

Professional Policies Approved by the 2015 ASHP House of Delegates

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The new professional policies approved by the ASHP House of Delegates at its June 2015 session are listed below. Policies proposed by councils or other ASHP bodies are first considered by the Board of Directors and then acted on by the House of Delegates, which is the ultimate authority for ASHP positions on professional issues.

The background information on these policies appears on the ASHP Web site (www.ashp.org); click on “Practice and Policy” then on “House of Delegates,” and then on “Board of Directors Reports on Councils” (<http://www.ashp.org/DocLibrary/Policy/HOD/CouncilReports.aspx>).

The complete proceedings of the House of Delegates will be provided to delegates and will be posted on the ASHP Web site.

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.

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 supersedes ASHP policy 1307.

1503

Pharmaceutical Product and Supply Chain Integrity

Source: Council on Public Policy

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 include a readily available means to retrieve the name and location of the facility that manufac-

tured the specific lot of the product; 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 urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

This policy supersedes ASHP policy 0907.

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 supersedes ASHP policy 0116.

1505

Statutory Protection for Medication-Error Reporting

Source: Council on Public Policy

To collaborate with other health-care 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.

1506

Premarketing Comparative Clinical Studies

Source: Council on Public Policy

To advocate that the Food and Drug Administration have the authority to impose a requirement for comparative clinical trials.

This policy supersedes ASHP policy 0514.

1507

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 adequate representation on state boards of pharmacy and related agencies by pharmacists who are knowledgeable about all areas of pharmacy practice (e.g., hospitals, health systems, clinics, and nontraditional settings) to ensure appropriate oversight; 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 pharmacists competent about the applicable area of practice.

This policy supersedes ASHP policy 0518.

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.

1509

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 interchange-

ability 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,

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

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

To advocate for adequate reimbursement for biosimilar medications that are deemed interchangeable; 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.

This policy supersedes ASHP policy 1409.

1510

Naloxone Availability

Source: Council on Therapeutics

To recognize the potential public health benefits of naloxone for opioid reversal; further,

To support efforts to safely expand access to naloxone; further,

To advocate that individuals other than licensed healthcare professionals be permitted access to naloxone after receiving education; further,

To foster education on the role of naloxone in opioid reversal and its proper administration, safe use, and appropriate follow-up care; further,

To support state efforts to authorize pharmacists' prescribing authority for naloxone for opioid reversal.

1511

Complementary and Alternative Medicine in Patient Care

Source: Council on Therapeutics

To promote awareness of the impacts of complementary and alternative (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 patient safety; further,

To advocate for the inclusion of information about CAM products and their characteristics in medication-related databases; further,

To provide education on the impacts of CAM products on patient care in healthcare organizations; further,

To foster the development of up-to-date and readily available resources about CAM products.

1512

Development of Abuse-Resistant Narcotics

Source: Council on Therapeutics

To advocate that the Food and Drug Administration investigate the efficacy of abuse-resistant formulations in preventing prescription drug abuse.

1513

Quality Patient Medication Information

Source: Council on Therapeutics

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, and simplicity of written patient medication information (PMI); 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, for PMI; 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 PMI content development and maintenance that will ensure the highest level of accuracy, consistency, and currency; further,

To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly accessible central repository of PMI 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 PMI.

This policy supersedes ASHP policy 1012.

1514

Safety and Effectiveness of Ethanol Treatment for 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 treat AWS; further,

To educate clinicians about the availability of alternative therapies for AWS.

This policy supersedes ASHP policy 1010.

1515

Research on Drug Use in Obese Patients

Source: Council on Therapeutics

To encourage drug product manufacturers to conduct 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.

This policy supersedes ASHP policy 1013.

1516

Chemotherapy Parity

Source: Council on Therapeutics

To advocate that all insurance

payers design plans so that patient cost sharing for chemotherapy be equivalent regardless of route of administration; further,

To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of chemotherapy agents regardless of route of administration.

1517

Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship

Source: Council on Therapeutics

To advocate involvement of pharmacists in the clarification of penicillin allergy, intolerance, and adverse drug events; further,

To advocate for documentation of penicillin allergy, intolerance, reactions, and severity in the medical record to facilitate optimal antimicrobial selection; further,

To recommend the use of penicillin skin testing in appropriate candidates when clinically indicated to optimize antimicrobial selection.

1518

Developing Leadership Competencies

Source: Council on Education and Workforce Development

To work with healthcare organization leadership to foster opportunities for pharmacy practitioners to move into leadership roles; further,

To encourage leaders to seek out and mentor pharmacy practitioners in developing administrative, managerial, and leadership skills; further,

To encourage pharmacy practitioners 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 develop-

ment 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 pharmacists to use on a daily basis in their roles as leaders in patient care.

This policy supersedes ASHP policy 0509.

1519

Pharmacy Technician Training and Certification

Source: Council on Education and Workforce Development

To support the position that by the year 2020, the completion of a pharmacy technician training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required to obtain Pharmacy Technician Certification Board certification for all new pharmacy technicians entering the workforce; further,

To foster expansion of ASHP-ACPE accredited pharmacy technician training programs.

This policy supersedes ASHP policies 1015 and 0702.

1520

Impact of Insurance Coverage Design on Patient Care Decision

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 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 1017.

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 supersedes ASHP policy 0603.

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.

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.

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.

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.

1526

Prescription Drug Abuse

Source: Council on Pharmacy Practice

To affirm that pharmacists have leadership roles in recognition, prevention, and treatment of prescription drug abuse; further,

To promote education on prescription drug abuse, misuse, and diversion-prevention strategies.

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.

1528

Excipients in Drug Products

Source: Council on Pharmacy Practice

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To advocate that manufacturers 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 information about excipients; further,

To foster education on the allergenicity of excipients and documentation in the patient medical record of allergic reactions to excipients.

This policy supersedes ASHP policy 0808.

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 supersedes ASHP policy 0523.

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 supersedes ASHP policy 1018.

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 supersedes ASHP policy 8410.

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.*

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.*

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.*

*The ASHP statements approved by the House of Delegates are available on the ASHP Web site (www.ashp.org). Under "Practice and Policy," click on "Policy Positions & Guidelines" and then on "New Guidance Documents."

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