Policies Approved by the 2020 ASHP House of Delegates

2001
Safety and Effectiveness of Ethanol for Prevention or Treatment of Alcohol Withdrawal Syndrome
Source: Council on Therapeutics
To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,

To support hospital and health-system efforts that prohibit the use of oral or intravenous ethanol therapies to prevent or treat AWS; further,

To support the removal of oral or intravenous ethanol from hospital and health systems for the prevention and treatment of AWS; further,

To educate clinicians about evidence-based therapies for AWS.

This policy supersedes ASHP policy 1514.

Rationale
AWS can delay patient recovery and interfere with response to therapy. Based on a review of the available evidence, including treatment guidelines from the American Society of Addiction Medicine (ASAM), ASHP opposes the use of oral or intravenous ethanol to prevent or treat AWS. Limited and conflicting evidence of effectiveness, inability to achieve accurate and consistent dosing and blood levels, and the availability of safer and more effective therapies are among the reasons to oppose use of ethanol to prevent or treat AWS symptoms. Benzodiazepines are the preferred drugs for the treatment of AWS, along with other supportive and adjunctive therapies as clinically appropriate. Guidelines from the American Association of Family Physicians recommend benzodiazepines on a fixed schedule for AWS, outpatient detoxification, and enrollment in an alcohol treatment program. ASHP supports efforts to prohibit use of ethanol for AWS and advocates education to a variety of healthcare practitioner audiences to increase awareness of appropriate evidence-based therapies.

2002
Excipients in Drug Products
Source: Council on Therapeutics
To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To encourage manufacturers to publicly disclose all excipients in drug products; further,

To advocate that the Food and Drug Administration require manufacturers to declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate, expand, and maintain interoperable information about excipients; further,

To promote research that evaluates the safety of excipients to guide clinical practice and to support the reporting and dissemination of this information via published literature, registries, and other mechanisms; further,

To foster education on the potential adverse events that may be caused by excipients; further,

To encourage documentation of allergic reactions or intolerances to or restrictions on specific excipients in the health record.

This policy supersedes ASHP policy 1528.

**Rationale**

Excipients are intended to be inactive ingredients that assist in delivering a pharmaceutically elegant medication. Ideally, excipients should have a specific purpose, including serving as a binder, disintegrant, solubilizer, preservative, or for pH adjustment for the proper performance of the dosage form. The properties of the final dosage form (e.g., stability) are, for the most part, highly dependent on the excipients chosen, their concentrations, and interaction with both the active compound and each other. Poor aqueous solubility and rate of dissolution are often the two critical factors that affect the formulation and development process and as a result, some formulations of medications may include high percentages of excipients to ensure the active ingredients are able to be delivered. However, some excipients are added to formulations to enhance color or texture and are not necessary for a stable and soluble product.

In some patients, however, excipients may cause adverse events or aggravate medical conditions. Examples include patients with a red-dye allergy reacting to a suspension containing red dye, fillers that have a high carbohydrate content breaking ketosis in patients who are on a ketogenic diet for seizure management, exacerbation of kidney dysfunction in patients receiving a parenteral solution containing cyclodextrins, or metabolic ketoacidosis requiring dialysis in patients who are receiving high amounts of propylene glycol. Additionally, these adverse effects are not always well known or studied.

Inclusion of excipients in drug product labeling, including their derivative source would allow substitution of a nonallergenic alternative, modification of therapy (such as giving a tablet instead of a dextrose containing suspension), closer monitoring of organ function, or ordering...
pertinent lab values that may alert practitioners to toxicities associated with excipients as opposed to the active drug.

Additionally, many patients and providers are unaware of the potential impact that excipients may have when selecting therapies and monitoring for adverse events. Currently, the FDA only provides guidance on excipient safety for new products but does not require it unless specific regulatory or statutory requirements are cited. These guidance documents do not establish legally enforceable responsibilities nor do they require the manufacturer to disclose these excipients unless specifically requested by the FDA. Conversely, the European Union requires manufacturers to declare excipients on labelling if the medicinal product is an injectable, topical, or an eye preparation, as well as requiring excipients known to have a recognized action or effect to be declared on the labelling of all other medicinal products.

Education of manufacturers, pharmacists and other healthcare professionals, and patients regarding the use and potential adverse effects of excipients will be required. Medication-related databases will need to be configured and continuously updated to include information about drug product excipients, and electronic health record systems will need to permit documentation of allergies and medical conditions related to excipients.

2003
Anticancer Treatment Parity
Source: Council on Therapeutics

To support anticancer treatment parity legislation at both the state and federal level that ensures equality of access and insurance coverage for all anticancer drug products approved by the Food and Drug Administration (FDA); further,

To advocate all insurers and manufacturers design plans containing limits on out-of-pocket expenditure so that patient cost sharing for anticancer treatment is equivalent, regardless of treatment modality or route of administration; further,

To encourage the development of policies and endorse practices that contribute to a decrease in anticancer treatment costs to the consumer; further,

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

This policy supersedes ASHP policy 1516.

Rationale

An estimated $200 billion will be spent on cancer care by 2020, and a recent survey showed if faced with a cancer diagnosis, 57% of Americans say they would be most concerned about either the financial impact on their families or about paying for treatment. Additionally, there is an increase in insurance premiums, co-pays, co-insurance, and deductibles. Most insured cancer patients in the U.S. are responsible for a portion of the cost of their anticancer agents, which can be significant. The average out-of-pocket expense for Medicare patients with cancer is 23.7% of household income. Cancer survivors are 2.7 times more likely to file for bankruptcy.
Traditionally, intravenous (IV) and injected treatments were the primary methods of chemotherapy delivery. Patient-administered anticancer agents have become more prevalent and are now the standard of care for many types of cancer. Oral anticancer agents account for approximately 35% of the oncology development pipeline. Many oral anticancer agents do not have infusible or injectable alternatives, and are the only treatment option for some cancer diagnoses. Oral agents have been embraced because of convenience, efficacy, and safety, but because insurers cover them differently than intravenous drugs, prescribing oral anticancer agents can impose burdensome levels of cost-sharing on patients.

While IV anticancer treatments are covered under a health plan’s medical benefit, often requiring patients to pay a minimal co-pay or no cost at all for the medication, oral anticancer agents are usually covered under the pharmacy benefits. This results in increased out-of-pocket costs. Cost sharing of oral specialty drugs has increased from 3% in 2004 to 25% in 2013, and continues to rise.

The impact of rising out-of-pocket prescription costs for cancer patients can negatively affect adherence and subsequently treatment outcomes. Co-pays can be hundreds or thousands of dollars per month and, as a result, almost 10% of patients choose not to fill their initial prescriptions for oral anticancer agents. A study of claims data from more than 38,000 people who received a new prescription for one of 38 oral anticancer agents from 2014 to 2015 found that, as out-of-pocket costs rose, fewer patients filled their prescriptions. When the required co-pay was less than $10, only 10% of patients failed to pick up their prescriptions. This increased to 32% for patients whose out-of-pocket costs were between $100 and $500, and to 41% when costs were between $500 and $2000. When the out-of-pocket costs exceeded $2000, nearly half of patients (49%) never filled their prescriptions. Delayed initiation of treatment was also significantly higher for those with higher cost-sharing burdens.

Oral parity is a proposed legislative solution to alleviate coverage discrepancies between oral and intravenous anticancer agents. Parity laws are currently state laws designed to ensure that orally administered agents for treating cancer are not more costly for patients than anticancer agents given via infusion at a clinic or hospital. At this point, 43 states and Washington, DC, have enacted parity laws that require patients to pay no more for an oral cancer treatment than they would for an infusion.

However, state parity laws only apply to certain commercial health insurance plans, including those purchased by small groups and individuals. Self-funded patients, patients covered by health plans that fall under federal law (large, multi-state health plans), or those covered by Medicare and other federally funded insurance plans are not eligible. An estimated fifty percent of cancer patients are currently not protected under state parity laws.

The Cancer Drug Parity Act of 2019 (H.R. 1730, introduced on March 13th, 2019; formerly introduced in 2017 as H.R. 1409) would require any health plan that currently provides coverage for cancer treatment to provide coverage for self-administered anticancer agents at a cost no less favorable than the cost of IV, port-administered, or injected anticancer agents.

There may be false patient perception that oral anticancer agents are less dangerous than IV chemotherapy, furthering supporting the important role of the pharmacist in educating the patients about the agent, its adverse effects, how to manage toxicities, and when to contact their healthcare team. Pharmacists monitor oral chemotherapy treatments to prevent medication and food interactions, adverse drug reactions, and medication errors. Pharmacists
are also positioned to play an integral role in shared decision-making and assisting with procurement.

Treatment of cancer also continues to evolve, and many agents may not fall under the category of traditional chemotherapy (e.g., biologic agents, antimicrobials, and others). As a result, practitioners and legislatures have moved away from the singular term chemotherapy and use chemotherapy, anticancer and cancer drug interchangeably, with anticancer being the preferred term.

2004
Evaluation of Abuse-Deterrent Drug Mechanisms
Source: Council on Therapeutics
To encourage manufacturers to develop safe and efficacious abuse-deterrent formulations for drugs known to be abused and misused; further,

To promote research on the efficacy of abuse-deterrent mechanisms in preventing prescription drug abuse, and to support the reporting and dissemination of this information; further,

To advocate for legislation that would limit out-of-pocket expenditures for such formulations.

This policy supersedes ASHP policy 1512.

Rationale
The abuse of certain classes of prescription drugs, including narcotics and stimulants, has had a large impact on public health. One way the Food and Drug Administration (FDA) has sought to curb this activity is through the use of abuse-deterrent formulations (ADFs). ADFs are formulations that permit treatment of a patient’s medical condition but reduce the likelihood of diversion, misuse, and abuse, and related adverse outcomes through various mechanisms, such as hindering the extraction of active ingredients, limiting their bioavailability, preventing administration through alternative routes, or making abuse of the manipulated product less attractive or rewarding.

The FDA has been taking steps to incentivize and support the development of opioid formulations with progressively better abuse-deterrent properties. These steps include working with individual sponsors on promising abuse-deterrent technologies, developing appropriate testing methodologies for both innovator and generic products, and publishing guidance on the development and labeling of abuse-deterrent opioids.

Despite these efforts, prescription stimulants used to treat attention deficit hyperactivity disorder have become drugs of choice for young adults, with as many as 20% of college students using such drugs for nonmedical purposes. According to a 2011 study, benzodiazepines were involved in 30.6% of prescription drug-related overdose deaths. However, to date, the FDA has not provided guidance on ADFs for any controlled substance other than opioids.

Despite the groundswell of support for abuse-deterrent opioid formulations, there is not strong evidence that such formulations deter abuse. One study of 232,874 patients across 437 facilities found an increase in abuse prevalence of all opioids after introduction of an abuse-
deterrent formulation. That study showed little success in deterring abuse, finding instead that patients had switched to alternative drugs. There may also be unintended consequences of preferring abuse-deterrent formulations to regular formulations, such as increased costs borne by patients who legitimately need the drugs.

There also is a need to demonstrate that these formulations are truly abuse deterrent as well. In April 2015, the FDA published an industry guidance document on Abuse-Deterrent Opioids – Evaluation and Labeling. The document explains the FDA’s “current thinking about the studies that should be conducted to demonstrate a given formulation has abuse-deterrent properties.”

Addressing the growing rate of prescription drug abuse will require a multifaceted strategy; no one tactic will solve the problem. While ASHP supports measures such as abuse-deterrent formulations and rescheduling to prevent abuse, more research is necessary to determine which tactics are the most effective at deterring abuse.

2005
Quality Consumer Medication Information
Source: Council on Therapeutics
To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, accessibility, targeting, and simplicity of consumer medication information (CMI); further,

To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level and standardized, patient-focused templates, for CMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

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

To advocate that the FDA engage a single third-party author to provide editorial control of a highly structured, publicly and easily accessible central repository of CMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of CMI.

This policy supersedes ASHP policy 1513.

Rationale
ASHP supports the intent of efforts to improve the quality, consistency, and simplicity of consumer medication information (CMI). The Food and Drug Administration (FDA) defines CMI (previously called patient medication information, or PMI) as “written information about prescription drugs developed by organizations or individuals other than a drug’s manufacturer that is intended for distribution to consumers at the time of drug dispensing.” CMI is not reviewed or approved by the FDA or a drug’s manufacturer.

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

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

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

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

ASHP further advocates that state legislatures and regulatory agencies require that all dispensers distribute CMI according to FDA-established standards and be held accountable if CMI content or format is modified in a manner that results in nonconformance to the standards.
Creation and maintenance of CMI by a single third-party author (subject to FDA-contracted standards and quality assurance metrics) would provide clear, concise, unbiased, evidence-based CMI that is both timely and consistent for the same drug and for relevant information within the same drug class. Such coordination of the medication information database would allow for consistency in style and content, as well as more frequently updated content.

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

2006
Pharmacist’s Leadership Role in Anticoagulation Therapy Management
Source: Council on Therapeutics
To advocate that pharmacists provide leadership in caring for patients receiving drug products for anticoagulant therapy management; further,

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

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

This policy supersedes ASHP policy 1703.

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

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

2007
Use of Surrogate Endpoints for FDA Approval of Drug Uses
*Source: Council on Therapeutics*
To support efforts by the Food and Drug Administration (FDA) and other stakeholders to qualify the appropriateness of surrogate endpoints; further,

To support the continued use of qualified surrogate endpoints by the FDA as a mechanism to evaluate the effectiveness and safety of new drugs and new indications for existing therapies, when measurement of definitive clinical outcomes is not feasible; further,

To advocate that the FDA consistently enforce existing requirements that drug product manufacturers complete postmarketing studies for drugs approved based on qualified surrogate endpoints in order to confirm that the expected improvement in outcomes occurs, and to require that these studies be completed in a timely manner.

*This policy supersedes ASHP policy 1011.*

*Rationale*
Expedited approval programs provided by the FDA have resulted in substantial public health benefits, as illustrated by the use of surrogate endpoints to approve therapies for HIV and AIDS in the 1990s. The FDA provides four mechanisms to expedite the development and review process for drugs: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The structure and requirements for each of these mechanisms differs as described in a [2013 draft guidance for industry](#). However, to qualify for any of these programs, a drug must (1) address an unmet medical need, (2) provide benefit over available drug treatments, and (3) be used in the treatment of a serious or life-threatening condition. Further, the FDA guidance states that these programs are “intended to help ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies’ benefits justify their risks.” Processes used to ensure a favorable risk–benefit profile include, but are not limited to, requirements for postmarketing studies to evaluate safety and effectiveness of the drug as used in real-world scenarios. However, the accelerated approval program is the only program that includes postmarketing studies as a requirement of the program. The FDA has discretion to require additional studies on a case-by-case basis for drug products approved via the other expedited mechanisms. Despite these safeguards, some features of these programs (e.g., smaller clinical trials, alternate trial designs, or limited-duration trials) can result in increased patient risk because less is known about a drug’s side effect profile and efficacy due to limited patient exposure. In addition, as with all drugs, safety assessments benefit from use of the drug in post-approval patient populations, which better reflect real-world use than the controlled environment of a clinical trial.

Because these drugs represent medical advances, their post-approval use can be extensive. Further, off-label use of these drug products, like all therapies, is common.
Unfortunately, prescribers and other clinicians are frequently unaware that an expedited pathway was utilized and that evidence limitations exist. This scenario raises significant concerns about whether there is sufficient clinician awareness to ensure appropriate use of drugs approved via these pathways. Therefore, ASHP proposes unique labeling requirements that would increase awareness through use of a logo or other mechanism that would be used on an interim basis to inform clinicians about data limitations and provide guidance on appropriate use. This labeling would describe appropriate patient populations and monitoring parameters. Similar labeling requirements have been proposed for a new pathway being considered for the development of antibiotics used to treat life-threatening infections. ASHP supports the approach, but recommends that the increased labeling requirements be discontinued once the drug product manufacturer and FDA agree that sufficient data is available to support safe and effective use, or after the drug manufacturer completes any required postmarketing study commitments.

Given data limitations associated with approval of these therapies, ASHP advocates that the FDA be extremely diligent in ensuring that postmarketing commitments are met. Further, the FDA should use its existing authority as described under 21 CFR 314 subpart H and 21 CFR 601 subpart E if timelines or expectations for these commitments are not satisfactory. This authority allows the FDA to take legal action through penalties that include requiring labeling changes or rescinding marketing approval.

Finally, ASHP believes that there is a need for research to determine whether these expedited pathways are achieving the desired benefits, which include decreasing the time and costs associated with drug product development, lowering overall healthcare costs, and increasing patient access to safe and effective drug therapies.

2008
Health-System Facility Design
Source: Council on Pharmacy Management
To advocate the development and the inclusion of contemporary pharmacy and medication-use specifications in national and state healthcare design standards to ensure adequate space for safe provision of pharmacy products and patient care services; further,

To promote pharmacist involvement in the design-planning and space-allocation decisions of healthcare facilities.

This policy supersedes ASHP policy 0505.

Rationale
Often the design and location of health-system pharmacy departments are less than ideal. Many pharmacy departments do not have adequate square footage, and too often the pharmacy is located in the basement of the hospital, far removed from the patients. The impact of physical space on staff satisfaction may also contribute to staff turnover. Pharmacy design often occurs before pharmacy leadership has an opportunity for input on the design, location, or size.

Healthcare architects and facility engineers need to be knowledgeable in the
contemporary and future needs of pharmacy design and the facility requirements for medication use (e.g., medication preparation rooms, temperature monitoring, automated dispensing cabinets). This includes, for instance, the inclusion of technical specifications (including those in applicable compendial standards of the United States Pharmacopeia) for pharmacies in national healthcare design standards.

Regarding facility design, pharmacist collaboration with the Association of Healthcare Engineers and the American Institute of Architects is paramount to design success. The Guidelines for Design and Construction of Hospital and Health Care Facilities is the primary document driving design decisions by architects and healthcare engineers. Research results on optimal, evidenced-based facility design to support safe medication use should be incorporated in new or renovation construction plans.

2009
Role of the Pharmacy Workforce in Identifying and Caring for Victims of Human Trafficking
Source: Council on Pharmacy Practice
To recognize that human trafficking is a significant public health problem in the U.S.; further,

To affirm that the pharmacy workforce has important roles in identifying and caring for victims of human trafficking; further,

To foster education, training, and the development of resources to prepare the pharmacy workforce for their roles in identifying and caring for victims of human trafficking.

Rationale
The U.S. Department of Health and Human Services Office on Trafficking in Persons (OTIP) describes human trafficking as a form of modern slavery that "occurs when a trafficker exploits an individual with force, fraud, or coercion to make them perform commercial sex or work." OTIP outlines two types of trafficking: labor trafficking, in which individuals are compelled to work or provide services; and sex trafficking, in which "adults are compelled to engage in commercial sex by force, fraud, or coercion or minors are compelled to perform a commercial sex act regardless of the presence of force, fraud, or coercion."

Combating human trafficking is one of the central goals of the American Hospital Association Hospitals Against Violence Initiative. All healthcare providers have a role in identifying and caring for victims of human trafficking. These roles include recognizing indicators of human trafficking; being aware of common healthcare issues faced by human trafficking victims; providing for a patient’s medical and nonmedical needs while providing a safe and comfortable environment; complying with applicable laws regarding reporting of suspected human trafficking, including child abuse; and providing care and resources for survivors of human trafficking.

2010
Use of Two Patient Identifiers in the Outpatient Setting
Source: Council on Pharmacy Practice
To encourage the use of two identifiers to confirm patient identity when transferring filled prescriptions to the possession of the patient or patient’s agent for outpatient use.

*This policy supersedes ASHP policy 1024.*

**Rationale**
Errors caused by dispensing medications to the wrong patient are largely preventable. Although two patient identifiers are routinely used when medications are administered in inpatient settings, similar practices are not employed when dispensing medications for outpatient use. ASHP supports consistent use of two patient identifiers and believes that this safety strategy should be used to confirm patient identity at the time patients or their agents pick up filled prescriptions for outpatient use.

2011
**Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice**
*Source: Council on Public Policy*
To recommend the use of credentialing and privileging in a manner consistent with other healthcare professionals to assess a pharmacist’s competence to engage in patient care services.

*This policy supersedes ASHP policy 1907.*

**Rationale**
Credentialing and privileging processes are key to ensuring clinician competence to provide safe and effective patient care. They are also critical elements to securing reimbursement for healthcare services. ASHP opposes the development of credentialing or privileging processes by government agencies or payers without significant pharmacist input. We recognize that state laws, state boards of pharmacy, and payers will each approach credentialing and privileging differently, making a consistent process extremely beneficial. When possible, pharmacists should be included as providers in medical staff bylaws.

2012
**Importation of Drug Products**
*Source: Council on Public Policy*
To oppose wholesale importation of drug products as a method to lower drug costs.

*This policy supersedes ASHP policy 0413.*

**Rationale**
Recent efforts to rein in drug pricing have centered on proposals to allow the wholesale importation of drugs (meaning importation of drugs by healthcare providers and distributors on a larger scale, rather than by individuals on a small scale) from foreign countries (e.g., Canada) as a means to reduce patient costs. Although states (e.g., Florida and Colorado) have passed wholesale importation laws, those laws cannot take effect until the state has crafted an
importation plan, the Food and Drug Administration (FDA) has signed off on it, and the Department of Health & Human Services (HHS) Secretary has made the required certification to Congress.

Current law allows wholesale importation only in very limited circumstances (i.e., shortages) and requires the HHS Secretary to certify to Congress that allowing importation of drugs will not put public health and safety at risk and that it will result in significant savings. No Secretary has ever been able to make such a certification.

ASHP believes that wholesale importation of drugs cannot be accomplished while: (1) maintaining the integrity of the pharmaceutical supply chain and avoiding the introduction of counterfeit products into the U.S.; (2) providing for continued patient access to pharmacist review of all medications and preserving the patient-pharmacist-prescriber relationship; and (3) providing adequate patient counseling and education, particularly to patients taking multiple high-risk medications. Further, wholesale importation is unlikely to result in significant cost savings and reduces focus on drug pricing solutions that can reduce prices over the long term.

Nothing in this policy should be construed to oppose personal importation of drugs, or importation of drugs and related medical devices to alleviate a drug shortage when such importation is overseen by the FDA.

2013

Public Quality Standards for Biologic Products

Source: Council on Public Policy

To oppose federal or state legislation that would remove the requirement for biologic products to adhere to public quality standards; further,

To review and evaluate current public standards to ensure that they are relevant and appropriate to biologic products.

Rationale

ASHP has long recognized that application of quality standards (e.g., United States Pharmacopeia monographs or other applicable guidance) helps guarantee safe use of drugs. ASHP joined virtually all national pharmacy groups, including more than 30 state pharmacy associations, in opposing Congressional efforts to eliminate monographs for biologic medications in the 115th and 116th Congresses. The FDA advocates voluntary standards for biologic products on the basis of reduced costs and improved access, but the agency does not provide data to justify that stance. The arguments against requiring monographs center on their potential use as a barrier to competition, because manufacturers could incorporate patentable characteristics relevant to the product’s safety and efficacy. However, removing monographs for one class of drugs could open the door to removal of standards for other drug classes and to laxer safety standards generally. There is evidence that the monographs do not dampen innovation, as new products continue to enter the market.

2014

Naloxone Availability

Source: Council on Therapeutics
To recognize the public health benefits of naloxone for opioid reversal; further,

To support efforts to safely expand patient and public access to naloxone; further,

To support state efforts to authorize pharmacists’ prescribing authority for naloxone for opioid reversal; further,

To advocate for the development of affordable formulations of naloxone to increase accessibility; further,

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

To support legislation that provides protections for those seeking or providing medical help for overdose victims.

*This policy supersedes ASHP policy 1510.*

**Rationale**

According to the Centers for Disease Control and Prevention (CDC), prescription drug abuse is a national epidemic. Deaths from prescription opioid overdose number 10,000 per year; in contrast, deaths from heroin overdose number 2000. People at risk for opioid overdose include not only substance abusers, but also opioid-naive patients, such as those being admitted for or discharged from ambulatory surgery.

Naloxone is a competitive opioid antagonist that rapidly rescues patients from opioid overdose by displacing mu2 opioid receptors in the central nervous system. Naloxone has an excellent safety profile. The World Health Organization includes naloxone on its model list of essential medicines.

Evidence has demonstrated a clear public health benefit from expanding access to naloxone. Naloxone is currently distributed without a prescription via standing orders, collaborative practice agreements or pharmacist prescribing authority in all 50 states to ensure liberal access to this lifesaving drug. Several states have also started to permit pharmacy technicians to dispense naloxone under these provisions as well.

Currently there are several formulations of naloxone on the market, including subcutaneous injection, something caregivers or peers may have difficulty doing properly, and intranasal formulations. These nasal devices have shown that intranasal naloxone is as effective as injectable routes in rapid opioid reversal. However, its cost (which ranges from $130 to $300 per kit) presents a barrier to widespread use. ASHP encourages the Food and Drug Administration to explore ways to get more user-friendly and less costly formulations to the market for patients and caregivers.

Despite this expanded access to naloxone, there are still significant barriers to its widespread use, including hesitancy among pharmacists to dispense naloxone. Uniform education for those administering the drug, training on safe administration, and recommendations on follow-up care with abuse treatment programs for treated individuals is
needed. Laws, including medical amnesty and those that provide protection against legal liability for persons administering naloxone (i.e., Good Samaritan laws), are needed as well as laws protecting individuals who call for help for someone who has overdosed from prosecution from minor drug possession or drug paraphernalia.

2015

**Network Connectivity and Interoperability for Continuity of Care**

*Source: Council on Pharmacy Management*

To advocate the use of electronic information systems, with appropriate security controls, that enable the integration of patient-specific data that is accessible in all components of a health system; further,

To support the use of technology that allows the transfer of patient information needed for appropriate medication management across the continuum of care; further,

To urge computer software vendors and pharmaceutical suppliers to provide standards for definition, collection, coding, and exchange of clinical data used in the medication-use process; further,

To pursue formal and informal liaisons with appropriate healthcare associations to ensure that the interests of patient care and safety in the medication-use process are fully represented in the standardization, integration, and implementation of electronic information systems; further,

To strongly encourage health-system administrators, regulatory bodies, and other appropriate groups to provide health-system pharmacists with full access to patient-specific clinical data; further,

To advocate that client-vendor agreements include timelines for data destruction; further,

To oppose the selling of data for unauthorized uses; further,

To educate health-system leaders about potential use and misuse of shared data.

*This policy supersedes ASHP policy 0507.*

**Rationale**

For the past two decades, the U.S. health system has been racing to take advantage of the potential that digital health information offers for improved patient care. Each institution and practice has invested in information systems that work for its specific situation. These systems were developed by multiple vendors, each with their own proprietary structures and labels. Information was and continues to be found in silos, within health systems, within institutions, even within departments.

In 2004, an executive order created the Office of the National Coordinator for Health
Information Technology (ONC). ONC is the primary federal entity charged with coordination of nationwide efforts to implement and advance health information technology and the electronic exchange of health information. The 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act provided the Department of Health and Human Services with additional authority to promote health information technology, including the secure exchange of electronic health information.

As defined by the Healthcare Information and Management Systems Society (HIMSS), interoperability is “the ability of different information systems, devices, or applications to connect, in a coordinated manner, within and across organizational boundaries to access, exchange and cooperatively use data amongst stakeholders, with the goal of optimizing the health of individuals and populations.” ONC has developed a roadmap for interoperability and created calls to action for entities with specific roles in our healthcare system (e.g., the Calls to Action for People and Organizations That Deliver Care and Services).

As government agencies, standards-setting organizations, and professional associations work toward interoperability of health information technology, it is important to ensure this includes the ability of healthcare providers and patients to securely access and use health information from different sources and settings relevant to medication use to ensure patient-centered continuity of care.

Along with secure access and sharing of health information, providers and health systems must be cognizant of how a vendor will handle data, how it plans to safeguard data, and whether and how data will be used for secondary purposes (e.g., research, advertising).

ASHP recognizes that continuity of care is a vital requirement in the appropriate use of medications. Pharmacists have responsibility for ensuring continuity of care as patients move from one setting to another (e.g., ambulatory care, inpatient care, community pharmacy, home care). Achieving information systems that have the ability to share relevant patient care data securely across care settings is a critical step in optimizing medication use across care settings.

2016 Medication Formulary System Management

Source: Council on Pharmacy Management

To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; (2) must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; and (3) should not be based solely on economic factors; further,

To support the concept of a standardized medication formulary system among components of integrated health systems when standardization leads to improved patient outcomes; further,

To oppose independent payer-directed formulary decisions that would increase the complexity of the medication-use system.

*This policy supersedes ASHP policies 9601 and 1805.*
Rationale

A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications, standardized medication concentrations, and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for healthcare organizations to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and cost-effective medication therapy. The formulary system is the ongoing process through which a healthcare organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

As described in more detail in the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System, a fundamental characteristic of the formulary system is that all decisions are made based on factors that result in optimal patient care, include the involvement of appropriate healthcare professionals, and are not based solely on economic factors.

Formulary management techniques may differ under an integrated or network system versus an individual healthcare entity. Standardized drug formularies within integrated health systems increase coordination complexity, but help drive standardized medication use processes across sites of care.

Additionally, insurance coverage of medications should not interfere with the safe and effective provision of care. For example, some hospitals are currently being forced to administer a specific payer-preferred biosimilar drug to a covered patient, which requires hospitals to stock a different product for each payer and then ensure the correct one is dispensed. This costly and resource-intensive practice also has medication safety implications and negatively affects supply chain efficiency. Biosimilar drugs are considered to be therapeutically equivalent, but the current Food and Drug Administration (FDA) approval process does not include a determination of interchangeability between reference and biosimilar products. Because the substitution of a biosimilar for a reference product is a decision outside the FDA regulatory process, it is therefore a matter of state pharmacy law. The obligation to have a specific payer-preferred biosimilar results in hospitals and health systems devoting significant resources to procure, store, label, and dispense payer-preferred biosimilars. This duplication adds complexity to the medication-use process, and as more biosimilars become available, the potential for harmful medication errors will increase. The use of biosimilars was a key cost-reduction concept in the Affordable Care Act. However, in May 2018, the price linkage cost-reduction concept within Medicare Part B was rescinded. Going forward, reimbursement will be based on the specific biosimilar product pricing. The full impact of this change for individual healthcare organizations will depend on patient and payer mix. Biosimilars that are priced at a lower acquisition cost compared to the innovator product are likely to stagnate or lose market share due to a low reimbursement margin. As a result, pricing
of biosimilars may increase to make the reimbursement margin competitive with the innovator product, leaving healthcare organizations in search of other cost reduction opportunities.

2017
Role of the Pharmacy Workforce in Preventing Accidental and Intentional Firearm Injury and Death
Source: Council on Pharmacy Practice
To recognize that accidental and intentional firearm injury and death in the U.S. is a public health crisis; further,

To affirm that the pharmacy workforce has important roles in the comprehensive public health and medical approach to reducing death and disability from firearm injury.

Rationale
A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications, standardized medication concentrations, and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for healthcare organizations to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and cost-effective medication therapy. The formulary system is the ongoing process through which a healthcare organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

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2018
Safe Use of Transdermal System Patches
Source: Council on Pharmacy Practice
To encourage hospitals and health systems to implement policies and procedures to ensure safe use of transdermal system patches; further,

To advocate for enhanced patient and consumer education and product safety requirements for transdermal system patches; further,

To encourage manufacturers of transdermal system patches to collaborate with pharmacists and other stakeholders to identify and implement packaging, labeling, and formulation changes that prevent accidental exposure and facilitate safe disposal.

This policy supersedes ASHP policy 1404.

Rationale
There have been many reports of errors associated with and abuse or misuse of transdermal system patches. Pharmacists are in a unique position to improve the safe use of these products by encouraging implementation of best practices such as electronic health record builds; regular nursing checks for transdermal patches; and policies for ordering, handling, and disposal of these products. Better patient and consumer education specific to this unique dosage form, especially for outpatient use, is also an important component of safe use. Manufacturers could also take additional steps to prevent misuse of these products by collaborating with pharmacists and other stakeholders to identify and implement packaging, labeling, and formulation changes that would facilitate safe disposal and prevent accidental exposure.

2019
Access to Affordable Healthcare
Source: Council on Public Policy
To advocate for access to affordable healthcare for all, including coverage of medications and related pharmacist patient care services; further,

To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective healthcare services; (2) optimize treatment outcomes; (3) minimize overall costs without compromising quality; and (4) ensure patient choice of healthcare providers, including pharmacy services; further,

To advocate that healthcare payers seek to optimize continuity of care in their design of benefit plans.

This policy supersedes ASHP policy 1001.

**Rationale**
This policy expresses ASHP’s stance on access to healthcare in the United States. The policy emanated from ASHP policies dealing with affordability and accessibility of pharmaceuticals. ASHP believes that it is important to address the larger issue of healthcare access, particularly due to the impact of the cost of medications on the nation’s overall healthcare budget as well as pharmacy budgets in hospitals and health systems. Healthcare should be affordable, but also sufficient to ensure patient access to services.

**2020**

**Care-Commensurate Reimbursement**

*Source: Council on Public Policy*

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

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

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

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

2021

Funding, Expertise, and Oversight of State Boards of Pharmacy

*Source: Council on Public Policy*

To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,

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

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

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

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

*This policy supersedes ASHP policy 1507.*

*Rationale*

In recent years, the regulatory scope of boards of pharmacy has grown to address new and expanded scopes of practice and healthcare while fulfilling their mission of protecting the public health. In addition, coordination with federal agencies (e.g., Food and Drug Administration, Drug Enforcement Administration) and related state agencies add to the complexity of a state board’s mission. With this expanded scope and mission comes the need for additional resources, both financial and human. Specific knowledge acquired by pharmacists and pharmacy technicians is essential to the safe regulation of practice. Thus, inspectors need to have demonstrated competency in the applicable area of practice in order to assure the health and safety of the public.
Dispensing by Nonpharmacists and Nonprescribers
Source: Council on Public Policy
To reaffirm the position that to ensure optimal patient outcomes all medication dispensing functions must be performed by, or under the supervision of, a pharmacist; further,

To reaffirm the position that any relationships that are established between a pharmacist and other individuals in order to carry out the dispensing function should preserve the role of the pharmacist in (a) maintaining appropriate patient safety, (b) complying with regulatory and legal requirements, and (c) providing individualized patient care; further,

To advocate that all medication dispensing, regardless of setting, be held to the same regulatory standards that apply to dispensing by a pharmacist; further,

To urge pharmacists to assume a leadership role in medication dispensing in all settings to ensure adherence to best practices.

This policy supersedes ASHP policy 0010.

Rationale
The Council recognizes the reality of limited pharmacist availability and lack of comprehensive pharmacy services in many settings, including public health clinics, rural and urban outreach clinics, and hospital emergency departments. However, the Council believes that responsibility and services of pharmacists are critical to safe medication use and that all dispensing, regardless of setting, should meet the same standards that apply to pharmacies and pharmacists. The Council believes that the current ASHP Minimum Standard for Pharmaceutical Services in Ambulatory Care is explicit and pertinent to the practice of dispensing by nonpharmacists and nonprescribers. The Council also noted that this type of drug delivery and dispensing arrangement does not constitute collaborative drug therapy management as defined in ASHP policy 9903.

2023
New Categories of Licensed Pharmacy Personnel
Source: Council on Public Policy
To oppose the creation of new categories of licensed pharmacy personnel.

Rationale
State efforts to introduce a “pharmacist assistant” category conflict with longstanding ASHP efforts to support the professional growth of licensed or registered pharmacy technicians. Pursuant to these state proposals, pharmacists could delegate a number of activities that fall under the purview of their practice to the pharmacist assistant, such as receiving telephone calls, prescriptions, tech-check-tech, etc. In effect, this would create another midlevel provider in the pharmacy. Not only would this create confusion regarding terminology and job roles, it would undermine ASHP’s work to professionalize the technician role. The policy should not be read as impeding the use of current licensed personnel, including technicians and students.
2024
Safety and Efficacy of Compounded Topical Formulations

Source: Council on Therapeutics

To encourage pharmacists to take a leadership role in developing processes that would ensure quality, safety, and effectiveness of compounded topical formulations; further,

To advocate that ASHP expand its repository of evidence-based formulations that could serve as a resource for compounding topical formulations; further,

To advocate that public and private payers and healthcare providers collaborate to create standardized and efficient methods for authorizing payment for medically necessary compounded topical formulations; further,

To encourage hospitals and health systems to develop policies and procedures to guide clinicians in making informed decisions regarding the prescribing and use of compounded topical formulations; further,

To encourage pharmacists to take a leadership role in developing and providing education on the safety and efficacy of compounded topical formulations to providers and consumers.

Rationale

Compounded topical formulations are meant to be customized for individuals whose needs cannot be met by commercially available drugs. Unlike the drugs made by conventional manufacturers that require Food and Drug Administration (FDA) approval, compounded drugs such as various topical formulations are not evaluated by the FDA for safety, effectiveness, or quality, and many are exempt from the new-drug approval process, current good manufacturing practice, and other FDA requirements. In addition, quality standards for compounded drugs are generally lower than those for FDA-approved drugs; therefore, compounded drugs can pose increased safety risks (e.g., being contaminated or having the wrong potency) or lack efficacy.

Because some drugs do have FDA approval for topical application, clinicians and patients may not be aware of potential safety risks or potential lack of effectiveness associated with certain ingredients and combinations of ingredients in compounded topical pain creams. When these agents are compounded, at least one of the ingredients is an active ingredient in an FDA-approved topical pain cream (e.g., lidocaine), while the remaining ingredients may be active ingredients in drugs approved by the FDA for nontopical administration to treat non-pain-related indications (e.g., antidepressants, anticonvulsants, antivirals, narcotics). In addition, the literature supporting the use of the additional agents outside their normal vehicle of administration is often not well designed or sufficiently powered to demonstrate efficacy. A study published by the U.S. Department of Defense found that these combination-compounded pain creams were no better than placebo creams and, given their higher costs, which had escalated to cost of $6 million per day, should no longer be used.
Issues of fraud are also well known with compounded topical formulations. In August 2018, the Department of Health and Human Services Office of Inspector General (OIG) found that from 2006 to 2015, spending for these drugs increased 625%, and spending for compounded topical drugs—such as creams, gels, and ointments—grew at an even faster pace. Medicare Part D sponsors cover these drugs under certain circumstances. The OIG also found that Part D spending for compounded topical drugs increased 2353% from 2010 to 2016, rising from $13.2 million to $323.5 million. Much of this growth occurred from 2014 to 2016, when spending increased by more than $200 million and raised concerns that the drugs that were billed to Part D were not always dispensed or medically necessary. Upon investigation, the OIG found that many of the parties charging Part D were located in a handful of cities, with thousands of prescriptions written by a single provider and filled by a limited number of pharmacies. This led HHS to conclude that the prescribers may not have had legitimate doctor-patient relationships with the beneficiaries.

Given these challenges, pharmacists will need to assume a leadership role in developing processes to ensure the quality, safety, and effectiveness of compounded topical formulations, including developing and providing education on compounded topical formulations for providers and consumers, and expanding the ASHP repository of evidence-based formulations. Public and private payers and healthcare providers will need to collaborate to create standardized and efficient methods for authorizing payment for medically necessary compounded topical formulations, and hospitals and health systems will need to develop policies and procedures to guide clinicians in making informed decisions regarding prescribing and use of compounded topical formulations.

2025
Postmarketing Studies
Source: Council on Therapeutics
To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest and to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA and other agencies to fulfill this expanded mission related to postmarketing surveillance and studies; further,

To advocate that such studies compare a particular approved drug product or licensed biologic product with (as appropriate) other approved drug products, licensed biologic products, medical devices, or procedures used to treat specific diseases; further,

To advocate expansion of studies of approved drug products or licensed biologic products to improve safety and therapeutic outcomes and promote cost-effective use; further,

To encourage impartial public-private partnerships or private-sector entities to also conduct such studies.
This policy supersedes ASHP policies 1004 and 0515.

Rationale
Pharmacists, other members of the healthcare team, patients, and private and public payers need objective, authoritative, and reliable evidence to make the best treatment decisions. Since the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Agency for Healthcare Research and Quality (AHRQ) has been tasked with studying the outcomes, comparative clinical effectiveness, and appropriateness of healthcare items and services. For such research to contribute to the practice of evidence-based patient care, good clinical decision-making, and rational drug use, AHRQ must evaluate devices, invasive procedures, and prescription and nonprescription medications, including both labeled and unlabeled uses of prescription drugs. Since prescription drugs represent a significant and growing portion of healthcare costs, the need for such research is increasingly important. Although impartial private sector entities can supplement the research efforts of government agencies such as AHRQ, only the federal government has the ability to support such independent research, provide oversight to safeguard the integrity of the research process, and disseminate the findings.

Furthermore, to ensure safety, the Food and Drug Administration (FDA) has several requirements for manufacturers and programs in place to monitor postmarket adverse events. These requirements and programs include the Division of Medication Error Prevention and Analysis, which is responsible for monitoring and preventing medication errors related to the naming, labeling, packaging, and design for CDER-regulated drugs and therapeutic biological products; the Risk Evaluation and Mitigation Strategy (REMS) program, which is designed to help reduce the occurrence and severity of certain serious risks; by informing and supporting the execution of the safe use conditions described in the medication's FDA-approved prescribing information; the Safe Use Initiative, a program that aims reduce preventable harm by identifying specific, preventable medication risks and developing, implementing, and evaluating cross-sector interventions with partners who are committed to safe medication use. Other programs include the FDA Adverse Event Reporting System (FAERS), which is a database that contains adverse event reports, medication error reports, and product quality complaints resulting in adverse events that were submitted to FDA, and MedWatch, the FDA Safety Information and Adverse Event Reporting Program, which permits voluntary reporting by consumers and healthcare professionals and mandatory reporting for regulated industry and user facilities. Additionally, the FDA requires that adverse drug events (ADEs) must be reported in accordance with the requirements of 21 CFR 310.305 and 314.80, which require three types of ADE reports: (1) 15-day reports of serious, unlabeled events; (2) 15-day narrative increased frequency reports of serious, labeled events; and (3) periodic reports.

2026
Gabapentin as a Controlled Substance
Source: Council on Therapeutics
To advocate that the Drug Enforcement Administration classify gabapentin as a Schedule V substance due to its potential for abuse and patient harm.
**Rationale**

Gabapentin is a structural analog of gamma-aminobutyric acid that is approved by the Food and Drug Administration (FDA) for post-herpetic neuralgia and as an adjunctive therapy for partial seizures. Gabapentin has been identified as an opportunistic drug of abuse which, when used in conjunction with other medications, particularly opioids, may result in serious adverse events such as respiratory depression and even death. Gabapentin is used due to its low cost, classification as a noncontrolled substance, and increasing rates of on- and off-label prescribing attributable to clinicians’ desire for an alternative to opioids for pain management. In the U.S., gabapentin is and remains a noncontrolled substance at the federal level despite evidence suggestive of diversion and abuse with opioids. Most recently, several states have made an effort to combat the diversion and abuse of gabapentin by examining various regulatory approaches, such as reclassification of gabapentin as controlled substance or mandating the reporting of the prescribing and/or dispensing of gabapentin to a state-level prescription drug monitoring programs (PDMPs). As recently as April 2019, the United Kingdom reclassified gabapentin as a Class C controlled substance, which required similar dispensing and monitoring as controlled substances in the U.S., due to the increase in abuse they have seen in this drug.

As defined by the Drug Enforcement Administration (DEA), Schedule V controlled substances “are defined as drugs with lower potential for abuse than Schedule IV” substances. Schedule IV substances “are defined as drugs with a low potential for abuse and low risk of dependence.” Recent data from multiple sources have shown a significant increase in gabapentin misuse, abuse, and diversion over the past 10 years, and one study found that 22% of a sample of 162 opioid-dependent patients had a prescription for gabapentin, of which 40% indicated they used more than prescribed to augment and enhance their opioid experiences.

The criteria used by DEA to determine whether to control or reschedule a drug include (a) the drug’s actual or relative potential for abuse; (b) scientific evidence of its pharmacological effect, if known; (c) the state of current scientific knowledge regarding the abuse of the drug or other substance; (d) its history or current pattern of abuse; (e) the scope, duration, and significance of abuse; (f) what, if any, risk there is to public health; (g) its psychic or physiological dependence liability; and (e) whether the substance is a precursor of a substance already controlled under the law. Based on an assessment using these criteria, gabapentin is similar to other controlled substances found in Schedule V and should therefore be assigned to Schedule V. Because some states have already taken steps to reschedule gabapentin as Schedule V or have added it to their PDMPs, the DEA should take steps to change the schedule status of gabapentin to ensure continuity of care and monitoring.

While it is difficult to predict the impact rescheduling may have on abuse, the current extent of abuse is likely exacerbated by easy access to and excessive supply of these therapies. However, the potential public health benefit of rescheduling must be weighed against concerns about restricting patients’ access to treatment and increasing administrative and other burdens on pharmacists and other clinicians. The proposed change to a more restrictive schedule would require stricter recordkeeping and security processes, which could in turn make providers reluctant to prescribe these therapies for patients who need pain management. In balancing these concerns, it should be noted that increased control of drugs with abuse potential is in the best interests of patients and public health. DEA and other stakeholders should monitor the
impact of this scheduling change on patient access and practice, as well as monitor the impact of other strategies that have been implemented to minimize the abuse and diversion of these therapies.

2027

Residency Training for Pharmacists Who Provide Direct Patient Care

Source: Council on Education and Workforce Development

To recognize that optimal direct patient care by a pharmacist requires the development of clinical judgment, which can be acquired only through experience and reflection on that experience; further,

Pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience; further,

To support the position that the completion of an ASHP-accredited postgraduate-year-one residency be required for all new college or school of pharmacy graduates who will be providing direct patient care.

This policy supersedes ASHP policies 0701 and 0005.

Rationale

Pharmacists who engage in direct patient care can improve patient outcomes and significantly decrease the overall costs of the healthcare system. Completion of a postgraduate pharmacy residency enables a pharmacist to maximize the provision of these direct patient care services. The use of well-trained pharmacy technicians and technological advances will minimize pharmacists’ dispensing roles. Based on the assumption that in the next 20-30 years most pharmacists will be providing direct patient care, it is incumbent upon the pharmacy profession to ensure that pharmacists are in a position to make the most effective interventions when selecting, modifying, and monitoring patients’ drug therapy regimens.

Pharmacy students who graduate meet the minimum competency requirements based on pharmacy licensing examinations; however, pharmacists who have completed a residency are better equipped to provide direct patient care due to advanced training based on repetitive practice, preceptor guidance, and the additional interdisciplinary training they receive. This direction is consistent with ASHP’s Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems.

Similar to the medical model in which medical school graduates complete a residency that allows for the standardization of physician training and the attainment of an appropriate level of competency, the profession of pharmacy would benefit from a similar standardization of training. The value of pharmacy residency programs has been demonstrated over time and has stimulated a significant increase in accredited residency programs as well as employer demand for residency-trained pharmacists. An increasing number of pharmacy graduates are completing one or two years of residency training after graduating in order to bolster their clinical skills and develop clinical judgement, which is acquired only through experience and reflection on that experience.
The number of PGY1 residencies continues to grow with the number of available residencies in the U.S. is now nearly 2600 programs. The growth in the number of pharmacy school graduates has begun to plateau while PGY1 residency positions has grown 11% in the last three years.

2028
Pharmacist’s Role in Health Insurance Benefit Design
Source: Council on Pharmacy Management
To advocate that pharmacy practice leaders collaborate with internal and external partners who design, negotiate, and select their own organization’s health plans and pharmacy benefit management contracts to preserve patient continuity of care and the integrity of the health-system pharmacy enterprise; further,

To provide education and resources for all partners on the health plan development process, analysis of pharmacy benefit design, contemporary formulary review processes, and application of medication safety principles on formulary decision-making.

Rationale
Pharmacy leadership should be directly involved in the selection of the health system’s pharmacy benefit manager (PBM) servicing their employee’s health plan, and the terms of that contract with that PBM. Employers typically look to balance value for the employee while attempting to control costs. As health systems evaluate and select plans, there may not always be due consideration given to the potential impacts on patient continuity of care and on that health system’s pharmacy enterprise and financial solvency in servicing employees’ prescriptions through the selected PBM. Aside from the safety and continuity of care implications to the patient if the health system’s pharmacy is excluded from the employees’ network, organizations may unknowingly undermine utilization of their outpatient cancer and infusion programs. Three PBMs control the majority of the PBM market, exerting heavy influence in costs, pharmacy participation, formulary, and prior authorization criteria. By including pharmacy leadership to help make a well-informed decision about selecting a servicing PBM for a health system, and the contract terms associated with that PBM (i.e., clinical and financial aspects), some of these unintended consequences could be avoided.

2029
Preserving Patient Access to Pharmacy Services by Medically Underserved Populations
Source: Council on Pharmacy Management
To advocate for funding and innovative payment models to preserve patient access to acute and ambulatory care pharmacy services by rural or medically underserved populations; further,

To support the use of telehealth to maintain pharmacy operations and pharmacist-led comprehensive medication management that extend patient care services to and enhance continuity of care for rural or medically underserved populations; further,
To advocate that the advanced communication technologies required for telehealth be available to rural or medically underserved populations; further,

To advocate for funding of loan forgiveness or incentive programs that recruit pharmacists and pharmacy technicians to practice in rural or medically underserved populations.

**Rationale**

Medically Underserved Areas (MUAs) and Medically Underserved Populations (MUPs) are areas or populations designated by the Health Resources and Services Administration as having too few primary care providers, high infant mortality, high poverty, or a high elderly population. Whereas MUAs are a geographic designation, MUPs have a shortage of primary care health services for a specific population subset within an established geographic area. MUPs may face economic, cultural, or linguistic barriers to healthcare; examples include low-income, Medicaid-eligible, homeless, migrant or seasonal worker, or Native American populations. Many federal programs use different types of shortage designations to determine eligibility. The Health Center Program and Physician J-1 Visa Waiver Program, for example, use both MUA and MUP, whereas the CMS Rural Health Clinic Program only uses MUA. Trends within the healthcare industry are also increasing the number of MUPs. Waning interest in primary care practice among medical graduates and the fiscal challenges of providing care in areas with declining populations or fewer insured patients contribute to this problem.

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

Today, many rural hospitals are facing a similar fate. Nationally, 430 rural hospitals are at high financial risk due to low reimbursement rates and decreasing local populations. These factors make it difficult for hospitals to cover fixed costs, let alone remain up to date with technological advances and emerging healthcare practices.

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

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

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

With the number of hospital deserts increasing, residents are forced to seek care elsewhere, if at all. In a 2018 Government Accountability Office report, elderly and low-income populations were more likely to be negatively impacted by rural hospital closures, and these populations were also found to be more likely to delay or forgo care after a hospital closure if the patient had to travel longer distances.

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

2030

** Interstate Pharmacist Licensure**

*Source: Council on Pharmacy Management*

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

**Rationale**

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

2031
Continuity of Care in Insurance Payer Networks
*Source: Council on Pharmacy Management*
To oppose provider access criteria that impose discriminatory requirements or qualifications on participation in insurance payer networks that interfere with patient continuity of care or patient site-of-care options.

*Rationale*
As hospitals and healthcare organizations have become more engaged in developing ambulatory care services, pharmacies (e.g., specialty, outpatient infusion) and pharmacists working in those settings increasingly find themselves excluded from healthcare payer networks. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to profitably operate), but when creating provider networks, payers should also consider the potential impacts on a patient’s care and choice. Patients generally choose pharmacies that are most convenient for them. When providers or pharmacies are locked out of a payer network, patients may face barriers (e.g., physical access) to therapy, which can delay or otherwise frustrate treatment. Pharmacies within health systems have an advantage when it comes to electronic health record (EHR) integration, proximity and relationship to providers, and in some cases onsite clinical pharmacy specialists. This clinically superior environment, coupled with health systems’ ability to measure and meet outcome-based metrics, allows them to easily show their performance against other pharmacies. Therefore, giving payer network access to integrated health-system pharmacies could improve care coordination and quality-based care, and reduce overall cost.

2032
Health-System Use of Medications Supplied to Hospitals by Patients, Caregivers, or Specialty Pharmacies
*Source: Council on Pharmacy Management*
To support care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further,

To encourage hospitals and health systems not to permit administration of medications supplied to the hospital or clinic by the patient, caregiver, or specialty pharmacy when storage conditions or the source cannot be verified, unless it is determined that the risk of not using such a medication exceeds the risk of using it; further,

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications.

*This policy supersedes ASHP policy 0806.*

*Rationale*
Medications supplied to a hospital or health system without an institution’s direct oversight raise questions about a product’s proper storage and pedigree. These include patient home
medications, including specialty pharmaceuticals (i.e., brown-bagging) brought in by the patient or caregiver, and specialty pharmaceuticals shipped directly from a specialty pharmacy directly to the location where they are being administered (i.e., white-bagging). The hospital or health system should have policies and procedures in place and make a reasonable attempt to verify the medication pedigree and product integrity to ensure safe and appropriate administration of medications. Health and pharmacy benefit management models should ensure fair reimbursement and payment for medication preparation and administration and in the provision of direct patient care services for medications supplied to patients from a supplier outside of a hospital or health system.

2033
Health-System Use of Administration Devices Supplied Directly to Patients
Source: Council on Pharmacy Management
To recommend that hospitals and health systems have a system in place for determining the risk versus benefit of permitting a patient to use his or her own medication administration devices; further,

To advocate that hospitals and health systems have policies and procedures, including the training of staff, on the use and management of medication administration devices and devices that augment medication administration (e.g., continuous glucose monitors); further,

To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team; further,

To advocate for adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices.

This policy supersedes ASHP policy 0806.

Rationale
The potential exists for serious patient safety and liability issues for healthcare staff when the use of patients’ own infusion devices is allowed. Devices unfamiliar to staff are particularly risky and may result in patient harm. There are, however, occasions when the benefits of using patients’ own devices may outweigh the risks. Organizational policies and procedures should exist for handling such situations, complemented by expedient methods to gain familiarity and competency demonstration with a device. A pharmacist should be available to verify the medication and the associated device and use a technique (e.g., Situation, Background, Assessment and Recommendation [SBAR], team huddle) for communicating critical information to the interprofessional care team.

2034
Staffing for Safe and Effective Patient Care
Source: Council on Pharmacy Management
To encourage pharmacy leaders to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care and employee engagement; further,

To encourage pharmacy leaders to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, telehealth practices, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings.

This policy supersedes ASHP policy 0201.

Rationale
The advancement of the pharmacy profession over the past decade has prepared and positioned pharmacists to care for complex patients and adapt to the dynamic and rapidly progressive field of medicine. Throughout the years, an increased involvement of pharmacists in specialty areas such as transplant, critical care, oncology, and pain and palliative care has been observed. Therefore, it is imperative that such advancement is considered when developing staffing models, in order to ensure the pharmacy workforce is appropriately allocated for the provision of consistent, safe, and high-quality patient care.

The complexity of patient care will continue to increase, and with that, so will the expected responsibilities, opportunities, and skills of the pharmacy workforce. Consequently, pharmacists engaged in direct patient care are encouraged to pursue and maintain their training and credentialing in order to continue to enhance their competency, skills, and participation in innovative practice. The expansion and dynamic nature of the pharmacy profession requires new approaches to explore flexible staffing models to avoid a stagnant practice, encourage continual advancement, and accommodate the evolving priorities of the pharmacy workforce.

The development and implementation of flexible staffing models can enable pharmacists to engage in further professional development and career advancement (e.g., training in areas of specialization, degree programs) and enjoy a more stable work-life integration experience. Recently, more attention has been drawn to burnout, resilience, and job satisfaction among the pharmacy workforce. Research has shown that pharmacists are reporting increased job stress over the previous years and that approximately 53% of pharmacists are reporting a high degree of burnout, which can consequently threaten patient safety. Therefore, there is an imperative to develop staffing models to meet staff members’ changing priorities and provide additional flexibility in the workplace. Implementation of flexible staffing models could improve performance and promote employee engagement in the workplace. Pharmacy leaders should be committed to maintaining high-quality and consistent patient care services and to also promote models that balance patient care with staff priorities.

Various options to consider when exploring flexible staffing models include telehealth practices, remote order review and verification (i.e., telecommuting), and productivity measures to ensure patient census is well distributed among pharmacists in charge of providing clinical services. Another concept related to flexible staffing models is leveraging pharmacy
technicians’ roles to support pharmacist engagement in direct patient care activities. Some institutions have explored data-driven, staffing-to-demand models based on real-time patient-volume metrics. The concept is to allocate staff to tasks based on the current workload, which is evaluated daily. Other institutions are also utilizing metrics such as number of doses dispensed at a certain point in time and volume of order verification throughout the day in order to divide patient care units evenly among pharmacists that perform order verification or provide clinical services. Flexible staffing models should support the following principles:

- Sufficient qualified staff must exist to ensure safe and effective patient care.
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care.
- Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services.
- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

Other healthcare disciplines (e.g., nursing) have historically utilized flexible staffing models to optimize services, reduce the risk of adverse events, and improve patient outcomes. The different models explored by nursing include patient ratio, patient acuity, collaborative staffing, and supplemental staffing model. There is limited literature on the use of flexible staffing models, but the concept is being explored by various health-system pharmacy departments.

2035
Role of the Pharmacy Workforce in Violence Prevention
Source: Council on Pharmacy Practice
To recognize that violence in the U.S. is a public health crisis; further,

To affirm that the pharmacy workforce has important roles in a comprehensive public health and medical approach to violence prevention, including leadership roles in their communities and workplaces; further,

To encourage members of the pharmacy workforce to seek out opportunities to engage in violence prevention efforts in their communities and workplaces; further,

To promote collaboration between the pharmacy workforce and community and healthcare organizations in violence prevention efforts; further,

To foster education, training, and the development of resources to prepare the pharmacy workforce for their roles in violence prevention; further,
To support research and dissemination of information on the effectiveness of pharmacy-focused violence-prevention strategies.

**Rationale**
The World Health Organization defines violence as “the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation.” The Centers for Disease Control and Prevention (CDC) reports that in the U.S. 7 people die a violent death each hour -- 47,000 from suicide and 19,500 from homicide annually -- and a 2015 report found more than 2.5 million violence-related injuries annually. The CDC estimates that violence costs the U.S. $9 billion annually in medical costs and lost work, and a separate estimate places the cost of violence as a whole to U.S. hospitals and health systems at $2.7 billion dollars in 2016. The staggering human loss and soaring costs have led numerous organizations of healthcare and public health professionals to label violence a public health crisis and take action to address violence as a public health problem. One prominent example is the American Hospital Association Hospitals Against Violence Initiative, which provides examples and best practices to address its three central topics: workforce and workplace violence, combating human trafficking, and preventing youth violence.

ASHP believes that members of the pharmacy workforce have “a responsibility to participate in global, national, state, regional, and institutional efforts to promote public health” and that the pharmacy workforce has important roles in primary, secondary, and tertiary interventions to prevent violence. The CDC National Center for Injury Prevention and Control, Division of Violence Prevention states that the different forms of violence they identify—child abuse and neglect, youth violence, intimate partner violence, sexual violence, elder abuse, and suicidal behavior—are strongly connected and share common risk and protective factors. Interventions the pharmacy workforce could be involved in include but are not limited to

- improving access to mental health services, including treatment for substance use disorder;
- screening to identify victims of or individuals at risk of violence;
- providing trauma informed care;
- providing lethal means counseling;
- supporting hotlines and community support systems for people in crisis;
- providing or promoting Stop-the-Bleed bystander training; and
- participating in or promoting community- or hospital-based violence prevention organizations.

To fill these important roles, members of the pharmacy workforce will need appropriate education, training, and resources. Although some education, training, and resources are appropriate for different healthcare providers, ASHP is committed to the development of resources to prepare the pharmacy workforce for pharmacy-specific roles in violence prevention and to supporting research and dissemination of information on the effectiveness pharmacy-focused violence-prevention strategies. In addition, institutional and community leaders need to be aware of the pharmacy workforce’s commitment to preventing violence. ASHP is committed to raising awareness with other stakeholders of the profession’s
commitment to collaborate to end the cycle of violence in their institutions and communities.

2036  
**Racial and Discriminatory Inequities**  
*Source: House of Delegates*  
To acknowledge that racism, discrimination, and inequities exist in healthcare and society; further,

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

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

**Rationale**  
ASHP and its members have long been committed to eliminating racial and ethnic disparities in healthcare and recognize the need to further strengthen that commitment following the recent killings of George Floyd, Ahmaud Arbery, and Breonna Taylor. ASHP has pledged to take actionable steps through the creation of a Board of Directors–appointed Task Force on Racial Diversity, Equity, and Inclusion. The Task Force is charged with taking inventory of ASHP’s efforts in the areas of racial diversity, equity, and inclusion as they relate to issues facing Black Americans, and for making related recommendations on new or enhanced efforts ASHP may undertake. ASHP further seeks to help eliminate racism, discrimination, and inequities that impact other minority and underrepresented populations and to help improve diversity, equity, and inclusion in healthcare and society.

2037  
**Support of the World Health Organization**  
*Source: House of Delegates*  
To strongly support the mission and work of the World Health Organization in its role in public health preparedness, prevention, and control to improve the health and well-being of people globally.

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

2038
ASHP Statement on the Use of Artificial Intelligence in Pharmacy
Source: Section of Pharmacy Informatics and Technology
To approve the ASHP Statement on the Use of Artificial Intelligence in Pharmacy.