Summary of the Actions of the ASHP House of Delegates

June 3 and 5, 2018

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The House of Delegates

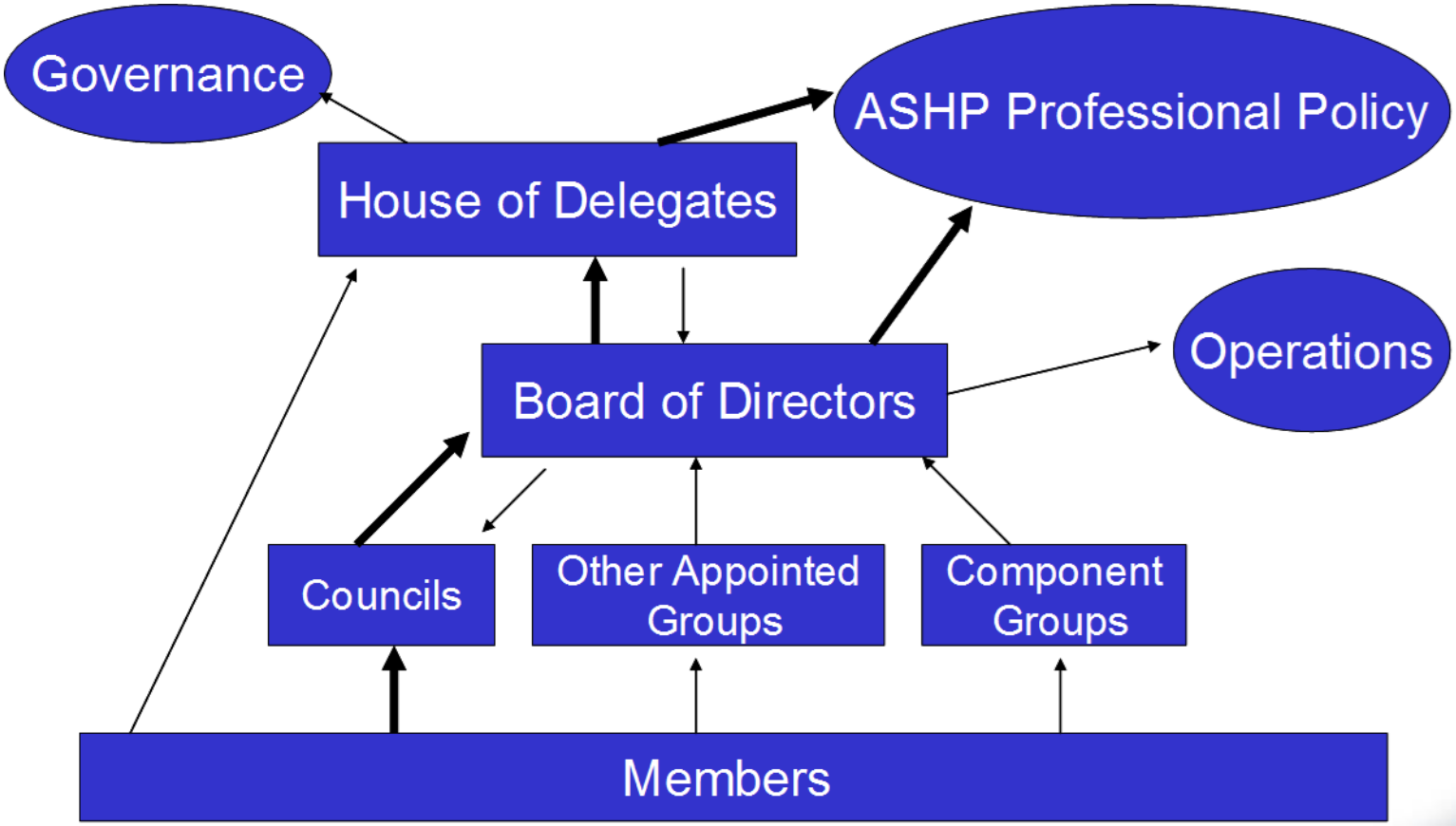
Ultimate authority over ASHP professional policies

One annual session consisting of 4 meetings: 2 meetings at the ASHP Summer Meetings and 1 virtual meeting in the spring and fall

Reviews policy proposals that have been approved by the Board of Directors

Most of these professional policy proposals are contained in reports from ASHP councils

ASHP Policy Process



2018 ASHP House of Delegates Policy Recommendations

During the 2018 Policy Cycle, the House of Delegates has considered 40 policies to date:

- **The March Virtual House of Delegates voted on 10 policies, nine of which were approved (five discontinuations and four new policies) and one was sent to the June House for consideration.**
- **The June House of Delegates considered and debated 31 policies.**
- **At the June meeting, one policy was defeated and 20 were amended or edited.**
- **In total, the 2018 House of Delegates approved 30 new policies, discontinued seven, and defeated one.**
- **The House of Delegate may hold a virtual meeting in November.**

1801 - 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 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.

This policy supersedes ASHP policy 0309.

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.

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.

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.

1805 - 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.

This policy supersedes ASHP policy 0102.

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.

1807 - Reimbursement and Pharmacist Compensation for Drug Product Dispensing

Source: Council on Pharmacy Management

To collaborate with payers in developing improved methods of reimbursing pharmacies and pharmacists for the costs of drug products dispensed, pharmacy and pharmacist services, and associated overhead; further,

To educate pharmacists and stakeholders about those methods.

This policy supersedes ASHP policy 1304.

1808 - 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 and pharmacies providing patient care services within their scope of practice when such services are covered benefits; further,

To advocate for laws and regulations that allow pharmacists and pharmacies to participate as a provider within a healthcare payer's network if the pharmacist or pharmacy meets the payer's criteria for providing those healthcare services; 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 that healthcare payers be required to disclose to pharmacists and pharmacies applying to participate in a provider network the criteria used to include, retain, or exclude pharmacists or pharmacies.

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.

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.

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.

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.

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.

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.

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.

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,

1816 - Biosimilar Medications (cont'd)

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.

1817 - 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 legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; further,

To advocate with state Medicaid programs to ensure that reimbursement policies promote 340B program stability; 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,

1817 - 340B Drug Pricing Program Sustainability (cont'd)

To encourage pharmacy and health-system leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the 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 expanded services and access provided by 340B participants to patients in fulfillment of its mission.

This policy supersedes ASHP policy 1407.

1818 - Federal Quality Rating Program for Pharmaceutical Manufacturers

Source: Council on Public Policy

To advocate that the Food and Drug Administration (FDA) assign quality ratings to pharmaceutical manufacturers based on the quality of their manufacturing processes, sourcing of active pharmaceutical ingredients and excipients, selection of contract manufacturers, and business continuity plans; further,

To advocate that the FDA consider offering incentives for manufacturers to participate in the program.

This policy supersedes ASHP policy 0814.

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.

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.

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.

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.

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.

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.

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,

1825 - Clinician Well-being and Resilience (cont'd)

Source: Council on Education and Workforce Development

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.

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.

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.

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.

1829 - Pharmacy Training Models

Source: Council on Education and Workforce Development

To promote pharmacy training models that: (1) provide experiential and residency training in interprofessional patient care; (2) use the knowledge, skills, and abilities of student pharmacists and residents in providing direct patient care; and (3) promote use of innovative and contemporary learning models; further,

To support the assessment of the impact of these pharmacy training models on the quality of learner experiences and patient care outcomes.

This policy supersedes ASHP policy 1316.

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.

One Item Was Defeated

CPuP 6: Federal Review of Anticompetitive Practices and Price Increases by Drug Product Manufacturers

The 2018 House of Delegates received one item of New Business at the June meeting

New Business:

- Submitted in writing (with background) to the onsite ASHP Executive Office by 4:00 p.m. Monday before the second meeting on Tuesday afternoon.
- House decides whether any further action or review should take place (approves or defeats).
- Policy committees will discuss during September meetings.
- Automatic referral to the Board of Directors (report to House at next session).
- New Business items are debatable and amendable.

New Business Item

The Pharmacist Role in Suicide Prevention

MOTION:

ASHP convene a broad-based task force of appropriate stakeholders to explore opportunities to enhance suicide awareness and prevention. Stakeholders to be considered are ASHP members, state affiliates, colleges/schools of pharmacy, pharmacy professional organizations, pharmacy students, pharmacy residents and non-pharmacy entities. Areas for exploration should include the adoption of training models and tools for suicide screening, detection and intervention as well as the identification of methods for operationalizing suicide prevention strategies in various pharmacy practice and academic settings.

Questions or Suggestions?

Feel free to contact:

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ASHP: https://www.ashp.org/Pharmacy-Practice/Policy-Positions-and-Guidelines/Participate-in-Guidance-Development