

2018 ASHP House of Delegates Policy Recommendations

The House of Delegates

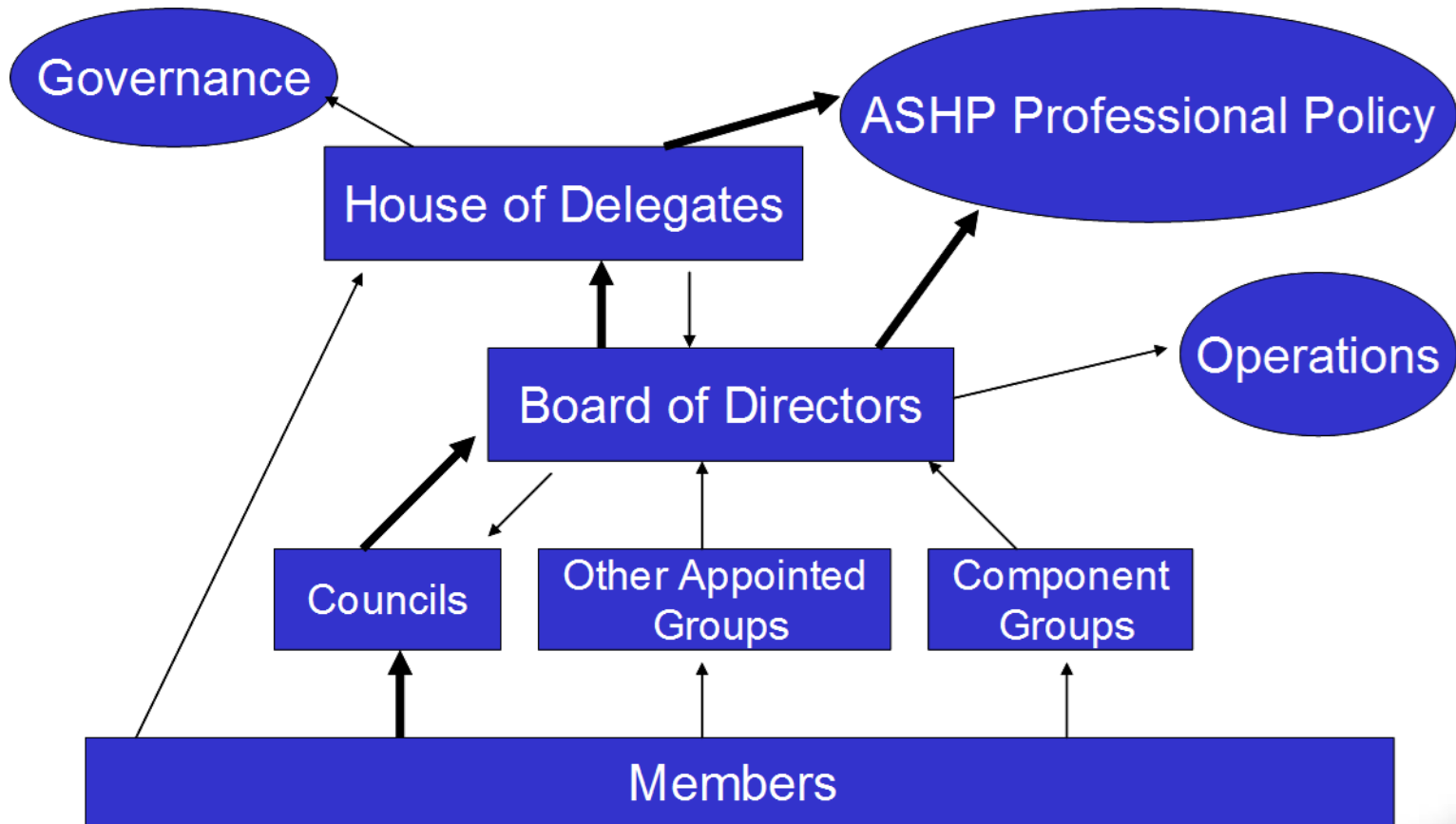
Ultimate authority over ASHP professional policies

One annual session consisting of 4 meetings: 2 meetings at the ASHP Summer Meeting and 2 virtual meetings 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



March Virtual House of Delegates

The policy recommendations on the next 10 slides will be voted on during the March virtual House of Delegates to be held March 16-23.

- The online voting process does not permit amendments.
- Delegates are encouraged to vote against recommendations they feel should be amended.
- ≥85% votes needed for approval
- <85% policies will be presented at the June House
- Policies not reaching that level of consensus will be considered by the House of Delegates in June.

CEWD: Pharmacy Practice Training Models

Source: Council on Education and Workforce Development

To promote pharmacy practice 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 the pharmacist layered learning model; further,

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

(Note: This policy would supersede ASHP policy 1316.)

CPM: 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.

(Note: This policy would supersede ASHP policy 0309.)

CPM: 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.

(Note: This policy would supersede ASHP policy 0103.)

CPhP: Medications Derived from Biologic Sources

Source: Council on Pharmacy Practice

To discontinue ASHP policy 0809, Medications Derived from Biologic Sources, which reads:

To encourage pharmacists to take a leadership role in their health systems for all aspects of the proper use of medications derived from biologic sources, including preparation, storage, control, distribution, administration procedures, safe handling, and therapeutic applications; further,

To facilitate education of pharmacists about the proper use of medications derived from biologic sources.

(Note: Section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] defines biological product as follows: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine [or any other trivalent organic arsenic compound], applicable to the prevention, treatment, or cure of a disease or condition of human beings.)

CPhP: Role of Pharmacists and Business Leaders in Health Care Services and Policies

Source: Council on Pharmacy Practice

To discontinue ASHP policy 9819, Role of Pharmacists and Business Leaders in Health Care Services and Policies, which reads:

To support the principle that business leaders and health professionals must share responsibility and accountability for providing optimal health care services to patients; further,

To support the principle that business leaders should expect practicing pharmacists to formulate policies that affect the prerogative of pharmacists to make optimal care decisions on behalf of patients.

CPuP: 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.

(Note: This policy would supersede ASHP policy 9010.)

CPuP: Size, Color, and Shape of Drug Products

Source: Council on Public Policy

To discontinue ASHP policy 8310, Size, Color, and Shape of Drug Products, which reads as follows:

To approve the authority of manufacturers to copy the size, shape, and color of generically equivalent drug products as a means of promoting better patient compliance (rational drug therapy), but only when the source and identity of the product are readily ascertainable from a uniform mark or symbol on the product.

COT: 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.

(Note: This policy would supersede ASHP policy 1720.)

COT: Appropriate Dosing of Medications in Patient Populations with Unique Needs

Source: Council on Therapeutics

To discontinue ASHP policy 0228, Appropriate Dosing of Medications in Patient Populations with Unique Needs, which reads:

To advocate reforms in medication-use systems, including electronic systems, and healthcare provider education and training that facilitate optimal patient-specific dosing in populations of patients with altered pharmacokinetics and pharmacodynamics.

COT: DEA Scheduling of Hydrocodone Combination Products

Source: Council on Therapeutics

To discontinue ASHP policy 1314, DEA Scheduling of Hydrocodone Combination Products, which reads:

To advocate that the Drug Enforcement Administration (DEA) reschedule hydrocodone combination products to Schedule II based on their potential for abuse and patient harm and to achieve consistency with scheduling of other drugs with similar abuse potential.

June House of Delegates

- The policy recommendations in the next set of slides are scheduled to be considered at the June live meeting of the House of Delegates June 3 and 5 in Denver, Colorado.
- If any of the policy recommendations from the March virtual House of Delegates meeting are defeated, they will also be considered to the June House meeting.
- Proposed policies are found on the House of Delegates website and are debated on the ASHP House of Delegates Connect community by delegates and other ASHP members.
- All ASHP members, including delegates, are encouraged to use the ASHP House of Delegates Connect community to review and comment on any of the proposed policies. Web-based discussion in advance of a House meeting may influence how delegates vote, and it also permits delegates to discuss potential amendments before the June House.

CPM: 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.

(Note: This policy would supersede ASHP policy 0102.)

CPM: Manufacturer-sponsored Patient Assistance Programs

Source: Council on Pharmacy Management

To encourage pharmaceutical manufacturers to extend their patient assistance programs (PAPs) to serve the needs of both uninsured and underinsured patients, regardless of distribution channels; further,

To advocate that pharmaceutical manufacturers and PAP administrators enhance access to and availability of such programs by standardizing application criteria, processes, and forms, and by automating PAP application processes through computerized programs, including Web-based models; further,

To advocate expansion of PAPs to include high-cost drug products used in inpatient settings; further,

To encourage pharmacists, other patient care providers, and pharmaceutical manufacturers to work cooperatively to ensure that essential elements of pharmacist patient care are included in these programs.

(Note: This policy would supersede ASHP policy 1420.)

CPM: Product Reimbursement and Pharmacist Compensation

Source: Council on Pharmacy Management

To collaborate with public and private payers in developing improved methods of reimbursing pharmacies for the costs of drug products dispensed, pharmacist services (e.g., compounding, dispensing, drug product administration, patient monitoring, and patient education), and associated overhead; further,

To educate pharmacists about those methods.

(Note: This policy would supersede ASHP policy 1304.)

CPM: Patient Access to Pharmacist Care Within Provider Networks

Source: Council on Pharmacy Management

To advocate for laws that would require healthcare payers, when creating provider networks, to include pharmacists and pharmacies providing patient care services within their scope of practice when such services are covered benefits when delivered by other healthcare providers; further,

To advocate for laws that would allow a pharmacy or pharmacist to participate as a provider within a healthcare payer's network if the pharmacy or pharmacist 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.

CPM: 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.

(Note: This policy would supersede ASHP policy 1520.)



CPM: 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 evidenced-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.

(Note: This policy would supersede ASHP policy 1303.)

CPhP: Use of International System of Units for Patient-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-related measurements and calculations; further,

To advocate that healthcare organizations use clinical decision support systems and equipment that allow input and display of patient-related measurements and calculations in SI format only; further,

To promote education in the use of SI units and the importance of using SI units to prevent medical errors.

CPhP: 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 (e.g., multiple-dose vials or single-dose vials of differing doses); further,

To collaborate with regulators, manufacturers, and other healthcare providers to develop best practices on the appropriate use of single-dose, single-use, and multiple-dose vials.

CPhP: Use of Closed-System Transfer Devices to Reduce Drug Waste

Source: Council on Pharmacy Practice

To recognize that peer-reviewed 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 research on 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.

CPhP: Collaborative Drug Therapy Management

Source: Council on Pharmacy Practice

To discontinue ASHP policy 9801, which reads:

To support the participation of pharmacists in collaborative drug therapy management, which is defined as a multidisciplinary process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,

To recognize that pharmacists participate in collaborative drug therapy management for a patient who has a confirmed diagnosis by an authorized prescriber; further,

To recognize that the activities of a pharmacist in collaborative drug therapy management may include, but not be limited to, initiating, modifying, and monitoring a patient's drug therapy; ordering and performing laboratory and related tests; assessing patient response to therapy; counseling and educating a patient on medications; and administering medications.

CPuP: ASHP Statement on Advocacy as a Professional Obligation

Source: Council on Public Policy

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



CPuP: Direct and Indirect Remuneration Fees

Source: Council on Public Policy

To advocate that private payers be prohibited from recovering direct and indirect remuneration fees from pharmacies on adjudicated claims; further,

To oppose the application of plan-level quality measures on specific providers, such as participating pharmacies.

CPuP: Impact of Drug Litigation Ads on Patient Care

Source: Council on Public Policy

To oppose drug litigation advertisements that could lead patients to modify or discontinue therapy without consulting their providers; further,

To advocate that drug litigation advertisements that may cause patients to discontinue medically necessary drugs be required to provide a clear and conspicuous warning that patients should not discontinue drugs without seeking the advice of their healthcare provider.

CPuP: Approval of 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; further,

To support legislation and regulation to allow FDA approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore may be substituted 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,

CPuP: Approval of Biosimilar Medications

Cont'd

Source: Council on Public Policy

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 ASHP-directed 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.

(Note: This policy would supersede ASHP policy 1509.)



CPuP: 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,

CPuP: 340B Drug Pricing Program Sustainability Cont'd

Source: Council on Public Policy

To encourage pharmacy 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 (e.g., information technology) 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.

(Note: This policy would supersede ASHP policy 1407.)



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

Source: Council on Public Policy

To strongly oppose anticompetitive practices by drug product manufacturers that adversely affect drug product availability and price; further,

To encourage appropriate federal review of these practices; further,

To advocate that drug product manufacturers be required to provide public notification in advance of significant price increases.

(Note: This policy would supersede ASHP policy 0814.)



COT: Ensuring Effectiveness, Safety, and Access to Orphan Drug Products

Source: Council on Therapeutics

To encourage continued 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 these drug products for approved and off-label indications; further,

To urge health policymakers, payers, and pharmaceutical manufacturers to develop innovative ways to ensure patient access to orphan drug products; further,

To urge federal review to evaluate whether orphan drug status is being used inappropriately to extend patents and decrease competition, reducing patient access.

(Note: This policy would supersede ASHP policy 1413.)



COT: Rational Use of Medications

Source: Council on Therapeutics

To recognize that irrational medication use is inappropriate and can result in patient harm and increased overall healthcare costs; further,

To support and promote evidenced-based prescribing 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.

(Note: This policy would supersede ASHP policy 1312.)

COT: Responsible Medication-related Clinical Testing and Monitoring

Source: Council on Therapeutics

To recognize that overuse of clinical testing is an increasingly recognized problem in practice that can lead to unnecessary costs, waste, and patient harm; further,

To encourage pharmacists to engage in interprofessional efforts to promote the appropriate but judicious use of testing, monitoring, assessment of clinical progress, dose adjustment, and discontinuation of medication therapy, where appropriate; further,

To promote research that evaluates pharmacists' contributions and identifies opportunities for the appropriate use of procedures and test ordering in healthcare systems.

COT: Clinical Practice and Application on the Use of Biomarkers

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 (FDA) approved qualified medication 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 evidenced based application in practices.

(Note: This policy would supersede ASHP policy 0816.)

COT: Medication Overuse

Source: Council on Therapeutics

To discontinue ASHP policy 1312 Medication Overuse, which reads:

To define medication overuse as use of a medication when the potential risks of using the drug outweigh the potential benefits for the patient; further,

To recognize that medication overuse is inappropriate and can result in patient harm and increased overall healthcare costs; further,

To advocate that pharmacists take a leadership role in interprofessional efforts to minimize medication overuse.

CEWD: Clinician Well-being and Resilience

Source: Council on Education and Workforce Development

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

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

To encourage healthcare organizations to develop programs aimed at prevention, recognition, and treatment of burnout, and to support participation in these programs; further,

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

To foster research on stress, burnout, and well-being, especially in pharmacy; further,

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

CEWD: 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 prior to 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 programs for treatment and recovery; further,

To encourage colleges of pharmacy to use validated testing panels that have demonstrated effectiveness detecting commonly misused, abused, or illegally used substances.

CEWD: 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.

(Note: This policy would supersede ASHP policies 0315 and 0804.)

CEWD: 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 acute and ambulatory settings to the general public, public policymakers, payers, other healthcare professionals, and healthcare organization decision-makers; further,

To provide ASHP information and recruitment materials highlighting opportunities for pharmacy careers in acute and ambulatory settings.

(Note: This policy would supersede ASHP policy 0703.)

CEWD: Practice Sites for Colleges of Pharmacy

Source: Council on Education and Workforce Development

To discontinue ASHP policy 0315, Practice Sites for Colleges of Pharmacy, which reads:

To encourage practitioner input in pharmacy education; further,

To encourage that institutional and health-system environments be used as sites for experiential training of pharmacy students; further,

To encourage colleges of pharmacy and health systems to define and develop appropriate organizational relationships that permit a balance of patient care and service, as well as educational and research objectives, in a mutually beneficial manner; further,

To include the administrative interests of both the health system and the college of pharmacy in defining these organizational relationships to ensure compatibility of institutional (i.e., health system or university) and departmental (i.e., pharmacy department and department in the college) objectives; further,

To encourage pharmacists and pharmacy leaders to recognize that part of their professional responsibility is the development of new pharmacy practitioners.

Questions or Suggestions?



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