

House of Delegates

Policies Approved by the 2018 ASHP House of Delegates

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.

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 improve public health and patient safety, 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.

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

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.

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 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.

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

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.

Rationale

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). 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.

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.

Rationale

As hospitals and healthcare organizations have become more engaged in developing ambulatory care services, 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 include pharmacists and pharmacies 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 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. Ensuring pharmacists and pharmacies have

the opportunity to engage and have access to payers and payer networks will improve patient access to pharmacists' care.

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 [2016 study](#) estimated that the U.S. may spend close to \$2 billion on oncology drug products that are discarded because they come in vials in which the volume of drug product exceeds what is needed for most doses. Since that landmark study, policymakers, healthcare providers, and payers have been calling for action on vial sizes. The Centers for Medicare & Medicaid Services (CMS) has begun to require that billing for Part B drug products distinguish between claims for those received by a patient and those for discarded drug product, and the Office of the Inspector General (OIG) of the Department of Health and Human Services has initiated a study to determine the cost of such waste. Considerable savings could be gained if vial sizes more closely matched doses, and one of the goals of the OIG study is to determine how much could be saved by using vial sizes available overseas that more closely match doses. As [one analysis](#) has pointed out, pharmacoeconomic analyses done in the U.S. typically do not incorporate leftover drug product in cost calculations, which may inflate cost-effectiveness ratios, and drug manufacturers may be exploiting that omission. In contrast, the United Kingdom National Institute for Clinical Excellence [requires](#) manufacturers to include the cost of leftover drug in manufacturers' submissions, and vials of two cancer drugs studied (bortezomib and pembrolizumab) contain 1 mg and 50 mg, respectively, in the U.K., and 3.5 mg and 100 mg in the U.S. Further, the availability of different vial sizes can enhance patient and worker safety. Vial sizes that more closely match doses can minimize preparation time and steps, reducing employee fatigue and the number of opportunities for error.

ASHP advocates that pharmaceutical manufacturers provide drug products in vial sizes that reduce drug waste (e.g., multiple-dose vials or single-dose vials of differing doses), and that regulators, manufacturers, and healthcare providers cooperate to develop and implement best practices for drug vial optimization.

1813**Use of Closed-System Transfer Devices to Reduce Drug Waste**

Source: Council on Pharmacy Practice

To recognize that a growing body of evidence supports the ability of specific closed-system transfer devices (CSTDs) to maintain sterility beyond the in-use time currently recommended by United States Pharmacopeia Chapter 797, when those CSTDs are used with aseptic technique and following current sterile compounding standards; further,

To foster additional research on and develop standards and best practices for use of CSTDs for drug vial optimization; further,

To educate healthcare professionals, especially pharmacists and pharmacy technicians, about standards and best practices for use of CSTDs in drug vial optimization.

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

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,

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.

Rationale

Statutory and other policy changes to the federal drug pricing (“340B”) program in recent 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. Policymakers and other stakeholders have raised questions about the integrity of the program as well as its original intent. In addition, compliance with the current program continues to be challenging. Specifically, clarification to existing policy guidance or via newly proposed regulation is needed with respect to various issues. These include the definition of a patient, use of contract pharmacies, eligibility by various hospitals, and use of group purchasing organizations to purchase drugs for inpatient and outpatient use. Moreover, 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 believes that the program should expand in alignment with its intent, which may or may not include use in the inpatient setting. 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 state Medicaid programs to ensure optimization of benefits from the 340B program and Medicaid reimbursement policies. Because manufacturers must offer 340B discounts to covered entities to have their drugs covered by Medicaid, Medicaid policies will impact organizations with a 340B program. These impacts include but aren’t limited to disproportionate share adjustment percentages, outpatient drug reimbursement policies, and drug rebate programs (i.e., whether a covered entity is “carved in” or “carved out”).

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.

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.

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

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.

Rationale

Pharmacy training models are continually 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, students, 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 students 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.

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.

Policies 1801 -1804 were approved by the virtual House of Delegates in March. Policies 1805-1830 were approved at the June meetings of the House of Delegates. Policy 1831 was approved at the virtual House of Delegates in November.