House of Delegates

Policies Approved by the ASHP House of Delegates March-June 2023 (with rationales)

2301
Education and Training in Digital Health
Source: Council on Education and Workforce Development
To acknowledge that digital health is a growing modality that supports the pharmacy workforce in providing patient care; further,

To support training and education for the pharmacy workforce in innovative models that support digital health services; further,

To advocate for involvement of the pharmacy workforce in research on digital health services and outcomes.

Rationale
Continuous development of digital health technology is rapidly redefining the provision of healthcare. Digital health is a broad, multi-faceted term used to describe a wide category of practices, products, and processes. The U.S Food and Drug Administration has stated that "the broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine."

To ensure that pharmacists are involved in the care of patients using digital health technologies, training and education must be developed that supports the pharmacy workforce. The interoperability and integration of digital health technologies into electronic health records is crucial. Research supporting digital health technologies for improved patient outcomes, while maintaining security and improving interoperability with electronic health records, is needed to foster continued development of these technologies and applications.

2302

Digital Therapeutics Products

Source: Council on Pharmacy Management

To affirm the essential role of the pharmacist in the team-based evaluation, implementation, use, and ongoing assessment of digital therapeutic products to ensure the safety, effectiveness, and efficiency of medication use; further,

To encourage the pharmacy workforce to promote broader and more equitable use of digital therapeutic products by identifying and addressing barriers to patient and healthcare worker access to those products; further,

To encourage clinicians and researchers to establish evidence-based frameworks to guide use of digital therapeutic products; further,

To advocate that insurance coverage and reimbursement decisions regarding digital therapeutic products be made on the basis of those evidence-based frameworks.

Rationale

Digital health is a broad, multi-faceted term used to describe a broad category of practices, products, and processes. The Food and Drug Administration (FDA) describes digital health as "the broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine." The Digital Therapeutics Alliance describes digital therapeutics products, a component of digital health, as products that "deliver evidence-based therapeutic interventions that are driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes." Generally, digital therapeutic products are used to monitor indicators of a patient's condition (e.g., blood pressure, hemoglobin A1c) or encourage behaviors (e.g., adherence to medication or behavioral therapies) and share several similar features: a digital interface used by patients, clinicians, and sometimes medical devices; wearable devices that provide information about a patient's conditions to patients, clinicians, or medical devices; integration of disparate sources of data; enhanced patient engagement with their data and treatment; and automated or live digital coaching features to improve patient adherence with medication and/or behavioral therapies. The Access to Prescription Digital Therapeutics Act of 2022 would expand Medicare coverage to prescription digital therapeutics products and would help ensure that these products are tested for safety and efficacy and have a defined FDA approval process.

The proliferation of digital therapeutics products has the potential to create fundamental shifts in patient care. When digital therapeutics products impact medication use, pharmacists can and should participate in the evidence- and team-based decision-making about how those products are selected and used. Pharmacist expertise is essential in the team-based evaluation, implementation, use, and ongoing assessment of those products to ensure the safety, effectiveness, and efficiency of medication use. Pharmacists' medication-use expertise can assist in appropriate patient selection, product prescribing and ordering, and patient

education regarding product use.

Appropriate use of digital therapeutics products will require healthcare decision-makers (e.g., clinicians, researchers, pharmacy and therapeutics committees, and payers) to establish evidence-based frameworks to guide use of and coverage and reimbursement decisions regarding use. Although evidence used in the approval process for these products should inform these decisions, ongoing research will be required to assess the absolute and comparative safety and effectiveness of digital therapeutics products. In addition, to promote optimal use, members of the pharmacy workforce will require education and training in the evaluation and use of digital therapeutics products.

Finally, one of the major drivers of societal inequities is the digital divide that separates those with access to technology from those without. ASHP encourages the pharmacy workforce to promote broader and more equitable use of digital therapeutic products by identifying and addressing barriers to patient and healthcare worker access to those products.

2303

Interoperability of Patient-Care Technologies

Source: Council on Pharmacy Management

To encourage interdisciplinary development and implementation of standards that foster foundational, structural, semantic, and organizational interoperability of health information technology (HIT); further,

To encourage the integration, consolidation, and harmonization of medication-related databases used in patient-care technologies to reduce the risk that outdated, inaccurate, or conflicting data might be used and to minimize the resources required to maintain such databases; further,

To encourage healthcare organizations to adopt HIT that utilizes industry standards and can access, exchange, integrate, and cooperatively use data within and across organizational, regional, and national boundaries.

This policy supersedes ASHP policy 1302.

Rationale

The interoperability of patient-care technologies should be a standard across any hospital or health system. The development and implementation of standards would promote timely and seamless portability of information and optimize patient-care technologies that utilize medication-related databases. The installation of these technologies will aid pharmacy data, data analytics, and support activities that mitigate medication errors, medication diversion, and other health outcomes. This form of uniformity in information sharing will increase workflow efficiency and reduce delay in duties for pharmacy and other healthcare workers.

Although it is important to recognize the differences among technologies used in patient care, there is a need to have both a standardized format to describe medications as well as means for efficiently managing the medication databases in order to safely populate and update the different technologies that rely on drug information. Coalitions such as the

Pharmacy e-Health Information Technology Collaborative are important in providing expertise, organizing and participating in stakeholder events, and advocating for best practices. It may, however, be necessary for other organizations to convene stakeholders to develop standards for the harmonization of medication-related databases.

2304
Patient Medication Delivery Systems
Source: Council on Pharmacy Practice
To foster the clinical and technical expertise of the pharmacy workforce in the use of medication delivery systems; further,

To advocate for key decision-making roles for the pharmacy workforce in the selection, implementation, maintenance, and monitoring of medication delivery systems; further,

To urge hospitals and health systems to directly involve departments of pharmacy and interprofessional stakeholders in performing appropriate risk assessments before new medication delivery systems are implemented or existing systems are upgraded; further,

To advocate that medication delivery systems employ patient safety-enhancing capabilities and be interoperable with health information systems; further,

To encourage continuous innovation and improvement in medication delivery system technologies; further,

To foster development of tools and resources to assist the pharmacy workforce in designing and monitoring the use of medication delivery system.

Rationale
Technological advances in medication delivery systems and administration devices frequently enable improved control of medication administration. Smart infusion pumps are becoming the standard of care for delivering intravenous fluids and medications because they allow for a greater level of control, accuracy, and precision with drug delivery. They are designed to provide users with clinical decision support for programmed doses and infusion rates in order to identify errors before medications or fluids are infused. Smart pump technology and data systems can help improve safety practices by recording and offering reports regarding pump-related errors, alerts, compliance to the institution's drug library, and overrides. ASHP advocates that to enhance patient safety, medication delivery systems interface with information systems, allow interoperability with the electronic health record, and employ dose error reduction software, including but not limited to standardized medication drug libraries with dosing limits, clinical advisories, and other patient safety-enhancing capabilities.

The design, maintenance, monitoring, and continuous quality improvement of medication delivery systems is an interdisciplinary process that requires ongoing collaboration among many disciplines. The pharmacy workforce has an integral role in ensuring the safe and effective management of medication delivery systems, including advising the interprofessional

care team on their use. Pharmacists are a resource for education, therapy selection, monitoring, and troubleshooting of smart pump and other drug delivery systems to help improve patient safety and reduce medication errors. In efforts to optimize drug use, pharmacists should participate in organizational and clinical decisions with regard to these systems and devices.

2305
Education About Performance-Enhancing Substances
Source: Council on Pharmacy Practice
To encourage pharmacists to engage in and advise community outreach efforts informing the public on the risks associated with the use of performance-enhancing substances, including but not limited to medications; further,

To educate patients on the importance of disclosing the use of performance-enhancing substances that may or may not be prescribed for legitimate medical indications; further,

To encourage pharmacists to advise athletic authorities, athletes, the community, and healthcare providers on the dangers of performance-enhancing substances and other products that are prohibited in competition; further,

To advocate for the role of the pharmacist in all aspects of performance-enhancing substances control.

This policy supersedes ASHP policy 1305.

Rationale
The risks of using performance-enhancing substances (PES) are well documented in sports medicine journals and other biomedical literature. The U.S. Anti-Doping Agency (USADA) maintains a comprehensive list of performance-enhancing substances that are banned for U.S. athletes competing in the Olympics. In addition to anabolic steroids, the list includes hormones and hormone-like substances (e.g., insulin, tamoxifen); beta-2 agonists; diuretics; red blood cells (RBC) in any form and RBC enhancers; agents that alter genes or genetic expression; stimulants (including caffeine and nicotine); narcotics; cannabinoids; and glucocorticoids. Certain dietary supplements that are known to contain prohibited substances are also banned. The U.S. Food and Drug Administration has also identified dietary supplements that contain pathogens (e.g., Salmonella), contaminants (e.g., lead or mercury), or undeclared prescription drug ingredients (e.g., ephedrine, sildenafil, or dexamethasone).

Although such authorities as the National Collegiate Athletic Association and the USADA have implemented bans on use of these agents and drug testing policies to enforce them, these strategies have been only partially effective in curbing the use of PES. In addition, use of PES has spread beyond professional athletes to military personnel, recreational body builders, professional entertainers, and others wishing to lose weight, increase muscle mass, improve alertness, and increase stamina.

Pharmacists, as medication-use experts and the most-accessible healthcare provider in

many communities, can play an important role in community outreach efforts to provide education regarding the use of performance-enhancing substances, including medications, and the importance of disclosing any such use to their healthcare providers.

2306
Support for FDA Expanded Access (Compassionate Use) Program
Source: Council on Public Policy
To advocate that the Food and Drug Administration (FDA) Expanded Access (Compassionate Use) Program be the primary mechanism for patient access to drugs for which an investigational new drug application (IND) has been filed, in order to preserve the integrity of the drug approval process and assure patient safety; further,

To advocate for broader patient access to such drugs under the FDA Expanded Access Program; further,

To advocate that IND applicants expedite review and release of drugs for patients who qualify for the program; further,

To advocate that the drug therapy be recommended by a physician and reviewed and monitored by a pharmacist to assure safe patient care; further,

To advocate for the patient's right to be informed of the potential benefits and risks via an informed consent process, and the responsibility of an institutional review board to review and approve the informed consent and the drug therapy protocol; further,

To support the use of the Right-to-Try pathway in instances in which all other options have been exhausted, provided there is (1) a robust informed consent process, and (2) institutional and clinical oversight by a physician and a pharmacist.

This policy supersedes ASHP policy 1508.

Rationale
Patient access to drugs for which an investigational new drug application (IND) has been filed is made available on a limited basis to individual patients under a compassionate-use program regulated by the FDA. With information about clinical trials and drugs under development readily available to patients, there is an increased demand for access to these therapies. In addition, three states have passed laws to permit patients who have exhausted approved drugs and treatment to have access to these potentially lifesaving drugs. Other states may follow suit in the future, and the FDA has begun to respond to this growing patient demand by streamlining its application process for individual patient expanded access. In order to respond to state legislative proposals, ASHP advocates preserving the integrity of drug development through strengthening the evidence-based clinical trial process and expanded patient access.

In 2018, Congress passed Right-to-Try legislation, which, per FDA, “is one pathway for patients diagnosed with life-threatening diseases or conditions who have exhausted all

approved treatment options and are unable to participate in a clinical trial to access certain drugs that have not been approved by the Food and Drug Administration (FDA).” The program functions outside of FDA control, with patients and their physicians coordinating directly with manufacturers for access to investigational new drugs. ASHP advocates that the FDA’s Compassionate Use Program remain the primary access point for investigational new drugs, but supports the use of Right-to-Try for patients who have exhausted all other options. Furthermore, ASHP advocates for additional patient safety requirements related to informed consent and clinician monitoring for patients accessing investigational new drugs through the Right-to-Try pathway.

2307
Biosimilar Medications
Source: Council on Public Policy
To encourage the development of safe and effective biosimilar medications in order to make such medications more affordable and accessible; further,

To encourage research on the safety, effectiveness, and interchangeability of biosimilar medications; further,

To support legislation and regulation to allow Food and Drug Administration (FDA) approval of biosimilar medications that are also determined by the FDA to be interchangeable and therefore supports substitution for the reference product without the intervention of the prescriber; further,

To oppose the implementation of any state laws restricting biosimilar interchangeability; further,

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

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

To advocate for adequate reimbursement for biosimilar medications that are approved by the FDA; further,

To promote and develop education of pharmacists, providers, and patients about biosimilar medications and their appropriate use within hospitals and health systems; further,

To advocate for patient, prescriber, and pharmacist choice in selecting the most clinically appropriate and cost-effective therapy.

This policy supersedes ASHP policy 1816.

Rationale

A provision in the Patient Protection and Affordable Care Act created a new pathway for the FDA to approve biosimilar products. The FDA approved its first biosimilar application in March 2015 for filgrastim-sndz, and others (e.g., adalimumab-adbm, adalimumab-atto, bevacizumab-awwb, etanercept-szzs, infliximab-abda, infliximab-dyyb) have followed. The FDA defines a biosimilar drug as "a biologic that is highly similar to and has no clinically meaningful differences from another biologic that is already approved by the FDA (known as the reference product)." During the FDA approval process, a new biosimilar undergoes tests to assess structural and functional components as well as limited pre-clinical and clinical studies. In order for a biosimilar to be considered interchangeable with its reference product, the FDA requires the manufacturer to additionally show that their biosimilar produces the same clinical result and switching to their biosimilar does not result in any additional risks or diminished efficacy. This typically requires additional trials, which are time consuming and costly. As of 2022, there are over 30 biosimilars approved, not all of which are commercially available, but only a select few have qualified as interchangeable due to these extensive regulatory processes.

At the state level, legislation has been proposed and enacted requiring patient and/or prescriber notification that a biosimilar medication has been interchanged. It is important to note that pharmacists cannot substitute a biosimilar medication unless the FDA has deemed that biosimilar to be interchangeable. As of 2019, 46 states and Puerto Rico have passed biosimilar substitution laws. In some states the prescriber/patient notification is similar to what is required for generic substitution, but in others it goes further. For example, Georgia's biosimilar law requires the pharmacist to notify the prescriber within 48 hours of dispensing the medication (excluding weekends and holidays).

Despite the lack of interchangeable biosimilars, insurance companies have started requiring use of "preferred" biosimilars, leading to issues when attempting to maintain reasonable hospital formularies, patients being required to switch between biosimilar products for nonmedical reasons, and increased burden on the dispensing process when pharmacists have to contact the prescriber with every required biosimilar switch. Therefore, while health systems appear to acquire the biosimilars at lower costs, most are forced to maintain extensive formularies with all of the biosimilars in order to provide the payers preferred biosimilar for a patient. Additionally, this requirement extends into logistical burdens associated with storing, handling, and dispensing multiple similar products and increases the potential for medication errors. Due to lack of interchangeable biosimilars and payers requiring certain biosimilars to be used, a pharmacist is required to contact a prescriber each time a biosimilar needs to be changed. This interrupts workflows and prolongs the process of the patient receiving the drug. Inadvertently dispensing the wrong product to a patient may actually lead to higher cost to the patient if their payer will not cover the dispensed product. Initially identifying which product is covered for a patient, in addition to maintaining documentation about which product is needed for future dispenses, is a time-consuming task on an already strained healthcare system.

ASHP recognizes FDA's authority to determine biosimilar interchangeability, and in cases in which biosimilar products are deemed interchangeable, supports substitution for the reference product without the intervention of the prescriber. Further, ASHP opposes the implementation of any state laws regarding biosimilar interchangeability prior to finalization of FDA guidance and opposes any state legislation that would require a pharmacist to notify a

prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed. FDA's determination of interchangeability should be all that is needed in order to substitute the biosimilar with the reference product. Although FDA guidances are distinct from FDA regulations, they often have profound impacts on healthcare decisions and delivery, so ASHP encourages the FDA to include healthcare practitioners in their development.

ASHP recognizes that postmarketing surveillance and pharmacist evaluation as part of the formulary system before biosimilar use are required to guarantee safe use of biosimilar medications. ASHP also advocates for adequate reimbursement for biosimilars approved by the FDA. This includes opposing payer ability to dictate preferred biosimilars. ASHP encourages payers to work with health systems to align their preferred biosimilar products and for payers to cover multiple biosimilars in order to allow health systems to maintain cost-effective formularies.

2308
Pharmacogenomics
Source: Council on Therapeutics
To advocate that pharmacists take a leadership role in pharmacogenomics-related patient testing, based on current or anticipated medication therapy; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage health systems to support an interprofessional, evidenced-based effort to implement appropriate pharmacogenomics services and to identify and determine appropriate dissemination of actionable information to appropriate healthcare providers for review; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To advocate that all health insurance policies provide coverage for pharmacogenomic testing to optimize patient care; further,

To advocate that drug product manufacturers and researchers conduct and report outcomes of pharmacogenomic research to facilitate safe and effective use of medications; further,

To encourage research into the economic and clinical impact of preemptive pharmacogenomic testing; further,

To encourage pharmacy workforce education on the use of pharmacogenomics and its application to therapeutic decision-making.

This policy supersedes ASHP policy 2113.

Rationale

Clinical pharmacogenomics is the practice of using genetic information to guide optimal drug selection and drug dosing for patients to maximize therapeutic effects, improve outcomes, and minimize toxicity. Currently, pharmacogenomic testing is used for specific drug-gene pairs in patients currently taking a medication associated with gene or prior to initiating therapy. Pharmacists are especially prepared to take a leadership role in selecting appropriate tests as they have an understanding of pharmacokinetic and pharmacodynamics properties of drugs in specific diseases and patient populations.

Over the past 10 years, the Clinical Pharmacogenetics Implementation Consortium (CPIC) has published over 23 guidelines that cover 19 genes and 46 drugs across several therapeutic areas as well as resources to facilitate the implementation of pharmacogenomics into routine clinical practice and the electronic health record. These guidelines include indications for which drugs and genes are most likely to be clinically useful based on current evidence. However, barriers such as prioritizing testing, interpretation for actionable results, incorporation of genomic data into the electronic health record, and reimbursement remain. Furthermore, there is also the challenge of how to ensure that the results of pharmacogenomic tests stay with the patient throughout their health journey. Implementation of pharmacogenomic testing has the potential to improve patient care by decreasing failed treatment attempts due to medication ineffectiveness or adverse effects and by increasing effectiveness of improperly dosed medications.

The advent of widely available pharmacogenomic tests, many of which are also marketed to the public, introduces another layer of complexity. The Food and Drug Administration (FDA) has alerted patients and healthcare providers that claims for many genetic tests to predict a patient's response to specific medications have not been reviewed by the FDA and may not have the scientific or clinical evidence to support their use. Changing drug treatment based on the results from such a test could lead to inappropriate treatment decisions and potentially serious health consequences for the patient. It is imperative to identify clinically significant drug-gene pairs, as these may prevent adverse events, and such identification should be performed preemptively, as with DPYD genotyping prior to starting patients on fluoropyrimidines. There may also be a role for the FDA to provide incentives for manufacturers to conduct pharmacogenomic testing to optimize drug-gene patient paring.

Another barrier that many providers and patients encounter is insurance coverage of pharmacogenomic testing. A 2019 JAPhA article found that coverage and payments of pharmacogenomics varied by the company and gene-drug pairs and remain suboptimal. The article found that, of gene-drug indication group (GDIG), 50% were mentioned in policies but were covered less than 20% of the time. When mentioned in a policy, 7 GDIGs were uniformly covered, and 11 GDIGs were uniformly not covered. Overall, insurance companies covered approximately 40% of GDIGs mentioned in their policies. Additionally, preemptive pharmacogenomics suffers from a lack of economic and outcomes data supporting its more widespread adoption into practice. Such data would provide impetus for reimbursement from third-party payers. The number of genes tested in preemptive testing is typically greater than

for reactive testing, meaning the number of actionable pharmacotherapeutic interventions made will increase. To ensure a sustainable preemptive pharmacogenomic testing system, clinical decision support is crucial for the implementation of evidence-based treatment decisions because it will become less feasible for a clinician specializing in pharmacogenomics to provide a recommendation for each pharmacogenomically actionable medication.

Furthermore, the ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics states that pharmacogenomics has an essential place in pharmacy education because pharmacists should be educated to be able to recommend pharmacogenomic testing for drug and dosage selection; design patient-specific drug and dose regimens based on the patient's pharmacogenomic profile and other pertinent information; educate patients, pharmacists, and other healthcare professionals about pharmacogenomic principles and appropriate indications for clinical pharmacogenomic testing; and communicate pharmacogenomic-specific drug therapy recommendations to the healthcare team.

2309

Payer-Directed Drug Distribution Models

Source: Council on Pharmacy Management

To advocate that insurers and pharmacy benefit managers be prohibited from mandating drug distribution models that introduce patient safety and supply chain risks or limit patient choice.

Note: This policy supersedes ASHP policy 2248.

Rationale

Hospitals and health systems have a responsibility to confirm drug product integrity and pedigree to ensure safe and appropriate administration of drug products. Drug products supplied to a hospital or health system without an institution's direct oversight raise questions about the product's proper storage and pedigree. These drug products include patients' home drug products, including clinician-administered pharmaceuticals (i.e., brown bagging) brought in by the patient or caregiver, and clinician-administered pharmaceuticals shipped from an external pharmacy directly to the location where they are being administered (i.e., white bagging).

Due to patient safety and supply chain risks, hospitals and health systems should advocate for action from boards of pharmacy to directly address payer-mandated drug distribution models and encourage state policymakers to prohibit insurers and PBMs from mandating white and brown bagging, including prohibiting insurers and PBMs from steering patients away from hospitals and health systems that refuse to accept potentially dangerous white-bagged or brown-bagged drug products.

2310

Use of Social Determinants of Health Data in Pharmacy Practice

Source: Council on Pharmacy Management

To encourage the use of patient and community social determinants of health (SDoH) data in pharmacy practice to optimize patient care services, reduce healthcare disparities, and improve healthcare access and equity; further,

To educate the pharmacy workforce and learners about SDoH domains, including their impact on patient care delivery and health outcomes; further,

To encourage research to identify methods, use, and evaluation of SDoH data to positively influence key quality measures and patient outcomes.

Note: This policy supersedes ASHP policy 2249.

Rationale

Social determinants of health (SDoH) are defined by the Centers for Disease Control and Prevention (CDC) as the "conditions in the environments where people are born, live, learn, work, play, worship and age." These conditions can have a significant impact on healthcare outcomes, health equity, and the quality of life for individuals and communities. SDoH have been found to account for 80-90% of modifiable contributors to health outcomes. From a third-party payer perspective, the recent shift of many organizations from fee-for-service to value-based reimbursement models places more emphasis on SDoH, screening, and evidence-based decision-making to prioritize long-term health outcomes. Healthy People 2030, a national program developed by the Office of Disease Prevention and Health Promotion within the U.S. Department of Health and Human Services, includes 355 measurable, data-driven, national objectives to improve the health and well-being of the American public by the year 2030. Health People 2030 recognizes five distinct SDoH domains: Economic Stability, Education Access and Quality, Healthcare Access and Quality, Neighborhood and Built Environment, and Social and Community Context. Patient screenings and data collection from multiple data sources to ascertain SDoH would be optimized through the use of standardized codes (e.g., ICD-10-CM Z codes, SNOMED-CT value sets) that are consistent, discrete data elements that are reportable and can be shared with other technologies, leading to actionable intelligence to enhance quality improvement initiatives. To support this goal, there is a need for broader implementation of SDoH health information technology (IT) tools into general practice and development of policies for how to appropriately use SDoH in clinical decision-making. The Office of the National Coordinator for Health Information Technology has identified four priority areas for advancing interoperability and use of SDoH data: standards and data, infrastructure, policy, and implementation. Many health IT and electronic health record (EHR) vendors have invested significant resources in development of SDoH tools and products. Among these products are screening tools, population health metrics, referral and care transition tools, and analytic and reporting tools. Health systems must have access to appropriate technology-based platforms to exchange SDoH data and make referrals for patients at discharge or transfer to another institution. Lack of standardization of data and reporting across health systems makes sharing of best practices and metric goal-setting difficult.

Efforts to address SDoH through pharmacy practice have varied. A 2018 survey of postgraduate pharmacy residents and their program directors found that only 1% of residents and 4% of residency program directors stated they had received education and training on Healthy People 2020. (Chandra RN. Pharmacists' knowledge of social determinants of health in post-graduate pharmacy residency programs. Wright State University; Dayton, OH; 2018.) The

pharmacy workforce has opportunities to advance the use of SDoH in pharmacy practice (e.g., consults, medication reconciliation, patient assistance programs) to improve health outcomes. Tools available within some EHR platforms include those measuring quality of life, suicidal ideation rating, community service referral capabilities, and use of secondary survey data in conjunction with the CDC/ATSDR social vulnerability index to further evaluate population health at a community level. SDoH tools can be categorized as either single domain, such as the Hunger Vital Sign tool to evaluate food insecurity, or multiple domain, such as the WE CARE survey to evaluate education, employment/income, food insecurity, and housing/utility domains. The validity of each tool should be considered before implementing into practice, and more research is needed to determine the utility of specific tools in pharmacy practice. The Pharmacy Quality Alliance (PQA) has developed a Medication Access Framework for Quality Measurement and is evaluating a pharmacy measure concept to address the social determinants of health that hinder patient medication access and contribute to poor health outcomes.

2311

Pharmacy Accreditations, Certifications, and Licenses

Source: Council on Pharmacy Management

To advocate that healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidence-based principles of patient safety and quality of care; further,

To advocate that health-system administrators allocate the resources required to support medication-use compliance and regulatory demands.

Note: This policy supersedes ASHP policy 1810.

Rationale

Pharmacy leaders have years of experience managing the demands and challenges of ensuring that pharmacy services meet the standards of accreditation organizations. In the past, this responsibility was predominantly achieved through accreditation by The Joint Commission (TJC) and compliance with state laws and Board of Pharmacy regulations, as well as with federal requirements (e.g., those of the Drug Enforcement Administration). The number of accreditation standards pharmacy leaders needed to be knowledgeable about was limited. Healthcare organizations with ambulatory care services (e.g., home infusion, specialty pharmacy) have had to manage the additional accreditation process for these business units. Recent changes in healthcare have increased this challenge for pharmacy leaders: (1) TJC is no longer the only accreditor for hospitals and health systems; (2) healthcare organizations are developing or acquiring new business units that have their own accreditation processes that need to be integrated into existing ones; and (3) new accreditation, certification, or licensure processes have been created for services and businesses that fall under the responsibility of pharmacy leaders.

The expansion of healthcare organizations and the growth of the pharmacy enterprise are creating a new environment with multiple accreditors and regulators, presenting pharmacy

leaders with the growing challenge of compliance with overlapping accreditation, certification, and regulatory standards. Examples include the Michigan Board of Pharmacy requirement to obtain certification to conduct compounding and the California Board of Pharmacy requirement that each IV hood have its own pharmacy license. In addition, community pharmacy accreditation processes and standards are being implemented that pharmacy leaders need to consider as well.

ASHP recognizes the difference between certifications that are the sole responsibility of and have a direct impact on a pharmacy and certifications of a healthcare organization's service line (e.g., stroke or transplant services) that are the responsibility of the organization but have medication management components that need to be addressed by the pharmacy. Pharmacists and pharmacy departments are being challenged by a growing number of required accreditations, certifications, and licensures, which result in increased need for pharmacist-in-charge designations, workforce fatigue, and direct and indirect costs. Health-system administrators need to recognize this changing environment and allocate the resources required to support medication-use compliance and regulatory demands.

2312
ASHP Statement on Leadership as a Professional Obligation
Source: Council on Pharmacy Management
To approve the ASHP Statement on Leadership as a Professional Obligation.

Note: This statement supersedes the ASHP Statement on Leadership as a Professional Obligation dated June 12, 2011.

2313
Reducing Healthcare Sector Carbon Emissions to Promote Public Health
Source: Council on Pharmacy Practice
To promote reducing carbon emissions from the healthcare sector through collaboration with other stakeholders; further,

To encourage members of the pharmacy workforce to seek out opportunities to engage in efforts to reduce carbon emissions in their workplaces and communities.

Rationale
ASHP acknowledges the scientific consensus on the adverse impact of carbon emissions on human health and the environment and recognizes the need to reduce carbon emissions, including from the healthcare sector. Climate change negatively impacts human health and increases strain on the healthcare system. Health-related consequences of climate change that lead to increased morbidity and mortality include but are not limited to heat-related illnesses, respiratory illnesses, and vector-borne diseases. The 2015 Lancet Commission on Health and Climate Change concluded that addressing climate change is the greatest public health opportunity of the 21st century and that failure to adequately address climate change could undo most of the past century's progress in global health.

Carbon emissions are a target for addressing climate change. It has been estimated that

the healthcare sector is responsible for 8.5% of carbon emissions in the U.S. Sources of healthcare carbon emissions rank as follows: healthcare facility operations (estimated to account for 7% of healthcare sector emissions); purchased sources of energy, heating, and cooling (11%); and healthcare sector procurements or supply chain for services and goods (>80%).

Healthcare organizations have been called upon to reduce their carbon footprint ("decarbonize") as a measure to promote patient and public health. The federal government has goals to decrease carbon emissions by 50% by 2030 and to achieve net-zero levels by 2050. Many healthcare-related organizations have made climate change and decarbonization pledges, including the members of the Medical Society Consortium on Climate & Health and organizations engaged in the National Academy of Medicine (NAM) Action Collaborative on Climate Change and as. In the fall of 2021, NAM launched the Action Collaborative on Decarbonizing the U.S. Health Sector (the "Climate Collaborative"), mobilizing four work groups: healthcare supply chain and infrastructure; healthcare delivery; health professional education and communication; and policy, financing, and metrics.

The pharmacy workforce has an important role in reducing carbon emissions from healthcare-related sources (Beechinor RJ et al. Climate change is here: what will the profession of pharmacy do about it? *Am J Health-Syst Pharm.* 2022; 79:1393-6). ASHP encourages collaboration with stakeholders that share a commitment to reducing carbon emissions from the healthcare sector and encourages members of the pharmacy workforce to seek out opportunities to engage in efforts to reduce carbon emissions in their workplaces and communities. To fill their roles in reducing carbon emissions, the pharmacy workforce will require education, training, and resources on emissions-reduction strategies. The development of evidence-based strategies will require research and dissemination of information on ways to reduce carbon emissions.

2314

Manipulation of Drug Products for Alternate Routes of Administration

Source: Council on Therapeutics

To advocate that the Food and Drug Administration encourage drug product manufacturers to identify changes in pharmacokinetic and pharmacodynamic properties of drug products when manipulated for administration through an alternate delivery system or different route than originally studied, and to make this information available to healthcare providers; further,

To collaborate with stakeholders to increase research on clinically relevant changes to pharmacokinetic and pharmacodynamic properties of drug products when manipulated or administered through a different route and to enhance the aggregation and publication of and access to this data; further,

To research and promote best practices for manipulation and administration of drug products through alternate routes when necessary; further,

To foster pharmacist-led development of policies, procedures, and educational resources on the safety and efficacy of manipulating drug products for administration through alternate routes.

Rationale

Manipulation of a drug product can include crushing, splitting, or suspending it in a solvent, which can alter the pharmaceutical properties of the original dosage form. These manipulations are often performed because a patient requires the medication administered enterally but is unable to take the medication by mouth, requires a dose that is not readily available and so can only be delivered through manipulation, or is unable to swallow or has a feeding tube placed necessitating manipulation. For patients who lose the ability to swallow easily (e.g., due to stroke or cancer), it is sometimes quite difficult to provide all their drug products via liquid formulations or those that can be crushed, due to lack of such products.

Complicating the clinical picture is that in many studies of oral drug products the dose passes through the stomach, exposing it to a specific set of pH conditions. The stomach may be bypassed when drug products are administered via feeding tube to organ systems in the body that may have a different pH, affecting the adsorption, metabolism, or distribution of the drug. Some drug products cannot be administered because they are insoluble in aqueous solutions. In addition, the physical properties of the manipulated formulation may also cause obstruction and clogging of enteral tubes used for feeding and medication administration, leading to undesirable outcomes, including supra- or subtherapeutic concentrations in the body, which could lead for example to organ rejection in transplant patients, loss of viral suppression in HIV-positive patients, or toxicities when manipulating an extended-release tablet. There are also exposure risks to caregivers preparing or administering manipulated drug products that are carcinogenic or teratogenic.

Additionally, there are too few resources that provide guidance on how manipulation may affect the bioavailability of the drug product or whether the manipulated drug product remains bioequivalent with the original dosage form. There is even less research or publicly available information on the clinical effects of manipulated drug products. ASHP encourages manufacturers and independent clinical and practice-based researchers to conduct studies on these subjects and to disseminate this information via journal articles and other easily accessible resources. ASHP also encourages education of the pharmacy workforce and other healthcare providers regarding the basic principles of and drug dosing for manipulated drug products.

2315

Responsible Medication-Related Clinical Testing and Monitoring

Source: Council on Therapeutics

To recognize that overuse of clinical testing leads to unnecessary costs, waste, and patient harm; further,

To encourage the development of standardized measures of appropriate clinical testing to better allow for appropriate comparisons for benchmarking purposes and use in research; further,

To promote pharmacist accountability and engagement in interprofessional efforts to promote judicious use of clinical testing and monitoring, including multi-faceted, organization-level approaches and educational efforts; further,

To promote research that evaluates pharmacists' contributions and identifies opportunities for the appropriate ordering of medication-related procedures and tests; further,

To promote the use of interoperable health information technology services and health information exchanges to decrease unnecessary testing.

Note: This policy supersedes ASHP policy 1823.

Rationale

As the prevalence of collaborative practice grows and as pharmacist care expands into direct patient care services, so too do the responsibilities held by these practitioners. In many institutions, pharmacists' responsibilities now include ordering blood draws as a part of initiating a medication regimen, assessing drug levels, monitoring for adverse effects, or ordering imaging such as ultrasound for evaluating a deep vein thrombosis or an electrocardiogram to evaluate a QTc interval.

Overuse of medical care is a long-recognized problem in clinical medicine, and more spending and treatment do not translate into better patient outcomes and health. The number of articles on overuse nearly doubled from 2014 to 2015, indicating that awareness of overuse is increasing, despite little evidence of improved practice, which may mean that the overuse of diagnostic tests and lab monitoring is leading to patient harm and could outweigh benefits. Healthcare continues to be enthralled by high-technology innovation, including both therapies and tests. Once practice norms are established, clinicians are slow to de-implement services, even those that are found to be potentially dangerous. Reasons for excessive ordering of tests by healthcare providers include defensive behavior, fear, uncertainty, lack of experience, the use of protocols and guidelines, routine clinical practice, inadequate educational feedback, and clinician's lack of awareness about the cost of examinations. Inappropriate testing causes unnecessary patient discomfort, may lead to iatrogenic anemia from over-testing, entails the risk of generating false-positive results and unnecessary treatment, leads to overloading of diagnostic services, wastes valuable healthcare resources, and is associated with other inefficiencies in healthcare delivery, thus undermining the quality of health services. Furthermore, ordering unnecessary tests may also disproportionately affect vulnerable populations, including pediatric patients; trigger unnecessary therapies, such as for asymptomatic bacteriuria; and introduce bias, such as when screening for illicit drugs is performed but not as part of a differential diagnosis. A multi-faceted approach is recommended to reduce waste and support the judicious use of clinical testing. Key strategies include use of interoperable health information technology services and health information exchanges; optimization of test ordering through use of clinical decision support systems; provider and pharmacist education; benchmarking; and organization-level guidance, such as through establishment of a laboratory formulary

committee that includes formulary control. Additionally, a key limitation of current literature surrounding appropriateness of clinical testing is a lack of standardized definitions of "appropriateness." Guideline and professional organization-endorsed standards may be used to benchmark clinical testing, although variations by country or institutional practices may confound these definitions.

Choosing Wisely is a national program designed to help raise provider and public awareness and garner support for appropriate test utilization, with the goal of promoting conversations between providers and patients about choosing appropriate care in order to reduce both harm and waste. In 2016, ASHP announced its partnership with the ABIM Foundation on the Choosing Wisely campaign, and in 2017 became the first pharmacy organization to contribute recommendations to the campaign. ASHP has continued to support this partnership through regular review and updates of its recommendations.

2316
ASHP Statement on Precepting as a Professional Obligation
Source: Section of Pharmacy Educators
To approve the ASHP Statement on Precepting as a Professional Obligation.

2317
Emergency Medical Kits
Source: Council on Pharmacy Practice
To recognize the importance of standardized and readily accessible emergency medical kits (EMKs) in locations with inconsistent emergency medical services; further,

To advocate for the inclusion of pharmacist expertise in policy and regulations for the interprofessional decisions related to the contents, storage, and maintenance of medications in EMKs; further,

To collaborate with other professions and stakeholders to standardize the contents of and locations for EMKs, and to develop guidelines and standardized training for proper use of EMK contents by designated personnel employed in those settings.

Rationale
A social media movement called attention to the lack of standardization in emergency medical kits (EMKs) during an in-flight medical emergency. U.S. CFR 121.803 – Emergency Medical Equipment – requires certain medications and supplies for flights in case of medical emergencies but does not require the stocking of naloxone for reversing opioid overdoses or epinephrine auto-injectors for ease of administration, among many other medications and supplies. Many locations with inconsistent access to emergency medical services, such as airplanes, contain a stock of emergency supplies and medications that are not standardized and may not be adequate to manage some emergencies. In 2019, the Aerospace Medical Association Air Transport Medicine Committee sent recommendations to the Federal Aviation Administration regarding the contents of emergency medical kits, including recommendations to add naloxone and an epinephrine auto-injector (EpiPen).

The World Health Organization (WHO) has developed standardized health kits of medicines and medical supplies to meet different health needs in humanitarian emergencies and disasters. These kits are developed to provide reliable and affordable medicines and supplies quickly to those in need. The kits are used by United Nations agencies, nongovernmental organizations, and national governments. The contents of these kits are based primarily on the WHO's Essential Medicines list and guidelines on treatment of specific medical conditions. The contents of the kits are frequently reviewed and updated to adapt to changing needs based on experience in emergency situations. However, the WHO List of Essential Medicines does not specify an auto-injector for use in anaphylaxis.

There is growing concern regarding the need to standardize requirements set by a governing body to ensure that EMKs contain appropriate medications and supplies that are easy to use in an emergency, have been audited to ensure they contain the required items, have been stored appropriately, and do not contain expired products. Standardization of EMK contents would simplify training requirements for those using the kits, which should include what products are contained within the EMKs, how to use them (when appropriate), and when to provide the kits in the case of an emergency. Finally, it is critical to collect and track incident and outcomes data to promote improvement in emergency response, and pharmacist involvement in the interprofessional evaluation of that data is essential.

2318

Raising Awareness of the Risks Associated with the Misuse of Medications

Source: Council on Pharmacy Practice

To support the pharmacy workforce in outreach efforts to provide education to authorities, patients, and the community on the risks associated with use of medications for nonmedical purposes or from nonmedical sources.

Rationale

Misuse of medications involves the use of prescription and over-the-counter medications in ways that are not prescribed or directed. The use of medications for nonmedical purposes is also a category of misuse. Misuse may lead to serious consequences, such as emergency department visits, hospitalization, and death. While most of the evidence regarding medication misuse is related to opioids, central nervous system depressants, and stimulants, misuse of any medication may result in patient harm. As such, efforts to raise awareness of the risks of misusing any medication needs to prioritized, in addition to specific medications and medication classes. Pharmacists, as medication experts, can identify red flags and patterns of medication misuse and support community outreach efforts to help patients understand the risks associated with the misuse of medications.

2319

Standardization of Medication Concentrations, Dosing Units, Labeled Units, and Package Sizes

Source: Council on Pharmacy Practice

To support adoption of nationally standardized medication concentrations, dosing units, labeled units, and package sizes for medications administered to adult and pediatric patients,

and to advocate that the number of standard concentrations, dosing units, labeled units, and package sizes be limited as much as possible; further,

To encourage interprofessional collaboration on the adoption and implementation of these standards across the continuum of care; further,

To encourage manufacturers and registered outsourcing facilities to provide medications in those standardized concentrations, labeled units, and package sizes.

Note: This policy supersedes ASHP policy 1306.

Rationale

Standardization and simplification are widely accepted methods for reducing variability in processes and risk for error. With increased adoption of intelligent infusion devices, use of standard concentrations has enhanced infusion safety by eliminating most dosing and rate calculations. Standardizing concentrations reduces the potential for errors, particularly during transitions of care; simplifies ordering by providing fewer choices, which decreases provider uncertainty; reduces operational variations, which enhances provider efficiency; and streamlines manufacturing, which accelerates production and allows for the formulation of premixed medications. In addition, broader use of standard concentrations might stimulate industry to offer a broader array of ready-to-administer infusions and facilitate the development of drug libraries.

To improve patient safety and availability of products, units of measure used for ordering, labeling, and administration of medications need to be standardized as well, as do package sizes for liquid formulations. All liquid formulations, including intravenous, oral, and topical formulations, need to be included in the standardization process, and standards specific to pediatric and adult populations are needed and should be limited in number to the extent possible. Development of these standards requires a holistic view of the medication-use process that considers all these aspects, as they all intersect and impact patient safety and the interoperability of automated systems.

In 2015, ASHP launched the Standardize 4 Safety (S4S) initiative. Funded by the U.S. Food and Drug Administration (FDA) and helmed by ASHP, S4S is the first national, interprofessional effort to standardize medication concentrations to reduce errors resulting from confusion over nonstandardized drug concentrations and errors that result from concentration differences when patients transition their care from one setting to another. To date, the expert committees have developed four lists—standardized concentrations for adult continuous infusions, pediatric continuous infusions, compounded oral liquids, and PCA/epidural infusion—and the S4S Initiative offers the pharmacy workforce other resources to help implement standardized concentrations.

2320

Pharmacoequity

Source: Council on Pharmacy Practice

To raise awareness that disparities in clinical practice negatively impact healthcare outcomes and compromise pharmacoequity; further,

To recognize the impact of social determinants of health on pharmacoequity and patient outcomes; further,

To advocate for drug availability, drug pricing structures, pricing transparency, and insurance coverage determinations that promote pharmacoequity; further,

To advocate that the pharmacy workforce identify and address risks and vulnerabilities to pharmacoequity as part of comprehensive medication management services; further,

To advocate for resources, including technology, that improve access to care for marginalized and underserved populations where pharmacy access is limited; further,

To encourage the pharmacy workforce to identify and mitigate biases in healthcare decision-making that compromise pharmacoequity.

Rationale

Pharmacoequity aims to ensure that all individuals regardless of race and ethnicity, socioeconomic status, or availability of resources, have access to the highest quality medications required to manage their health needs. Barriers contributing to the lack of pharmacoequity include decreased access to care, increased costs of care, and differences in care based on provider bias (Essien UR, Dusetzina SB, Gellad WF. A policy prescription for reducing health disparities—achieving Pharmacoequity. *JAMA*. 2021;326(18):1793. doi:10.1001/jama.2021.17764). These barriers have helped raise awareness of the ABCs of solutions for promoting pharmacoequity: access, bias, and costs.

Decreased access to care may be due to insufficient prescription drug coverage or residing in a pharmacy desert. The current trends in the price of prescription drugs, combined with lack of insurance or underinsurance, results in lower use of prescribed medications and nonadherence. Pharmacists can help build culturally competent structures to reduce racial and ethnic disparities in healthcare through various means, including promoting a more diverse work force, increasing awareness of disparities, promoting culturally competent care and services, researching and implementing best practices for providing culturally competent care, and ensuring effective communication with patients and among providers (ASHP Statement on Racial and Ethnic Disparities in Health Care, *Am J Health-Syst Pharm.* 2008; 65:728–33, doi.org/10.2146/ajhp070398).

Ensuring that all individuals regardless of race and ethnicity, socioeconomic status, or availability of resources have access to the highest quality medications required to meet their needs will require a multifaceted approach. Promotion of culturally competent structures through increased awareness of disparities and diversification of the workforce, in addition to improving medication affordability and pharmacy access, are all steps needed to attain pharmacoequity.

2321
Medication Administration by the Pharmacy Workforce
Source: Council on Pharmacy Practice
To support the position that the administration of medications is within the scope of pharmacy practice; further,

To advocate that states grant pharmacists and appropriately supervised student pharmacists and pharmacy technicians the authority to administer medications; further,

To support the position that pharmacists should be participants in establishing procedures in their own work settings with respect to the administration of medications (by anyone) and monitoring the safety and outcomes of medication administration.

Note: This policy supersedes ASHP policy 9820.

Rationale
Laws, regulations, and local policies on medication administration vary greatly. Medications are routinely administered by many different practitioners, including nurses, physicians, radiology and nuclear medicine technologists, nurses aides, laboratory technologists, dental hygienists, respiratory therapists, and physical therapists. ASHP believes that administration of medications is within the scope of pharmacy practice and supports laws, regulations, and local policies that allow for it and for medication administration by appropriately trained and supervised student pharmacists and pharmacy technicians. Decisions about pharmacists' involvement in medication administration should be made by individual healthcare organizations, which have an awareness of their resources and the adequacy of their medication administration processes. Patient need should be the primary factor in deciding who administers medications in any institution, and pharmacists should be involved in the institution's decision-making process regarding procedures used to administer medications.

2322
Availability and Use of Fentanyl Test Strips
Source: Council on Therapeutics
To affirm that fentanyl test strips (FTS) have a place in harm reduction strategies for people who use drugs; further,

To support legislation that declassifies FTS as drug paraphernalia; further,

To promote public availability of and access to FTS, including zero-cost options; further,

To support the pharmacy workforce in their roles as essential members of the healthcare team in educating the public and healthcare providers about the role of FTS in public health efforts.

Rationale
In April 2021 the National Center for Health Statistics reported that in the past 12-month period

there were over 100,000 drug overdose deaths in the United States, with fentanyl responsible for over two thirds of those deaths. Fentanyl, a synthetic opioid, is 50 to 100 times more potent than morphine, and therefore the risk of overdose is higher than with other opioids, particularly when the person consuming the fentanyl is not aware of its presence or has not developed a tolerance to it.

Studies have shown that fentanyl test strips (FTS) are used by people who use drugs (PWUD) to check their drugs for the presence of fentanyl and mitigate overdose risk by making informed decisions about their safety when consuming. The findings of a 2018 study suggest that the distribution and use of rapid fentanyl test strips are a feasible and PWUD-accepted harm reduction tool to detect the presence of fentanyl in illicit drugs. As a result, as part of the effort to reduce overdoses and promote harm reduction, state and county health departments and community organizations across the United States have started to distribute FTS as a low-barrier, inexpensive drug-checking strategy. Through the SUPPORT Act, the Centers for Disease Control and Prevention, the U.S. Department of Health and Human Services, and the Substance Abuse and Mental Health Services Administration are permitted to provide funding to be used to purchase FTS as a part of harm reduction efforts.

Currently, a little more than half the states in the U.S. have laws that declassify FTS as drug paraphernalia. Laws in the remaining states that designate FTS as drug paraphernalia may prevent states and organizations from applying for those grants or using their own funds to purchase FTS. Although many states have legislation in the works to remove this barrier, some states are reluctant to make this change, due to the perception that the use of FTS as quality control devices could encourage PWUD to seek out a stronger high rather than reduce the use of fentanyl, reinforcing risky behavior.

The pharmacy workforce is well equipped meet the needs of PWUD and the use of FTS. For example, in June of 2022, the Illinois General Assembly passed H.B. 4556, which expands the ability of pharmacists and other healthcare professionals to distribute FTS. The Ohio State University School of Pharmacy offers a naloxone and FTS training and distribution event as an effort to reduce harm, to meet patients where they are, and to provide services along a continuum of care. Legislation and programs like these demonstrate the value of the pharmacy workforce and should be expanded throughout the United States.

2323

DEA Scheduling of Controlled Substances

Source: Council on Therapeutics

To advocate that the Drug Enforcement Administration (DEA) establish clear, measurable criteria and a transparent process for scheduling determinations; further,

To urge the DEA to use such a process to re-evaluate existing schedules for all substances regulated under the Controlled Substances Act to ensure consistency and incorporate current science-based evidence concerning scheduling criteria; further,

To advocate that the U.S. Congress, with input from stakeholders, enact clear definitions of the terms *potential for abuse*, *currently accepted medical use*, and *accepted safety for use* in the Controlled Substances Act; further,

To advocate for monitoring of the impact of DEA scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) on patient access to therapy and on healthcare provider workload; further,

To advocate for the elimination of federal and state laws that create barriers to research on therapeutic use of Schedule I substances.

Note: This policy supersedes ASHP policy 1315.

Rationale

Since its passage in 1970, the Controlled Substances Act (CSA) has served as the foundation of modern drug control policy by regulating the manufacture, importation, possession, use, and distribution of certain substances. The CSA lists eight factors to be considered by the Drug Enforcement Administration (DEA) when deciding if a molecular entity should be scheduled: (1) the potential for abuse; (2) scientific evidence of its pharmacological effect; (3) state of current scientific knowledge regarding the substance; (4) history and current pattern of abuse; (5) scope, duration, and significance of abuse; (6) risk to public health; (7) its psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled. The CSA then specifies that the three criteria used to determine the schedule of a substance include (1) its potential for abuse, (2) whether it has a medical use, and (3) its safety and risk of dependence. Several limitations of the aforementioned factors and criteria are worth noting. First, the eight factors are redundant and lack clarity. Second, the CSA does not specify the relationship between the eight factors and the three criteria for scheduling, and the DEA has not yet clarified this matter.

Additionally, the CSA does not explicitly define the terms *potential for abuse* or *accepted medical use,* giving the DEA much discretion to apply the scheduling criteria. The DEA has maintained broad discretion when scheduling substances according to their abuse potential, through court rulings that have upheld the DEA's comparison of the substance in question to already-scheduled substances. The DEA has formally defined the term *currently accepted medical use* in response to repeated litigation regarding the classification of Schedule I substances. The criteria under this definition include: (1) the drug's chemistry must be known and reproducible; (2) adequate safety studies; (3) adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.

The lack of regulatory clarity of the CSA has led to a complicated process and inconsistent scheduling of substances. The language of the CSA implies that for a substance to be placed into a particular schedule, it must fulfill all three criteria. It is entirely possible, however, for one substance to fail to meet all three criteria of one schedule. Nonetheless, the DEA maintains that all scheduled substances without an accepted medical use must be classified as Schedule I, illustrating the conflicting scheduling practices used.

Furthermore, the existing schedules do not take into account evolving evidence about the abuse potential of these drugs. For example, gabapentin and pregabalin are structural analogues of gamma-aminobutyric acid, with pregabalin being classified as Schedule V under

the CSA. Gabapentin, however, remains federally uncontrolled. An increase in its abuse has led some states to classify this medication as a Schedule V substance and/or mandate prescription reporting.

Finally, the CSA also places many restrictions on medical research into Schedule I substances, creating barriers that hinder the discovery of their potential therapeutic uses. Therefore, ASHP first recommends that the U.S. Congress use its legislative authority to define, with the input of stakeholders, the aforementioned terms in the CSA to provide a statutory basis for regulatory decision-making that will simplify the scheduling process. ASHP also advocates that the DEA establish clear, measurable criteria, to the extent possible for this complex subject, and a transparent process for scheduling determinations. Further, the DEA is encouraged to use those criteria to re-evaluate current schedule assignments for all controlled substances based on recent evidence. Finally, federal and state legislators are urged to eliminate laws that create barriers to research on Schedule I substances.

2324

Point-of-Care Testing and Treatment by Pharmacists

Source: Council on Therapeutics

To advocate for laws, regulations, and development of specific, structured criteria that include performing diagnostic point-of-care testing (POCT), interpreting test results, prescribing, dosing, and dispensing as clinically indicated by POCT within pharmacists' scope of practice, or referral; further,

To support the tracking of reportable diseases through pharmacist-managed POCT and reporting to public health agencies when appropriate; further,

To promote training and education of the pharmacy workforce to competently engage in POCT and related patient care services; further,

To foster research on patient access and public health improvements, cost savings, and revenue streams associated with pharmacist-managed POCT and related patient care services.

Note: This policy supersedes ASHP policy 2229.

Rationale

Point-of-care testing (POCT) is laboratory testing that takes place at or near the site where the patient is located. These tests are quality-assured pathology services using analytical tools such as blood gas; critical care analyzers; and meters for glucose, urinalysis, and other metabolites. They can be used for both communicable and noncommunicable disease states, including influenza A and B, strep throat, diabetes mellitus, hypertension, anticoagulation, congestive heart failure, and stroke. POCT can be performed by patients in their home, using for example a device that monitors international normalized ratio (INR) for warfarin management, or in the field by healthcare providers, such as rapid strep testing in community pharmacies. POCT devices fall under the Federal Food, Drug, and Cosmetic Act and therefore are also subject to

pre- and post-marketing surveillance and review.

As the shortage of primary care providers continues and POTC technology improves, there is ample opportunity to expand the pharmacy workforce's roles in disease screening, identification, and management. POCT provides fast results, which can reduce the time to therapeutic intervention through test-to-treat services, often at a lower cost to patients than an office visit. Pharmacists are well positioned to conduct risk assessments, provide appropriate treatment and referrals when necessary, provide disease state monitoring services, and in turn, improve adherence and identify unnecessary or inappropriate medications. For example, the availability of rapid influenza tests allows pharmacists to quickly diagnose and recommend treatment for influenza A and B, which has been found to reduce the time to first dose of antiviral drugs among individuals with influenza-like illness, compared to those referred to other providers. The combined benefits of telehealth and test-to-treat services should not be discounted. Newer technology that patients can use in the home, including smart scales that monitor changes in weight for congestive heart failure patients, home blood glucose monitoring systems for diabetic patients, and INR monitoring have already demonstrated improved patient outcomes in conjunction with pharmacist care. Numerous studies demonstrate that home POCT can be implemented to streamline healthcare services to patients with chronic and acute disease states and also limit hospital admissions, readmissions, and delays in care and can ultimately lead to better outcomes as well as cost savings for patients and providers.

State legislation concerning pharmacist-managed POCT varies widely. For example, in California, pharmacists are able to perform routine patient assessment procedures through POCT that includes testing for human immunodeficiency virus (HIV) antibodies, total cholesterol, glucose and hemoglobin A1c levels, opiates, blood ketones, thyroid-stimulating hormone, hematocrit, and prothrombin time. Most common is legislation that permits pharmacists in collaborative practice agreements to perform rapid testing to diagnose group A streptococcal pharyngitis and prescribe antimicrobial therapy when a test is positive. This practice model has been shown to decrease the cost of diagnosis and treatment for children and adults and has demonstrated increased patient satisfaction.

ASHP advocates development of specific and structured criteria for pharmacist prescribing, dosing, and dispensing of antimicrobials for this purpose, under a variety of models (e.g., autonomous prescribing authority for pharmacists, delegation protocols, or collaborative practice agreements). A 2018 study found that 69% of pharmacists are willing to perform POCT in a community pharmacy setting, and 86% either strongly agreed or agreed to be willing to recommend appropriate treatment for influenza and group A streptococcal pharyngitis. With collaborative practice agreements in place, patients can bypass visiting a primary care provider, empowering pharmacists to assume an active role not only in treating patients but also in promoting public health by reporting positive cases to local health departments, should rapid testing and reporting be a requirement of dispensing. A Washington State University study demonstrated that after a POCT training module, student pharmacists were not only able to proficiently perform POCT for group A streptococcal pharyngitis, influenza, and HIV, but also showed an increased willingness to perform and recommend the tests, which could expand access.

2325

Nonprescription Availability of Self-Administered Influenza Antivirals

Source: Council on Therapeutics

To support a behind-the-counter practice model that expands access to self-administered influenza antivirals.

Note: This policy supersedes ASHP policy 2116.

Rationale

Oseltamivir (Tamiflu), zanamivir (Relenza), and baloxavir (Xofluza) are self-administered drugs used for the treatment and chemoprophylaxis of influenza. ASHP supports the availability of self-administered influenza antivirals via a behind-the-counter practice model. Use of this practice model, which has already been adopted for medications such as pseudoephedrine and emergency contraception, would facilitate appropriate use of those antivirals and provide patients with an opportunity to receive assessment and professional consultation from a pharmacist.

There are several perceived advantages and disadvantages of the nonprescription designation for self-administered influenza antivirals. Potential benefits include quicker and improved access for patients, public health value by reducing exposure of sick individuals at provider visits, unlikely development of antiviral resistance (based on currently available data), and experience with oseltamivir as a nonprescription medication in New Zealand since 2007. Potential concerns include stockpiling, shortages, questionable effectiveness, adverse effects, potential reduction of influenza vaccination rates because of perceived antiviral availability, dosing considerations (e.g., renal function, pediatric weight-based dosing), costs, reimbursement for clinical services provided by pharmacists (e.g., point-of-care influenza testing, questionnaire screening tool for oseltamivir dispensing), blunting of other more severe underlying conditions without a provider visit, and overextension of pharmacist responsibilities and duties. Furthermore, potential public health benefits and risks of expanded access must also be considered. With availability over or behind the counter, patients may bypass visiting their primary care providers to obtainantivirals, and pharmacists will therefore need to assume an active role in promoting public health by reporting positive cases to local health departments, should rapid testing and reporting be a requirement of dispensing.

Given the interest in expanding patient access to self-administered influenza antivirals, ASHP advocates that any reclassification should not result in increased costs to patients or pharmacies. Modifications to national, regional, and local drug coverage decisions are needed to ensure that payer policies do not unintentionally restrict or prevent access. In addition, the reclassification will likely result in an increased workload and potential liability associated with pharmacist provision of this care, which includes patient screening (and point-of-care testing, if applicable), patient education, dosing, counseling, and documentation of the care provided in the pharmacy and medical record. ASHP policy 2020, Care-Commensurate Reimbursement, states that pharmacists should be compensated for these kinds of clinical and patient care services.

2326

Over-the-Counter Availability of Hormonal Contraceptives

Source: Council on Therapeutics

To advocate that hormonal contraceptives be available over the counter (OTC) without age restriction only under conditions that ensure safe use, including the availability of pharmacist consultation to ensure appropriate self-screening and product selection, and that maintain patient confidentiality; further,

To encourage the Food and Drug Administration to require manufacturers to include all patients of childbearing age, including adolescents, in studies to determine the safety and effectiveness of OTC hormonal contraceptives; further,

To advocate that all insurers and manufacturers maintain coverage and limits on out-of-pocket expenditure so that patient access is not compromised.

Note: This policy supersedes ASHP policy 1410.

Rationale

There have been repeated calls to make hormonal contraceptive products more widely available, with the intent of expanding access to women's reproductive health therapies and reducing unintended pregnancies. The American College of Obstetricians and Gynecologists (ACOG) advocates over-the-counter (OTC) access to hormonal contraception, including oral contraceptive pills, the contraceptive patch, contraceptive vaginal rings, and depot medroxyprogesterone acetate injections, without age restrictions. The American Medical Association (AMA), and the American Academy of Family Physicians (AAFP) support OTC access to oral contraceptives. ASHP agrees with ACOG and AMA that there is no clinical justification to restrict access to hormonal contraceptives by adolescents past menarche.

As with other OTC medications, there is recognition that both progestin-only and combined oral contraceptive use carries a very small amount of risk of adverse events and should be determined to be safe and effective for self-use. Progestin-only hormonal methods are generally safe and carry no or minimal risk of venous thromboembolism (VTE), and the VTE risk with combined oral contraceptive use is small compared with the increased risk of VTE during pregnancy and the postpartum period. ASHP advocates that OTC hormonal contraceptives should therefore be available where a patient has access to a pharmacist. Patient self-screening and product selection would be improved through pharmacist-provided consultation that assists patients in identifying absolute and relative contraindications (e.g., hypertension, heart or kidney disease), assessing other patient-specific factors (e.g., adherence practices), and determining when to recommend a referral to seek a higher level of care through the use of counseling and clinical decision-making tools. This process would guide the determination of which contraceptive product would be most safe and effective for an individual patient. ASHP does not believe that the current model for behind-the-counter access to some drug products (e.g., pseudoephedrine, emergency contraception) is appropriate for hormonal contraceptives because such a model would place the pharmacist in a gatekeeping rather than the clinical role that is necessary to ensure safe and effective use of these therapies.

Manufacturers will need to submit a supplemental new drug application for conversion from prescription to OTC status, including post-marketing surveillance reports and studies of consumer behaviors. It is critical that adolescents be included in these studies to assess their label comprehension, aptitude to self-select, and ability to effectively use the OTC hormonal contraceptives.

Given the intent to expand access to these therapies, ASHP advocates along with ACOG and AAFP that the proposed reclassification to OTC should not result in increased costs to patients and should include full insurance coverage without cost sharing. Modifications to national, regional, and local drug coverage decisions may be needed to ensure that payer policies do not unintentionally restrict or prevent access to OTC oral contraceptives.

2327

Therapeutic and Psychosocial Considerations of Patients Across the Gender Identity Spectrum

Source: Council on Therapeutics

To recognize the role of gender-affirming care in achieving health equity and reducing health disparities; further,

To advocate that gender identity is a critical component of medication and disease management of patients across the gender identity spectrum; further,

To advocate for equitable access to gender-affirming care, including access to a pharmacist who ensures safe and effective medication use; further,

To promote research, development, and implementation of therapeutic and biopsychosocial best practices in the care of patients across the gender identity spectrum; further,

To encourage the incorporation of specific education and training regarding patient gender identity into educational standards and competencies for the pharmacy workforce; further,

To encourage easily accessed, structured documentation of a patient's sex assigned at birth, self-identified gender, chosen name, personal pronouns, and relevant medical history in electronic health records; further,

To affirm that healthcare workers should be able to provide gender-affirming care per their clinical judgment and their conscience without fear of legal consequence, workplace sanctions, social stigmatization, harassment, or harm.

Note: This policy supersedes ASHP policy 1718.

Rationale

Transgender people are at risk for health and access inequities as a direct result of biases and stigma. Insurance coverage for medication therapies, corrective surgeries, and associated medical needs such as mental health and endocrine services may be limited or nonexistent due to these discriminatory barriers.

In its National Survey on LGBTQ Youth Mental Health 2020, which surveyed over 40,000 lesbian, gay, bisexual, transgender, queer, and questioning (LGBTQ) young people, the Trevor Project found that 29% of those who responded experienced housing instability; 40% seriously considered attempting suicide in the past 12 months, with more than half of transgender and nonbinary youth having seriously considered suicide; 68% reported symptoms of generalized anxiety disorder in the past 2 weeks, including more than 75% of transgender and nonbinary youth; and 48% reported engaging in self-harm in the past 12 months, including over 60% of transgender and nonbinary youth. The authors also reported that 60% of respondents identified that the ability to afford care was the strongest barrier to receiving mental health care, and that nearly half of transgender and nonbinary youth did not receive wanted mental healthcare due to concerns related to the LGBTQ competence of providers. Further, they found that when transgender and nonbinary youth had access to binders, shapewear, and gender-affirming clothing, they reported lower rates of suicide attempts compared to transgender and nonbinary youth without access. These findings are echoed by Safer and colleagues, who also identify a lack of providers who are sufficiently knowledgeable on the topic, financial barriers, discrimination, lack of cultural competence by providers, health-system barriers, and socioeconomic barriers to this patient population.

There are guidelines to help practitioners identify the health and biopsychosocial needs of transgender and gender-nonbinary people as well as inclusive language guidelines for all practitioners to incorporate into their lexicon.

Patients electing to transition from their sex assigned at birth to their self-identified gender may have surgeries and take higher doses of hormones to change their physical appearance to reflect their self-identified sex. These patients have significant requirements for therapeutic drug monitoring, as certain lab values may to appear out of normal limits but are clinically appropriate for the transgender patient, and the risk of drug-drug interactions may be higher because medications may be taken at a higher than normal doses. These patients may be more at risk for adverse effects, including thyroid disorders, and may more frequently require anticoagulation and management of diabetes as a result of medication therapy. Other unique needs of these patients include cardiovascular and thrombotic risk assessment, screening for certain types of cancers should they elect to keep their gonadal organs, and other associated primary care screenings associated with their birth sex. Considerations for transgender patients who wish to have children will add the complexity of fertility as well as attention to use of teratogenic medications to their needs. Because of the unique and complex healthcare needs of transgender patients, it is essential that they have adequate access to appropriate care, including pharmacist care. To help ensure appropriate patient identification, assessment, and treatment, a patients' sex assigned at birth, self-identified gender, chosen name, personal pronouns, and (if applicable) gender-confirming therapies or procedures should be documented in a structured way in electronic health records. This documentation also helps healthcare providers address another of the unique biopsychosocial needs of transgender patients; like other healthcare providers, pharmacists should address transgender patients by their self-identified gender and chosen name and personal pronouns.

Those caring for these patients should be knowledgeable regarding the clinical, social, and access needs of this patient population. Student pharmacists, pharmacy residents, pharmacists, and pharmacy technicians therefore should all be trained to appropriately care for

this patient population. The Affordable Care Act prohibits pharmacists from making their own decisions about the suitability of a prescribed medication in situations that would constitute discrimination against patients. Although ASHP policy 0610, Pharmacist's Right of Conscience and Patient's Right of Access to Therapy, recognizes the pharmacist's right of conscience, the policy also recognizes "the patient's right to obtain legally prescribed and medically indicated treatments" and states that "a pharmacist exercising the right of conscience must be respectful of, and serve the legitimate healthcare needs and desires of, the patient, and shall provide a referral without any actions to persuade, coerce, or otherwise impose on the patient the pharmacist's values, beliefs, or objections." In addition, ASHP believes that healthcare workers should be able to provide care per their clinical judgment and their conscience without fear of legal consequence, workplace sanctions, social stigmatization, harassment, or harm.

2328

Removal of Injectable Promethazine from Hospital Formularies

Source: Council on Therapeutics

To advocate that injectable promethazine be removed from hospital formularies; further,

To encourage regulatory and safety bodies to review patient safety data and conduct research on adverse events related to administration of injectable promethazine; further,

To encourage manufacturers to produce injectable promethazine in package sizes and concentrations that reduce risk.

Note: This policy supersedes ASHP policy 1831.

Rationale

In its 2020-2021 Targeted Medication Best Practices for Hospitals, the Institute for Safe Medication Practices (ISMP) included a recommendation to eliminate injectable promethazine from hospitals. This recommendation includes removal of injectable promethazine from all areas of the hospital, including the pharmacy; classification of injectable promethazine as a nonstocked, nonformulary medication; implementation of a medical staff-approved automatic therapeutic substitution policy; conversion of all injectable promethazine orders to another antiemetic; and removal of injectable promethazine from all computerized medication order screens and from all order sets and protocols. In 2018, only 56% of ISMP Survey respondents believed promethazine to be a high-alert medication, which was a *decrease* from 59% in 2014. The 2018 survey also found that 54% of respondents also thought that "IV promethazine" should be changed to "injectable promethazine," also underscoring the need for broader protections from intravenous administration use. This recommendation reiterated the identical 2018-2019 ISMP Best Practice recommendation, which was a change from previous ones in which ISMP promoted safe use by raising awareness about risks associated with intravenous (IV) promethazine administration. Despite the efforts to improve the safety of injectable promethazine use, sporadic and significant patient harm continues to occur.

Promethazine is a known vesicant that can cause tissue damage and necrosis when extravasation occurs during IV administration, and it has negative effects on cardiac conduction. Although therapeutic alternatives are available for most indications, the alternative therapies are also not without risk and may not be as effective in some clinical situations. Processes to limit the potential for patient harm when IV administration of promethazine is indicated include but are not limited to use of therapeutic alternatives (e.g., 5-HT_3 receptor antagonists, antipsychotic agents, antihistamines); use of alternate routes and modalities of administration (e.g., oral, rectal); and restrictions on use (e.g., nonformulary, nonstocked status and removal from order sets and protocols). While prior guidance provided practice recommendations to mitigate the risk of injectable promethazine use (e.g., minimum drug dilution, continuous nurse monitoring of infusion, administration through a running IV line), a 2006 ISMP survey of hospitals revealed poor adherence to these recommendations, despite the well-documented risks of circumventing them. Although medication regimens for some specific patient populations may include injectable promethazine, many guidelines for management of disease states in which promethazine may have a role do not recommend injectable promethazine as an agent of initial choice, indicating it should be used as last line/salvage therapy. Often, these guidelines do not include injectable promethazine as a therapeutic option at all; given the number and variety of suitable alternatives, the risks of using this medication outweigh the benefits.

In addition, because ISMP has recommended injectable promethazine's removal from formularies, there is not much data on its safety and efficacy, as implementation of the recommendation has varied across the U.S., and what data is available has been mostly anecdotal or case-based reports. ASHP encourages regulatory and safety bodies to review patient safety data and conduct research on adverse events related to administration of injectable promethazine. Finally, ASHP encourages manufacturers to produce injectable promethazine in package sizes and concentrations that reduce risk in a similar manner to those recommended by ISMP for administration of electrolytes (e.g., use of prediluted standardized solutions).

2329

Well-Being and Resilience of the Pharmacy Workforce

Source: Council on Education and Workforce Development

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

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

To declare that healthcare workforce well-being and resilience requires shared responsibility among healthcare team members and between individuals and organizations; further,

To provide resources to empower individuals and institutions to embrace well-being and resilience as a priority supported by organizational culture; further,

To promote that pharmacy leadership collaborate with their institutions to assess the well-being and resilience of the pharmacy workforce and identify effective prevention and intervention strategies; further,

To encourage hospitals and health systems to invest in the development and assessment of interprofessional programs that prevent occupational burnout while supporting well-being, and to support nonpunitive participation in these programs.

Note: This policy supersedes ASHP policy 1825.

Rationale

Clinician burnout can have serious, wide-ranging consequences on individual clinicians and learners, health care organizations, and patient care. Occupational burnout is a syndrome characterized by a high degree of emotional exhaustion, high depersonalization (e.g., cynicism), and a low sense of personal accomplishment from work due to both internal and external factors. The results follow a 2018 study in the *American Journal of Health-System Pharmacy* (*AJHP*) that found 53 percent of health-system pharmacists self-reported a high degree of burnout caused by increasing stresses and demands. Occupational burnout affects today's pharmacy workforce at unprecedented rates. At the individual level, pharmacy staff burnout can result in medication errors and increased patient harm. At the hospital or healthcare system level, the consequences of occupational burnout include disengagement, loss of productivity, and employee turnover, which can lead to inefficiency and financial problems for healthcare organizations. Stress in our clinical learning environment can affect all healthcare learners, with negative outcomes ranging from poor well-being to substance abuse to depression, even suicide. A 2017 *AJHP* article reported that pharmacy residents working more than 60 hours per week reported high levels of stress, depression, and hostility.

ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience in 2017. The goals of the Collaborative are to:

1. Raise the visibility of clinician anxiety, burnout, depression, stress, and suicide.
2. Improve baseline understanding of challenges to clinician well-being.
3. Advance evidence-based, multidisciplinary solutions to improve patient care by caring for the caregiver.

The NAM Action Collaborative Conceptual Model depicts both individual and external factors affecting well-being and resilience and indicates that it requires a combined effort from the individual and the system to address and prevent occupational burnout.

Studies suggest that burnout is a problem of the entire healthcare organization as well as individual clinicians, so maintaining clinician well-being and resilience requires a combined effort by the individuals and their employers. To be successful, interventional programs must promote prevention, recognition, and treatment of burnout, and healthcare organizations must foster a culture that supports not just nonpunitive participation in these interprofessional programs but a sense of personal empowerment for developing and maintaining resilience. A healthcare organization with a resilient workforce will provide the best healthcare outcomes.

Supporting the well-being of the pharmacy workforce requires sustained attention and action at organizational, state, and national levels, as well as investment in research and

information sharing to advance evidence-based solutions. A pharmacy workforce with the ability to thrive during adversity—a resilient workforce—is essential to combat burnout and support higher-quality care, increased patient safety, and improved patient satisfaction.

2330

Pharmacist Prescribing Authority for Antiretroviral Therapy for the Prevention of HIV/AIDS

Source: Council on Therapeutics

To affirm that drug products for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for human immunodeficiency virus (HIV) infection prevention should be provided to individuals in a manner that ensures safe and appropriate use; further,

To oppose reclassification of currently available drugs used for PrEP and PEP to nonprescription status; further,

To advocate for legislation and regulation that expands pharmacist scope of practice to encompass initiation of PrEP and PEP therapy; further,

To advocate that the therapies and associated care for PrEP and PEP are available to patients with zero cost-sharing; further,

To support establishment of specific and structured criteria to guide comprehensive pharmacist interventions related to PrEP and PEP; further,

To support the research, education, and training of the pharmacy workforce on the therapeutic, psychosocial, and operationalization considerations of pharmacist-provided PrEP and PEP therapy; further,

To support educating the public regarding the public health benefits of PrEP and PEP.

Rationale

Increasing access to pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for human immunodeficiency virus (HIV) infection prevention is a public health priority. The *Ending the HIV Epidemic in the U.S.* initiative (https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/), for example, includes expanded access to PrEP and PEP in its whole-of-society plan coordinated among agencies across the U.S. Department of Health and Human Services to end the HIV epidemic in the United States by 2030. Despite the increase in the availability of antiretroviral therapies for such prophylaxis, much of the patient population that would benefit from access, particularly those in the black, indigenous, and people of color communities, has been limited by stigma and other barriers, including a requirement for a prescription in many parts of the U.S. One of those barriers to access is that many states do not provide pharmacists independent authority to order and initiate PrEP and PEP therapy. Given the time-sensitive nature of these therapies, patients and their partners would benefit from being able to access them at community pharmacies. Those forced to seek medications through a physician's office or other site of care may struggle to find a timely appointment, especially if

they do not have an established primary care provider. In contrast to physicians, community pharmacists are often available without an appointment and pose a potential solution to expanding access to therapy. Through policy, education, and infrastructure changes, pharmacists can be an alternate source for PrEP, expanding availability and further reducing HIV transmission.

ASHP advocates expanding pharmacists' scope of practice to include initiation of PrEP and PEP therapy, including associated screening, testing, monitoring, referrals, product selection, and counseling, as well as the establishment of specific and structured criteria for prescribing, dosing, and dispensing of PrEP and PEP by pharmacists. As one example, California Bill 159, approved in October 2019, authorizes pharmacists who undergo a board-approved training program to supply PrEP and PEP every two years, with a 60-day supply cap and certain conditions under which the therapies can be prescribed. In addition, insurance companies are not allowed to require prior authorization for these drug products. The goal of this law is to get patients on PrEP and then direct them to a prescriber for further care management. Other states, including New York, Colorado, Missouri, and New Hampshire, are exploring similar programs. As these practices and programs vary from state to state, ASHP also recommends structured criteria be set that optimizes patient care and access to these drug products.

Expanding collaborative practice, in which pharmacists are permitted under an agreement with a prescriber to prescribe a defined list of medications along with associated monitoring, provides an effective way to advance the scope of pharmacy practice nationwide. A Seattle pharmacy operationalized such a program by forming a clinic in which pharmacists perform a history, risk assessment, lab testing, and education before dispensing PrEP. Implementation of a standing order for pharmacists to furnish PrEP for their patients may provide longitudinal benefit, and infrastructure for pharmacists to bill for these services, as well as the facilities to see patients, must accompany such policy changes. To ensure that patients who present for HIV prophylaxis receive comprehensive care, pharmacists should be allowed to order tests for other sexually transmitted infections at the patient's request when possible, as some community pharmacies and other sites of care may not have the ability to provide certain tests onsite.

ASHP opposes reclassification of currently available drugs used for PrEP and PEP (tenofovir and emtricitabine) to nonprescription status, because existing models for nonprescription dispensing do not provide the safeguards required to ensure safe and effective use.

Other barriers to access include a lack of insurance coverage and high out-of-pocket costs, insurers' refusal to cover brand medications when necessary, and insurers failing to cover all formulations, including pediatric formulations. Modifications to national, regional, and local drug coverage decisions are needed to ensure that payer policies do not unintentionally restrict or prevent access. To promote the broadest possible access, ASHP advocates that PrEP and PEP be available to patients with zero cost-sharing, regardless of income or insurance coverage.

Pharmacist initiation of PrEP and PEP therapies will likely result in an increased workload and potential liability associated with provision of this care, which includes patient screening (including point-of-care testing, if applicable), patient education, dosing, counseling, and documentation of the care provided in the pharmacy and medical record. ASHP policy 2020, Care-Commensurate Reimbursement, states that pharmacists should be compensated for these

kinds of clinical and patient care services.

A survey of community pharmacists revealed that education and training are needed to advance pharmacy practice in PrEP and PEP therapy. Training in necessary laboratory testing, trauma-informed care, destigmatizaton, and appropriate follow-up should be done to ensure an adequate knowledge base for pharmacists unfamiliar with the procedures. Finally, ASHP supports public education regarding the public health benefits of PrEP and PEP therapy.

2331

Sustainable Billing, Reimbursement, and Payment Models

Source: House of Delegates

To advocate for reimbursement, pay parity, and financially sustainable models related to cognitive services of pharmacist-accountable services, regardless of site of care; further,

To educate the pharmacy workforce and stakeholders about financially sustainable models of care; further,

To advocate that compensation for healthcare services be commensurate with the level of care provided, based on the needs of the patient; further,

To advocate for the development of consistent, transparent billing, reimbursement, and alternative payment model policies and practices by both government and commercial payers.

Rationale

The National Academy of Sciences recommends that payers, including Centers for Medicare & Medicaid Services (CMS), commercial insurers, and self-insured employers shift payment for healthcare services toward a hybrid model that includes fee-for-service and capitated payments, and that these models pay prospectively for interprofessional, integrated, team-based care. Due to lack of federal provider status for pharmacists and subsequent inability to directly bill Medicare as care providers, organizations and practices have become creative in maintaining financial sustainability of pharmacist services. Financial sustainability for services provided by pharmacists has been achieved using a variety of models. Some settings utilize indirect funding, while others take advantage of some of the limited direct insurance billing opportunities to fund pharmacist patient care. Direct billing opportunities vary based on the setting (e.g., hospital-based versus physician-based practices) as well as state-specific laws and regulations. Medicare, Medicaid, and commercial health plans may reimburse pharmacists for certain services, while some will require direct contracting with the health plan. Several states have passed pharmacist state provider status laws or reimbursement parity laws allowing for reimbursement for direct patient care pharmacist services by state Medicaid or commercial plans.

2232

Barcoding of Lot Number and Expiration Date

Source: House of Delegates

To advocate that the Food and Drug Administration and organizations that develop barcode standards require barcodes contain lot number and expiration date on all immediate product packages to enable automated collection and validation of this information during medication preparation, dispensing, and administration processes; further,

To educate regulatory and safety organizations that barcode scanning versus manual logging of lot numbers and expirations is critical for patient safety and preparation sterility and improves data visibility for medication recalls; further,

To advocate that state boards of pharmacy, regulatory agencies, and accrediting bodies delay punitive action on rules requiring logging of lot number and expiration dates during sterile product preparation until this information is made available on immediate product barcodes.

Rationale

The current Food and Drug Administration (FDA) barcode rule requires the National Drug Code (NDC), lot number, and expiration date on all saleable medication packages. FDA created an exception for immediate packages, which include unit dose packages and individual vials sold as lots in boxes. More than 90% of products dispensed in a hospital are immediate packages. The FDA exception requires that the barcodes on these immediate packages be linear (1D) barcodes. Due to the technology of 1D barcodes, it is difficult to fit the larger barcode containing additional characters needed to code lot number, expiration date, and NDC on labels of inner packages. As a result, the 1D barcodes required on inner packages only contain the NDC. 2D barcodes require less label space than 1D barcodes, and 2D scanners can read 1D and 2D barcodes. Many products dispensed are saleable packages that only contain 2D barcodes, and 2D barcode readers are significantly less expensive and more reliable than the 1D laser scanners used in the past. Hospitals have responded by widely adopting use of 2D scanners.

A proposed FDA rule will allow but not require 2D barcodes and require only the inclusion of the NDC in the barcode. The FDA states that the reason for these requirements is that the expansion of the NDC to 12 digits will create issues for manufacturers that code a 10-digit NDC number in the barcode and don't have the label space to expand the 1D barcode to 12 digits. The proposed rule will not guarantee that barcodes on inner products contain lot number and expiration date. FDA has stated that they are addressing the immediate package requirements in the revised rule, but this is only true for the NDC 12-character expansion and not for the encoding of lot and expiration date.

Multiple state boards of pharmacy, including California and Texas, require hospitals to log the NDC, lot number, and expiration dates on all intravenous (IV) products that are compounded or repackaged. United States Pharmcopeia (USP) Chapter 797 is adding the same requirements, effective November 1, 2023. The logging of lot numbers and expiration dates is not a second check but an attempt to track medications all the way to the patient in the case of recalls and event reporting. With IV workflow systems and barcodes with lot number and expiration dates, an IV product can be prepared and documented with only two barcode scans. Current linear barcodes require scans of the NDC, multiple mouse clicks, and many keystrokes on a keyboard to enter the data. For example, a two-component IV product with a base

solution and one additive was reported to require 22 keystrokes and 2 mouse clicks at a minimum if lot number and expiration date are not in the barcode. In addition, putting a keyboard into the sterile environment or pulling hands in and out of the sterile field threatens sterility. Dispersing this data entry work in the middle of a complicated IV workflow will not only create data entry or transcription errors but will increase the potential for computation errors, as the preparer keys in or handwrites a long series of seemingly random numbers while computing, measuring, and verifying doses.

Software vendors have acknowledged that their systems already have the functionality to capture lot number and expiration dates, if available, through barcode scanning, replacing numerous keystrokes. This functionality has not only been added to IV preparation functions but also to dispensing and medication administration functions as well. In addition, many systems allow barcode scans to be initiated by foot switches, permitting users to avoid touching scanners, therefore minimizing potential impacts on sterility. One vender has reported that they are in the process of adding automatic checks for expired medications and recalled lot numbers during all medication barcode scanning functions throughout the medication-use process. Significant safety improvements and time savings can be realized through automated checking of expiration dates and recalls throughout the medication-use process, including automated dispensing cabinet restocking.

Although state boards of pharmacy and USP are considering and implementing rules to track medications to the patient and validate expiration dates, there is a general lack of understanding how these rules impact IV preparation workflows and corresponding medication safety and sterility of IV preparation. It is important that rulemakers understand these impacts and implement rules to require the inclusion of lot number and expiration date on immediate product barcodes. Healthcare organizations should communicate the need for NDC, lot number, and expiration date on all immediate products, including repackaged products and investigational medications, to the FDA and GS1, the barcode standards organization that defines medication barcode standards, to assure the resulting barcodes meet the needs of health systems.