANENT HEALTH RECORD**

*Source: Council on Pharmacy Management*

To advocate for public and organizational policies that support pharmacist documentation of patient-care services in the permanent patient health record to ensure accurate and complete documentation of the care provided to patients and to validate the impact of pharmacist patient care on patient outcomes and total cost of care; further,

To advocate that electronic health records be designed with a common documentation space to accommodate all health care team members and support the communication needs of pharmacy.

*This policy was reviewed in 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

***Rationale***

Documentation in the patient record is a critical for a complete record for patient care and communication among members of the health care team. Documentation should be done within an electronic health record (EHR) or on paper. When documenting electronically, use of standardized and coded formats will allow for improved patient outcome measurements.

**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**

*Source: Section of Clinical Specialists and Scientists*

To approve the ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics.

*This statement was superseded by ASHP policy 1806.*

## 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 2018 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**

*Source: Council on Pharmacy Management*

To encourage interdisciplinary development and implementation of technical and semantic standards for health information technology (HIT) that would promote the interoperability of patient-care technologies that utilize medication-related databases (e.g., medication order processing systems, automated dispensing cabinets, intelligent infusion pumps, electronic health records); 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.

*This policy was reviewed in 2018 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

### **Rationale**

There are significant pharmacy management issues associated with the multiplicity of medication databases in hospitals and health systems. Among the issues are lack of standardization in the medication databases used in pharmacy order-processing systems, automated dispensing cabinets, intelligent infusion pumps, electronic health records, and other patient-care-related technologies dependent on accurate and harmonized medication databases. In addition, there is variability in the primary sources of medication information in these databases and in how the databases are updated. The longstanding issue of lack of interoperability of medication-related information technology compounds the problem. The risk-management implications of this situation are not fully understood, but the urgent need to address this complex issue increases as the dependence on information technologies and the accuracy of associated information proliferates to more aspects of patient care.

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 increasingly 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.

### **1303**

#### **PROLIFERATION OF ACCREDITATION ORGANIZATIONS**

*This policy was superseded by ASHP policy 1810.*

### **1304**

#### **DRUG PRODUCT REIMBURSEMENT**

*This policy was superseded by ASHP policy 1807.*

### **1305**

#### **EDUCATION ABOUT PERFORMANCE-ENHANCING SUBSTANCES**

*Source: Council on Pharmacy Practice*

To encourage pharmacists to engage in community outreach efforts to provide education to athletes on the risks associated with the use of performance-enhancing substances; further,

To encourage pharmacists to advise athletic authorities and athletes 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 sports doping control.

*This policy was reviewed in 2018 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

### **Rationale**

The risks of using performance-enhancing substances, more commonly called performance-enhancing drugs (PEDs), 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 FDA 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 sports doping. Physical and emotional developmental changes during adolescence, as well as the desirable celebrity status of professional sports figures, place younger athletes at significant risk for PED use.

The incidence of PED use among young athletes and the lack of guidance on this topic prompted the American Academy of Pediatrics (AAP) to issue a [policy statement](#) in 2005 that provides a working definition of PEDs and strongly opposes their use. The statement also emphasizes the important role of health care professionals in educating younger athletes about the inflated claims and serious risks of sports doping products.

Use of PEDs 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. In 2011, an American College of Gynecology (ACOG) [opinion statement](#) addressed abuse of anabolic steroids, growth hormone, thyroid replacement products, and dietary supplements by women for cosmetic purposes. Risk factors among younger women (negative body image, social pressure to perform in high school or college sports, and risk-taking behaviors) may lead to steroid abuse as early as the late teens. While steroid use among women and girls is far less common than among men, abuse can lead to liver damage, hyperlipidemia, decreased glucose tolerance, increased cardiovascular disease, thrombotic events, psychosis, and infertility. ACOG recommended that health care professionals educate patients about the unfavorable benefit-to-risk ratio of steroid use, encourage cessation in suspected users, or refer them to substance abuse treatment programs.



**1306****STANDARDIZATION OF INTRAVENOUS DRUG CONCENTRATIONS**

*Source: Council on Pharmacy Practice*

To develop nationally standardized drug concentrations and dosing units for commonly used high-risk drugs that are given as continuous infusions to adult and pediatric patients; further,

To encourage all hospitals and health systems to use infusion devices that interface with their information systems and include standardized drug libraries with dosing limits, clinical advisories, and other patient-safety-enhancing capabilities; further,

To encourage interprofessional collaboration on the adoption and implementation of standardized drug concentrations and dosing units in hospitals and health systems.

*This policy was reviewed in 2018 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 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 also simplifies ordering and preparation, and reduces risk of administration error. Attendees at ASHP's 2008 IV Safety Summit affirmed this safety strategy with a similar recommendation. Summit participants also suggested that 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.

Recent reports indicate, however, that numerous concentrations of high-risk and other drugs are still routinely used. While acknowledging that not all patients can or should be treated with a standard concentration, the Council, Board, and House clarified that the intent of this policy was to advocate limiting the number of standard concentrations to those that serve the needs of the majority of patients.

Council members further suggested that broad adoption of standardized concentrations would not be achieved without the support of the health-system pharmacist community and its active engagement with interprofessional stakeholders, and the Board and House agreed.

**1307****PHARMACIST RECOGNITION AS A HEALTH CARE PROVIDER**

*This policy was superseded by ASHP policy 1502.*

**1308****COMPOUNDING BY HEALTH PROFESSIONALS**

*This policy was superseded by ASHP policy 1406.*

**1309****PHARMACISTS' ROLE IN IMMUNIZATION**

*This policy was superseded by ASHP policy 2247.*

**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 2018 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 is an increasingly urgent need for state board of pharmacy regulation of the provision of pharmacist care services from off-site locations through electronic technology (telepharmacy). 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 policy 0716 was revised to address the provision of medication therapy management and other direct patient-care services in any regulation of telepharmacy services

and to advocate that patient safety, quality, and outcomes measures be developed and monitored. The policy was also revised to include advocacy to state governments to harmonize the practice of pharmacy across state lines and to update requirements for technician functions in the provision of telepharmacy services be performed by technicians that are certified by the Pharmacy Technician Certification Board (PTCB) and licensed by the state board of pharmacy. The revised policy also calls on ASHP 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 2018 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

***Rationale***

The Council discussed the increased use of centralized order fulfillment within health systems as well as fulfillment by contracted entities. 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.

The Council and Board recognized the importance of maintaining practice standards and related safeguards to assure patient safety. In fact, health systems use centralized facilities in order to have the most-qualified personnel prepare these medications in the safest facility. The Council and Board identified the need to seek regulatory changes at the state and federal level in order 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 2018 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**Rationale**

The Council, Board, and House of Delegates considered the rapid growth in FDA-approved devices and other products that contain drug therapies. 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. The Council stated that 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, and the Board and House agreed. For these reasons, the Council, Board, and House advocated 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. 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. The Council, Board, and House strongly encouraged pharmacists to participate in interprofessional discussions concerning use of these products and suggested that the pharmacy and therapeutics (P&T) 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, the Council emphasized that these studies are recommended, not required, by the FDA, and the Board and House agreed. In addition, it was noted that 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. Advocacy to the FDA and manufacturers of drug-containing devices was recommended by the Council, Board, and House to 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, the Council, Board, and House encouraged 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**

*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 evidence concerning the abuse potential of these therapies; further,

To monitor the effect of DEA scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to assess the impact on patient access to these medications and on the practice burden of health care providers.

*This policy was reviewed in 2018 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**Rationale**

The Council discussed the DEA's current classification structure used to determine the schedule of controlled substances as part of their discussion of proposals to reschedule hydrocodone combination products. The Council believed that the current stratification of abuse potential into low, moderate, and high categories lacks clarity and contributes to perception of inconsistency in assigning schedules. The Board concurred. The Council also noted that the existing schedules do not appear to take into account evolving evidence about the abuse potential of these drugs. Therefore, the Council and Board recommended that ASHP advocate that the DEA establish clear, measurable criteria, to the extent possible for this complex area, and a transparent process for scheduling determinations. Further, the DEA was encouraged to use those criteria to re-evaluate current schedule assignments for all controlled substances based on the most recent evidence.

**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 2018 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.

**1318****ASHP STATEMENT ON THE PHARMACIST’S ROLE IN SUBSTANCE ABUSE PREVENTION, EDUCATION, AND ASSISTANCE**

*This statement was superseded by ASHP policy 1533.*

**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.*

### 1202

#### QUALIFICATIONS AND COMPETENCIES REQUIRED TO PRESCRIBE MEDICATIONS

*This policy was superseded by ASHP policy 2251.*

### 1203

#### QUALIFICATIONS OF 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-accredited training program, be certified by the Pharmacy Technician Certification Board, and be licensed by state boards of pharmacy; further,

To advocate that beyond those requirements pharmacy technicians working in advanced roles should have additional training and should demonstrate ongoing competencies specific to the tasks to be performed; further,

To advocate that expansion of pharmacy technician duties into expanded, advanced roles should include consideration of potential risk to patients and that ongoing quality assurance metrics should be established to assure patient safety.

*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**

A growing number of hospitals utilize pharmacy technicians in advanced or specialized roles beyond those traditionally filled by technicians: medication preparation, distribution, and purchasing. These advanced or specialized roles include performing medication reconciliation, collecting laboratory data, and managing automation and technology, among others. While there has been a good deal of discussion about minimum standards for education and training of pharmacy technicians in general, there has been little discussion about technicians in these specialized roles. These advanced roles will require different skills and competencies, and



pharmacy technicians will require additional, task-specific training and should demonstrate competency before being allowed to perform such tasks. Hospitals and health systems will need to consider the potential risk to patients of expanding the roles of pharmacy technicians and establish quality assurance metrics to assure patient safety.

**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 2018 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**Rationale**

The Council discussed the technology requirements of the pharmacy enterprise and ASHP policies related to technology. The Council believed that one area where a gap in ASHP policy existed was in the area of clinical decision support. Current clinical decision support systems do not provide the functionality that is required in the future practice model that is envisioned by participants at the [Pharmacy Practice Model Initiative](#) (PPMI) Summit. The Council believed that ASHP should advocate for improvements in clinical decision support systems that provide actionable data analytics and support the medication-use process.

**1213****PHARMACIST PRESCRIBING IN INTERPROFESSIONAL PATIENT CARE**

*This policy was superseded by ASHP policy 2236.*

**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.*

**1218****APPROVAL OF BIOSIMILAR MEDICATIONS**

*This policy was superseded by ASHP policy 1409.*

**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 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**

*Source: Council on Education and Workforce Development*

To approve the ASHP Statement on the Role of the Medication Safety Leader.

**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.*

### 1103

#### DIRECT-TO-CONSUMER CLINICAL GENETIC TESTS

*This policy was superseded by ASHP policy 2101.*

### 1104

#### PHARMACOGENOMICS

*This policy was superseded by ASHP policy 2113.*

### 1105

#### SAFE AND EFFECTIVE USE OF IV PROMETHAZINE

*This policy was superseded by ASHP policy 1831.*

### 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 2021 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

### **Rationale**

The Council supported expanded use of validated patient-reported outcomes (PRO) tools—assessments of patient satisfaction, health-related quality of life, or health status—in clinical research and direct patient care, and the Board and House agreed. Although PRO tools are most often applied in the research setting, the Council, Board, and House believed that their increased application in direct patient care was warranted as a mechanism to integrate the patient perspective into the assessment and management of disease. Use of PRO tools was noted as consistent with the emphasis on patient-centered care advocated by the Institute of Medicine and other quality improvement initiatives. The Council, Board, and House supported the development of validated PRO tools that account for variability in patient cultural and health literacy and encouraged research to better define the relationship between PRO measures and overall patient outcomes. The need for clinician and patient education on the appropriate use of PRO tools was noted, including the importance of instructing clinicians to select PRO tools 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**

*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 acknowledge that, in addition to a robust curriculum, access to quality experiential educational sites and the availability of qualified faculty (including preceptors and specialty-trained clinical faculty) are essential determinants of the ability to expand enrollment in existing or additional colleges of pharmacy; further,

To oppose expansion of enrollment in existing or new colleges of pharmacy unless well-designed projections demonstrate that such enrollment increases are necessary to maintain a viable pharmacist workforce.

*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**

The growth in the number and capacity of colleges of pharmacy in recent years has been remarkable. Ten years ago, when there was a severe pharmacist shortage, new colleges were welcomed to help meet the anticipated needs of the pharmacy workforce. The pharmacist shortage has now abated, but new colleges continue to be established and capacity of existing colleges expanded. This growth, along with other factors, has led to considerable difficulty for

colleges of pharmacy in locating experienced faculty. There are also growing concerns about the limited number of quality experiential education sites and how future demands for training will be met. These two factors alone have raised worries about the quality of education and the readiness of new pharmacy graduates. High quality can be ensured through the existing mechanism of Accreditation Council for Pharmacy Education (ACPE) accreditation, regardless of the number of colleges and the number of students. However, this assumes rigid enforcement of ACPE's accreditation standards and guidelines, the availability of qualified faculty and preceptors, and an adequate capacity in practice to provide the necessary experiential education.

The Council discussed the mismatch between pharmacy workforce supply and demand. Demand far exceeded supply in 2000, but growth in colleges and other factors now have supply exceeding demand. The Council discussed how there could be better planning to avoid these situations, both of which are costly to the health care system and present risks to quality and patient care. It was suggested that well-designed workforce projections might be useful in determining the need for new or expanded educational capacity.

### 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.

**1122****STATE PRESCRIPTION DRUG MONITORING PROGRAMS**

*This policy was superseded by ASHP policy 1408.*

**1123****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 was reviewed in 2016 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

## 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 2015 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 2020 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 2020 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.

**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 2020 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 2020 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.*

**1013****RESEARCH ON DRUG USE IN OBESE PATIENTS**

*This policy was superseded by ASHP policy 1515.*

**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**

*Source: Council on Pharmacy Practice*

To affirm the essential role of the pharmacist in the evaluation, implementation, and ongoing assessment of all technology intended to ensure safety, effectiveness, and efficiency of the medication-use process.

*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**

Effective use of automation and technology solutions improves efficiency, allows more time for direct patient care, and ensures safe medication management. The Joint Commission Sentinel Event Alert published in December 2008 outlined patient safety concerns specific to technology implementation and recommended specific actions to reduce error and patient harm. The Institute for Safe Medication Practices (ISMP) has published related recommendations for specific technologies and noted recently that one drug delivery device was marketed to promote physician autonomy as a benefit of its use.

**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 2020 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****SCOPE AND HOURS OF PHARMACY SERVICES**

*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 2020 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Rationale**

Recent legislation in Texas exempts 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. Current ASHP policy supports pharmacist prospective order review and a consistent standard of care for all patients regardless of where that care is provided.

**1024****USE OF TWO PATIENT IDENTIFIERS IN THE OUTPATIENT SETTING**

*This policy was superseded by ASHP policy 2010.*

**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 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 2019 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 two 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 and the 2015 Initiative) or evolving Joint Commission requirements. 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 true health-system pharmacy productivity have been developed. The ASHP Section of Pharmacy Practice Managers has made recommendations for the effective use of workload and productivity systems in health-system pharmacy that elaborates the types of metrics that should be used.

## 0902

### PHARMACIST'S ROLE IN PROVIDING CARE FOR AN AGING POPULATION

*Source: Council on Pharmacy Practice*

To encourage expansion of geriatric health care services; further,

To foster expanded roles for pharmacists in caring for geriatric patients; further,

To support successful innovative models of team-based, interdisciplinary geriatric care; further,

To increase training of pharmacists in caring for geriatric patients within college of pharmacy curricula, in ASHP-accredited postgraduate-year-one residencies, and through the expansion of the number of ASHP-accredited postgraduate-year-two geriatric pharmacy residency programs.

*This policy was reviewed in 2019 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

#### **Rationale**

The 2008 report from the Institute of Medicine, *Retooling for an Aging America: Building the Health Care Workforce*, predicts a pending crisis caused by an inadequate workforce for a rapidly increasing elderly patient population and highlights issues significant for pharmacy. Although older adults currently make up only about 12% of the U.S. population, they account for approximately 26% of all physician office visits, 35% of all hospital stays, 34% of all prescriptions, 38% of all emergency medical service responses, and 90% of all nursing-home use. By 2030, the number of adults age 65 and older will have doubled to 70 million, or 20% of total population, which will place even more demands on an already undermanned workforce.

The report recommends three major immediate actions to retool the workforce: enhancing the competence of all health care practitioners in geriatric care, increasing the recruitment and retention of geriatric specialists and caregivers, and redesigning models of care to broaden provider and patient roles to achieve greater flexibility. The report discusses the significant role of pharmacists in counseling, monitoring of medication-related problems, and support of medication adherence. Many elderly people have a number of drug-related issues as well as cognitive impairment and complex needs. These factors increase the amount of expertise, time, and attention required to deliver appropriate care. The pharmacist's role on patient care teams and in medication therapy management will become more important with



increasing numbers of frail or chronically ill patients being treated with medication. Many pharmacists may not have received sufficient training to assume this role. While professional education for pharmacists provides basic competence for medication management in the elderly, education in geriatrics may vary widely, and there are comparatively few geriatric pharmacy specialists, as only 10 programs currently offer ASHP-accredited geriatric pharmacy residency training.

### **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 2019 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, and a lack of research.

**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.

#### 0904

##### **AUTOMATIC STOP ORDERS**

*This policy was superseded by ASHP policy 1405.*

#### 0905

##### **CREDENTIALING AND PRIVILEGING BY REGULATORS, PAYERS, AND PROVIDERS FOR COLLABORATIVE DRUG THERAPY MANAGEMENT**

*This policy was superseded by ASHP policy 1907.*

#### 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 2019 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 2019 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 2019 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.

**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 2019 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 pharmacy students and practice sites benefit from experiential rotations in rural 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 the interaction, 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 distances from the college that result in housing needs.

The Accreditation Council for Pharmacy Education currently requires colleges of pharmacy to ensure that graduates can provide patient-centered care that addresses cultural diversity. 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 2019 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**

*Source: Council on Education and Workforce Development*

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

*This policy was reviewed in 2019 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.*

#### ***Rationale***

ASHP is committed to achieving the goal that by the year 2020 all new college of pharmacy graduates who will be providing direct patient care will be required to complete an ASHP-accredited postgraduate-year-one residency (see ASHP policy 2027). To accomplish this goal,

ASHP will need to increase the number of ASHP-accredited pharmacy residency training programs and positions.

**0918****PHARMACIST LEADERSHIP OF THE PHARMACY DEPARTMENT**

*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 the pharmacy department 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 supporting role of nonpharmacists in leadership and management roles within pharmacy departments.

*This policy was reviewed in 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**Rationale**

The ASHP Long Range Vision for the Pharmacy Work Force in Hospitals and Health Systems sees a growing role for nonpharmacists in management and leadership positions in hospitals and health systems. Many factors are fueling this expansion, including a shortage of pharmacists, 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. Use of specialized nonpharmacist 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.

**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 2019 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.*

### 0807

#### STANDARDIZATION OF INTRAVENOUS DRUG CONCENTRATIONS

*This policy was superseded by ASHP policy 1306.*

### 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 2018 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**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 2018 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

## **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 2018 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

## **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.

(*Note:* 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.)

*This policy was reviewed in 2020 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**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.*

**0816****PHARMACIST'S LEADERSHIP ROLE IN ANTICOAGULATION THERAPY MANAGEMENT**

*This policy was superseded by ASHP policy 1703.*

**0817****GENERIC SUBSTITUTION OF NARROW THERAPEUTIC INDEX DRUGS**

*Source: Council on Therapeutics*

To support the current processes used by the Food and Drug Administration (FDA) to determine bioequivalence of generic drug products, including those with a narrow therapeutic index, and to recognize the authority of the FDA to decide if additional studies are necessary to determine equivalence; further,

To oppose a blanket restriction on generic substitution for any medication or medication class without evidence from well-designed, independent studies that demonstrate inferior efficacy or safety of the generic drug product.

*This policy was reviewed in 2020 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**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 2018 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 2014 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*

To approve the ASHP Statement on Criteria for an Intermediate Category of Drug Products.

*This statement was reviewed in 2018 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

## 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.*

### 0703

#### IMAGE OF AND CAREER OPPORTUNITIES FOR HOSPITAL AND HEALTH-SYSTEM PHARMACISTS

*This policy was superseded by ASHP policy 1828.*

### 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.*

**0710****ROLE OF PHARMACISTS IN SPORTS PHARMACY AND DOPING CONTROL**

*This policy was superseded by ASHP policy 1305.*

**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**

*Source: Council on Pharmacy Practice*

To approve the ASHP Statement on Racial and Ethnic Disparities in Health Care.

*This statement was reviewed in 2017 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

## 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.*

**0606**

**PHARMACIST LEADERSHIP OF THE PHARMACY DEPARTMENT**

*This policy was superseded by ASHP policy 0918.*

**0607**

**QUALITY OF PHARMACY EDUCATION AND EXPANSION OF COLLEGES OF PHARMACY**

*This policy was superseded by ASHP policy 1108.*

**0608**

**INTERDISCIPLINARY HEALTH PROFESSIONS EDUCATION**

*This policy was superseded by ASHP policy 1014.*

**0609**

**DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION AND NONPRESCRIPTION MEDICATIONS**

*This policy was superseded by ASHP policy 1119.*

**0610****PHARMACIST’S RIGHT OF CONSCIENCE AND PATIENT’S RIGHT OF ACCESS TO THERAPY**

*Source: Council on Legal and Public Affairs*

To recognize the right of pharmacists, as health care providers, and other pharmacy employees to decline to participate in therapies they consider to be morally, religiously, or ethically troubling; further,

To support the proactive establishment of timely and convenient systems by pharmacists and their employers that protect the patient’s right to obtain legally prescribed and medically indicated treatments while reasonably accommodating in a nonpunitive manner the right of conscience; further,

To support the principle that a pharmacist exercising the right of conscience must be respectful of, and serve the legitimate health care needs and desires of, the patient, and shall provide a referral without any actions to persuade, coerce, or otherwise impose on the patient the pharmacist’s values, beliefs, or objections.

*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**

ASHP affirms pharmacists’ 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 deeply held beliefs with his or her professional duty and the patient’s 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 the presentation of a prescription to a pharmacist or other employee who might exercise the right of conscience. The right of conscience therefore creates an affirmative responsibility on the part of the pharmacist to proactively notify his or her employer about therapies of concern. In addition, a pharmacist 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 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 pharmacist 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 pharmacist for a particular condition. When conscience requires a pharmacist also to decline to refer the patient to a specific provider who can provide the legally prescribed and medically indicated treatment, the pharmacist 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 decision to exercise the right of conscience should be nonpunitive.

**0611****REDISTRIBUTION OF UNUSED MEDICATIONS**

*This policy was discontinued in 2021.*

**0612****STREAMLINED LICENSURE RECIPROCITY**

*This policy was superseded by ASHP policy 1621.*

**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 2021 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**0615****INFLUENZA VACCINATION REQUIREMENTS TO ADVANCE PATIENT SAFETY AND PUBLIC HEALTH**

*This policy was superseded by ASHP policy 2138.*

**0616**

**SAFE AND EFFECTIVE EXTEMPORANEOUS COMPOUNDING**

*This policy was superseded by ASHP policy 2139.*

**0617**

**ACCREDITATION OF COMPOUNDING FACILITIES**

*This policy was discontinued in 2016.*

**0618**

**ELIMINATION OF SURFACE CONTAMINATION ON VIALS OF HAZARDOUS DRUGS**

*This policy was superseded by ASHP policy 1615.*

**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

*Source: Council on Administrative Affairs*

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

*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.*

### 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 2020 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

### 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****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 2020 by the Council on Education and Workforce Development and by the Board of Directors and was found to still be appropriate.*

**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.*

**0514****PREMARKETING COMPARATIVE CLINICAL STUDIES**

*This policy was superseded by ASHP policy.*

**0515****POSTMARKETING SAFETY STUDIES**

*This policy was superseded by ASHP policy 2025.*

**0516****MANDATORY REGISTRY 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 2015 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**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 2015 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**

*Source: Council on Professional Affairs*

To advocate that pharmaceutical manufacturers provide all medications used in ambulatory care settings in unit-of-use packages; further,

To urge the Food and Drug Administration to support this goal; further,

To encourage pharmacists to adopt unit-of-use packaging for dispensing prescription medications to ambulatory patients; further,

To support continued research on the safety benefits and patient adherence associated with unit-of-use packaging and other dispensing technologies.

*(Note: A unit-of-use package is a container--closure system designed to hold a specific quantity of a drug product for a specific use and intended to be dispensed to a patient without any modification except for the addition of appropriate labeling.)*

*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.*

**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.*

**0407**

**DOCUMENTATION OF PHARMACIST PATIENT CARE SERVICES**

*This policy was superseded by ASHP policy 1419.*

**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 2015 by the Council on Pharmacy Practice 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**

*Source: House of Delegates Resolution*

To support the development of policies and guidelines for health-system pharmacists designed to deter drug product theft and thereby enhance both the integrity of the drug distribution chain and the safety of the workplace; further,

To encourage the development of systems that limit the diversion and abuse potential of medications, including high-cost drugs and controlled substances, and thereby reduce the likelihood that these products will be targets of theft.

*This policy was reviewed in 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**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**

*Source: Council on Professional Affairs*

To support the position that care for dying patients is part of the continuum of care that pharmacists should provide to patients; further,

To support the position that pharmacists have a professional obligation to work in a collaborative and compassionate manner with patients, family members, caregivers, and other professionals to help fulfill the patient care needs, especially the quality-of-life needs, of dying patients of all ages; further,

To support research on the needs of dying patients; further,

To provide education to pharmacists on caring for dying patients, including education on clinical, managerial, professional, and legal issues; further,

To urge the inclusion of such topics in the curricula of colleges of pharmacy.

*This policy was reviewed in 2018 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**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 2018 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**0313****PATIENT-CENTERED CARE**

*This policy was discontinued in 2013.*

**0314****CULTURAL COMPETENCE**

*This policy was superseded by ASHP policy 1414.*

**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**

*Source: Council on Legal and Public Affairs*



To support state licensure eligibility of a pharmacist who has graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) or accredited by an ACPE-recognized accreditation program.

*This policy was reviewed in 2018 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**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 2018 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**0326****ASHP STATEMENT ON THE ROLE OF HEALTH-SYSTEM PHARMACISTS IN EMERGENCY PREPAREDNESS**

*This policy was superseded by ASHP policy 2223.*

**0328****ASHP STATEMENT ON THE PHARMACIST'S ROLE IN THE CARE OF PATIENTS WITH HIV INFECTION**

*This statement was superseded by ASHP Guidelines on Pharmacist Involvement in HIV Care dated September 17, 2015.*

## 2002 Policy Positions

### 0201

#### STAFFING FOR SAFE AND EFFECTIVE PATIENT CARE

*This policy was superseded by ASHP policy 2034.*

### 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**

*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.*

### 0103

#### GENE THERAPY

*This policy was superseded by ASHP Policy 1802.*

### 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 2021 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**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.*

**0112****PROFESSIONAL DEVELOPMENT AS A RETENTION TOOL**

*This policy was superseded by ASHP policy 2103.*

**0116****PATIENT ADHERENCE PROGRAMS AS PART OF HEALTH INSURANCE COVERAGE**

*This policy was superseded by ASHP policy 1504.*

**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

### 0001

#### PHARMACY WORK FORCE

*This policy was superseded by ASHP policy 0201.*

### 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 2015 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

### 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**

*Source: Council on Legal and Public Affairs*

To support the Food and Drug Administration's public health mission of ensuring the safety and effectiveness of drugs, biologics, and medical devices through risk assessment, appropriate product approval, labeling approval, manufacturing oversight, 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 was reviewed in 2020 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**0013****PATIENT'S RIGHT TO CHOOSE**

*Source: Council on Legal and Public Affairs*

To support the right of the patient or his or her representative as allowed under state law to develop, implement, and make informed decisions regarding his or her plan of care; further,

To acknowledge that the patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment; further,

To support the right of the patient in accord with state laws to (a) formulate advance directives and (b) have health care practitioners who comply with those directives.

*This policy was reviewed in 2015 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**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**

*Source: Board of Directors*

To approve the ASHP Statement on Reporting Medical Errors.

*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.*

## 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**

*Source: Council on Administrative Affairs*

To urge health-system pharmacists to assume leadership, responsibility, and accountability for the quality, effectiveness, and efficiency of the entire medication-use process (including prescribing, dispensing, administration, monitoring, and education) across the continuum of care; further,

To urge health-system pharmacists to work in collaboration with patients, prescribers, nurses, and other health care providers in improving the medication-use process.

*This policy was reviewed in 2019 by the Council on Pharmacy Management and by the Board of Directors and was found to still be appropriate.*

**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.*

**9911****PHARMACY RESIDENCY TRAINING**

*This policy was superseded by ASHP policy 0917.*

**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.*

**9802**

**CONSCIENTIOUS OBJECTION BY PHARMACISTS TO MORALLY, RELIGIOUSLY, OR ETHICALLY TROUBLING THERAPIES**

*This policy was superseded by ASHP policy 0610.*

**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 2018 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**9814**

**EDUCATING PHARMACISTS TO PROVIDE APPROPRIATE SUPPORT FOR DYING PATIENTS**

*This policy was superseded by ASHP policy 0307.*

**9816****APPROPRIATE PHARMACY SUPPORT FOR DYING PATIENTS**

*This policy was superseded by ASHP policy 0307.*

**9819****ROLE OF PHARMACISTS AND BUSINESS LEADERS IN HEALTH CARE SERVICES AND POLICIES**

*This policy was discontinued in 2018.*

**9820****MEDICATION ADMINISTRATION BY PHARMACISTS**

*Source: Council on Professional Affairs*

To support the position that the administration of medicines is part of the routine scope of pharmacy practice; further,

To support the position that pharmacists who administer medicines should be skilled to do so; further,

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

*This policy was reviewed in 2018 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**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.*

**9606**

**FDA REFORM**

*This policy was superseded by ASHP policy 0012.*

**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 2019 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**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.*

**9406****PATIENT'S RIGHT TO CHOOSE**

*This policy was superseded by ASHP policy 0013.*

**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**

*Source: Board of Directors*

To change the name of the American Society of Hospital Pharmacists, Inc. (ASHP) to the American Society of Health-System Pharmacists, Inc. (ASHP), effective January 1, 1995; further,

To amend the ASHP Charter, Second Article, by deleting Hospital and substituting Health-System; further,

To amend and restate the ASHP Bylaws, Article 1.1, to conform to the amended ASHP Charter; further,

To declare that this Charter amendment is advisable, and direct that the Charter amendment be submitted to the House of Delegates and the membership for consideration.

*The ASHP membership approved this action by mail ballot, September 1994.*

## 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*

To oppose the use of truth-verification testing such as polygraphs as routine employment practices because of the possible interference with the rights of individuals; further,

To recognize the limited use of such testing during employment where such testing may protect the rights of individuals against false witness.

*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.*

**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**

*Source: House of Delegates Resolution*

To work with the FDA, USP, and pharmaceutical industry to assure that drug products are named in a manner that clearly and without confusion permits identification of ingredients' strengths and changes.

*This policy was reviewed in 2019 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

## 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**

*Source: Council on Legal and Public Affairs*

To support the concept of therapeutic interchange of various drug products by pharmacists under arrangements where pharmacists and authorized prescribers interrelate on the behalf of patient care.

*This policy was reviewed in 2019 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*



**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****OUTPLACEMENT OF PHARMACY DIRECTORS**

*This policy was discontinued in 1999.*

**8310****SIZE, COLOR, AND SHAPE OF DRUG PRODUCTS**

*This policy was discontinued in 2018. .*

**8311****ASHP PLANNING PROCESS AND ASHP LONG-TERM GOALS**

*This policy was discontinued in 2003.*

**8312****DEA RECORDKEEPING REQUIREMENTS**

*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****STUDIES ON COSTS AND BENEFITS OF CLINICAL PHARMACY SERVICES**

*This policy was discontinued in 2006.*

**8207****MEDIATED CONTINUING EDUCATION PROGRAMMING**

*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**

**PHARMACY CRIME**

*This policy was discontinued in 1998.*

**8214**

**APPORTIONMENT/DELEGATE REPRESENTATION**

*This policy was discontinued in 2002.*

**8216**

**ANNUAL MEETING REGISTRATION FEES FOR DELEGATES**

*This policy was discontinued in 2007.*

**8219**

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*This policy was discontinued in 2002.*

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