House of Delegates

Policies Approved by the ASHP House of Delegates March-November 2024 (with rationales)

2401
Role of the Pharmacy Workforce in Improving Mental Health
Source: Council on Pharmacy Practice
To advocate for equitable and destigmatized access to mental healthcare services for all patients across their lifespan, including members of the healthcare workforce; further,

To affirm the essential role of pharmacists, as members of the interprofessional care team, in increasing patient access to mental healthcare services; further,

To urge all members of the pharmacy workforce to raise awareness of, screen for, triage, and provide education on mental health conditions; further,

To advocate for expansion of mental health-related comprehensive medication management services provided by pharmacists; further,

To advocate for adequate funding of mental health awareness programs and for funding that promotes equitable access to mental healthcare services.

Rationale
Mental health is a public and population health issue that requires support of mental healthcare needs for patients and members of the healthcare workforce. Mental health is recognized as a global public health issue, worsened by the COVID-19 pandemic. In addition, support for mental health and access to mental health services are important for the healthcare workforce. Despite the high prevalence of patients with mental health issues, access to services is significantly strained. Data prior to the pandemic demonstrated that nearly 6 of 10 people in the U.S. desired access to mental health services for themselves or a loved one. Barriers to access include a

limited and constrained healthcare workforce, high cost, insufficient insurance coverage, long wait times, lack of awareness, and stigma.

The pharmacy workforce plays a critical role in improving medication-use outcomes for populations of patients across the continuum of care. This role creates an opportunity for pharmacists with expertise in mental health to increase patient access to mental health services and improve mental health outcomes. Using a comprehensive medication management approach to care, pharmacists can assess mental healthcare needs, manage medication therapy regimens, educate patients and caregivers, monitor patients, and assess outcomes of mental healthcare services. It also creates an opportunity for the pharmacy workforce to engage as members of the interprofessional care team in population health strategies that increase awareness of, screening for, and treatment of mental health issues. The American Psychological Association outlines the following as principles to guide a population health framework for mental health:

- Use data and the best available science to inform policies, programs, and resources.
- Prevent when possible and otherwise intervene at the earliest moment.
- Strategize, analyze, and intervene at the community/population level (in addition to the individual).
- Reach broad and diverse audiences through partnerships and alliances.
- Utilize a developmental approach (e.g., change over time, age-appropriate interventions).
- Consider the "whole person" and the structural/systemic factors impacting individual behavior.
- Be culturally sensitive while also thinking transculturally.
- Recognize that inherent in every community is the wisdom to solve its own problems.
- Champion equity by addressing systemic issues (e.g., social determinants of health, access to treatment).

To ensure that the opportunity to leverage the pharmacy workforce in improving access to and quality of mental health services is realized, there needs to be greater awareness, advocacy and collaboration with other stakeholders, training efforts for building competency and expertise, and reimbursement that supports sustainable services.

2402
Suicide Awareness, Prevention, and Response
Source: Council on Pharmacy Practice
To support the goal of zero suicides; further,

To collaborate with key stakeholders in support of suicide awareness, prevention, and response; further,

To acknowledge that optimal suicide awareness, prevention, and response efforts focus both on patients and on the healthcare workforce; further,

To recognize that pharmacists, as key members of the interprofessional care team, are integral to suicide awareness, prevention, and response efforts, and to acknowledge the vital role of other members of the pharmacy workforce in those efforts; further,

To foster the use and development of clinically validated tools to aid the pharmacy workforce in assessing the influence of medications and other factors on suicidality; further,

To advocate for adequate government and healthcare organization funding for suicide awareness, prevention, and response; further,

To enhance awareness of local, state, national, and global suicide awareness, prevention, and response resources.

This policy supersedes ASHP policy 1901.

Rationale

The high and increasing number of suicides in the U.S. has created a call for national action. In 2021, the Centers for Disease Control and Prevention reported that suicide was the eleventh leading cause of death for Americans. Further, a *JAPhA* study showed that pharmacists are at an increased risk of death by suicide when compared to the general public. According to that study, the suicide rate among pharmacists in the United States is 20 per 100,000, which is higher than the general population rate of 12 per 100,000. The U.S. Surgeon General and the National Action Alliance for Suicide Prevention, in the 2012 National Strategy for Suicide Prevention and the 2021 Surgeon General's Call to Action on Suicide Prevention, provided general guidance for various societal approaches, including public awareness and development of effective clinical practices targeting suicide prevention. The National Strategy set an aspirational zero suicides goal for healthcare services, which will require a systemwide effort to improve healthcare's approach to suicide prevention, including clinician training and implementation of better referral systems.

In addition to calls for raising awareness and preventing death by suicide, there also needs an appropriate response in the event of suicide. Postvention, defined as activities that reduce risk and promote healing after a suicide death, is an important term for healthcare workers and communities to factor in response to death by suicide. ASHP partnered with the American Foundation for Suicide Prevention to customize two postvention toolkits for pharmacy residents and student pharmacists. Information in the toolkits is generalizable to the entire pharmacy workforce and aim to ensure a careful and appropriate response to death by suicide.

The responsibility for healthcare professionals to become involved in suicide prevention and response extends beyond those specializing in mental health services, as suicide may be viewed as a response to multiple biological, psychological, interpersonal, environmental, and societal influences that interact with one another and may change over time. Suicide prevention and response, when viewed as the collective efforts of government, public and private organizations, and care providers to reduce the incidence of suicide across the lifespan of a

person, requires a correspondingly broad response by healthcare professionals. In 2016, the Joint Commission published a Sentinel Event Alert urging healthcare organizations to develop policies, staff education, and comprehensive care plans to utilize suicide risk assessment tools and support patients with suicide risk factors. The Joint Commission urged all healthcare organizations to develop clinical environment readiness by identifying, developing, and integrating comprehensive behavioral health, primary care, and community resources to assure continuity of care for individuals at risk for suicide.

In addition, concern over drug-associated suicidal ideation and behavior has been increasing over the last decade. In 2012, the Food and Drug Administration (FDA) issued draft guidance on assessing the occurrence of suicidal ideation and behavior in clinical drug trials. Over 800 drugs have been linked to an increased risk of suicidal thoughts and depression, from central nervous system agents to antimicrobials. The ASHP Medications and Suicidality Web Resource Center contains guidelines and publications concerning drug-associated suicidality and maintains links to information on individual drugs associated with depression and suicidality. ASHP encourages continued research on suicidal ideation and behavior in clinical trials and supports safety measures by manufacturers and FDA (e.g., risk evaluation and mitigation strategies, boxed warnings) when appropriate.

Given the leading role of pharmacists in overseeing safe medication use, the dangers of medications relating to suicide risk, and the high degree of pharmacist interaction with patients, pharmacists are well positioned to play a key role in suicide awareness, prevention, and response efforts. The pharmacist's role could include, for example, ensuring appropriate use of medications in management of mental health and other medical conditions; identifying patients at risk for suicide, and evaluating that suicide risk; and recommending care, making referrals, and following up on referrals with patients and providers. Strategies could range from evaluating patients' prescribed medications and identifying those that increase risk for suicidality; to counseling patients, caregivers, and other healthcare providers about those risks; to educating the public about the dangers of unused medications and the need for proper disposal. Pharmacists trained in behavioral health could also be incorporated into behavioral health programs to offer comprehensive medication management to patients and serve as a resource to the interprofessional care team. Other pharmacy practitioners (student pharmacists and pharmacy technicians) could perform vital services in suicide awareness and prevention efforts as well, such as medication reviews. The goal of zero suicides will also require a combined effort from individual healthcare workers and the healthcare system as a whole to sustain clinician well-being and resilience, as further described in ASHP policy 2329, Clinician Well-Being and Resilience. In 2023, ASHP and partnering pharmacy organizations established the Pharmacy Workforce Suicide Awareness Day to be recognized annually on September 20 as part of September's Suicide Prevention Month.

To ensure that pharmacy practitioners have the competence and confidence to properly fill these key roles, ASHP is committed to providing education and tools to assist pharmacy practitioners in suicide awareness, prevention, and response efforts. Further, ASHP advocates inclusion of suicide awareness, prevention, and response in college of pharmacy curricula and postgraduate educational and training programs, through a multimodal approach. ASHP also advocates universal suicide awareness, prevention, and response training for the health workforce. Adequate government and private-sector funding of suicide awareness and prevention

efforts will be required to promote the success of suicide awareness, prevention, and response efforts. ASHP joins other organizations in supporting efforts to promote awareness of local, state, national, and global suicide awareness, prevention, and response resources, including the 988 Suicide & Crisis Lifeline.

Finally, ASHP urges research on suicide awareness, prevention, and response, including research on patient assessment tools, medications that increase the risk of suicidality, and practice models and strategies to identify and manage patients at risk for suicide.

2403
Medication Stewardship Programs
Source: Council on Therapeutics
To advocate that pharmacists are foundational members of any medication stewardship program; further,

To affirm that pharmacists bring unique clinical, operational, safety, and financial expertise to help organizations develop and manage medication stewardship programs; further,

To promote pharmacist leadership in medication stewardship teams; further,

To encourage healthcare organizations to develop comprehensive medication stewardship programs that align with applicable laws, regulations, and accreditation standards; further,

To support incorporation and development of the pharmacy workforce in medication stewardship efforts; further,

To enhance awareness that medication stewardship includes disease state management across all levels of care and addresses barriers at the patient and system levels in order to improve the quality, safety, and value of patient care.

Rationale
Stewardship is an approach to patient care whose goals are to improve the quality, safety, and value of care. These goals are achieved through evidence-based therapy to achieve optimal patient outcomes, with selection of the correct drug, appropriate dose, and subsequent optimization, and by reducing costs and barriers to the patient, healthcare system, and payers. The most well-known and successful stewardship programs are those for antimicrobial agents and opioids, because these programs are required by the Centers for Medicare & Medicaid Services. The Joint Commission also requires hospitals or health systems to allocate financial resources for staffing and information technology to support an antimicrobial stewardship program (ASP) and that a pharmacist be a part of the ASP.

As hospitals and health systems transition to value-based care and become more conscious of outcomes data, stewardship has become even more important. Clinical areas that could benefit from stewardship programs include anticoagulation, oncology/anti-cancer therapies, fluid management, pharmacogenomics, and psychiatry; all demonstrate the potential for and necessity of stewardship programs. Additionally, research has firmly demonstrated that

programs with pharmacist involvement result in the most improvement in costs, patient outcomes, and safety. Drug selection is typically a collaborative decision between the prescriber and the pharmacist, but pharmacists can add recommendations using several additional lenses. Pharmacists assess the drug to ensure an evidence-based approach is used, ensure the correct dose, assess for drug interactions or comorbidities, and help with dose adjustments, monitoring, and adherence. They also assist with identifying which drugs are restricted by formulary, which biosimilars are preferred, which high-cost drugs have patient- assistance programs, and with other patient-specific insurance issues. Stewardship takes a comprehensive approach to drug management that crosses multiple phases of care. ASHP believes that members of the pharmacy workforce have the clinical skills, training, and financial and operational knowledge that make them foundational members of any new stewardship program and leaders in established programs.

As stewardship programs evolve, so do their needs. The integration of pharmacy technicians is a logical next step for stewardship programs. In the United Kingdom, pharmacy technicians play a large role in ASPs. They conduct antimicrobial virtual chart reviews for de-escalation, review and flag penicillin allergies for the pharmacist, participate in audits, and more. The number of pharmacy technicians that perform clinical roles continues to grow in the United States, and incorporating them into stewardship programs is a natural extension of their evolving roles.

2404

Flexible Workforce Models

Source: Council on Education and Workforce Development

To advocate for flexible workforce models that promote patient safety and continuity of care, optimize pharmacy operations, and enhance recruitment and retention of the pharmacy workforce.

Rationale

Broader advocacy efforts are needed to ensure state laws do not prohibit the development of innovative pharmacy practice models that incorporate flexible approaches, specifically in the areas of telehealth practices and telecommuting. As the healthcare landscape and industry continue to evolve, the entire pharmacy workforce and its stakeholders need to embrace flexible workforce model approaches that optimize operational efficiencies and promote safety in support of patient care. Flexible workforce models may include hybrid, remote, and onsite work. Specific job roles and responsibilities, space, and cost implications must be taken into consideration in any new practice model that incorporates flexible approaches. More importantly, these flexible approaches must ensure continuity of patient care and augment team-based care.

As retention and recruitment grow increasingly challenging, embracing a flexible workforce model may further enhance staff satisfaction and recruitment to the pharmacy profession more broadly.

2405

Pharmacist Access to Provider Networks

Source: Council on Pharmacy Management

To advocate for laws and regulations that require healthcare payers to include pharmacists in their provider networks as standard coverage when providing patient care services within their scope of practice and the services are covered benefits; further,

To advocate that payers provide comparative, transparent sharing of performance and quality measure data for all providers in their networks, including pharmacists.

This policy supersedes ASHP policy 2134.

Rationale

As hospitals and healthcare organizations increase their ambulatory care service footprint, pharmacists providing patient care services within those settings may find themselves excluded from healthcare payer networks. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to profitably operate). When creating provider networks, however, payers should include pharmacists providing patient care services within their scope of practice as standard coverage, when the services are covered benefits. ASHP advocates for laws and regulations that require healthcare payer provider networks to consider all qualified pharmacists who apply to participate as a provider in the network and to reimburse all participating providers fairly and equitably for services that are a covered benefit (see ASHP policy 2331, Sustainable Billing, Reimbursement, and Payment Models). To ensure the same level of patient care and equity for healthcare providers within a payer network, payers should be required to (1) disclose to participating providers and those applying to participate in a provider network the criteria used to include, retain, or exclude providers; (2) ensure those criteria are standardized across all network providers; and (3) collect performance and quality measure data on how well providers meet those criteria and report that data to providers. Pharmacist scope of practice is defined at the state level and is highly variable. Provider status recognition is also highly variable. Only a few states formally recognize pharmacists as providers and have established payer mandates to ensure reimbursement in a manner similar to other disciplines that provide patient care. As a result, pharmacy leaders typically have very limited experience regarding how payers manage networks and reimbursement. When pharmacists obtain provider status, health systems will require a substantial amount of infrastructure to support pharmacists as providers. Pharmacy leaders will need to have relationships across a broad range of internal departments and committees, including finance, revenue integrity, provider relations, medical staff services, and credentialing and privileging. They will also need to engage in external collaborations with payers, which often includes departments such as provider relations and contracting that have a very limited understanding of pharmacist patient care services beyond prescription fulfillment and dispensing services. Despite the risk that payer transparency could reduce market competition, comparative, transparent sharing of performance and evidence-based quality measure data could demonstrate to payers and providers how a provider's performance and quality compares

to others. Ensuring that qualified pharmacists have access to payer networks improves patient access to pharmacist care, team-based coordination of care, and health outcomes.

2406
Risk Assessment of Health Information Technology
Source: Council on Pharmacy Management
To urge hospitals and health systems to directly involve departments of pharmacy in performing appropriate risk assessment before new health information technology (HIT) is implemented or existing HIT is upgraded, and as part of the continuous evaluation of current HIT performance; further,

To advocate that HIT vendors provide estimates of the resources required to implement and support new HIT; further,

To collaborate with HIT vendors to encourage the development of HIT that improves patient-care outcomes and user experience; further,

To advocate for changes in federal law that would recognize HIT vendors' safety accountability.

This policy supersedes ASHP policy 1418.

Rationale
The adoption of HIT in hospitals has been increasing at a quickening pace. The 2022 ASHP National Survey of Pharmacy Practice in Hospital Settings reports basic analytics (e.g., data from smart pumps, clinical decision support, compounding technology) are used in nearly 85% of hospitals and advanced analytics (e.g., artificial intelligence, machine learning, predictive analytics) are used in 8.7% of hospitals, an increase from 4% in 2021 and 2.6% in 2020.
Investing in HIT and properly integrating it within healthcare can prevent and decrease errors, improve quality, and prevent waste.

Before selecting or upgrading health IT, organizations must determine their needs and goals. The Office of the National Coordinator for HIT maintains the Health IT Playbook to help clinicians, administrators, and clinician-practice staff. The Health IT Playbook provides tools to help healthcare organizations choose and implement the right HIT systems for their needs. As hospitals and providers implement HIT within their institutions and practices, however, they often encounter new types of errors and problems. The medical literature is replete with many reports of the unintended consequences of HIT, so continuous monitoring of these systems is required. It has become increasingly important to properly assess the interface between HIT and users to identify whether any new risk has been introduced to the system and implement HIT appropriately, taking into account medication-use processes and human factors. Critical questions hospitals and health systems face include (1) when do HIT advances exceed the capacity for integration into workflow, (2) when does HIT begin to introduce risk into the medication-use process rather than improve patient safety, and (3) what are the accountabilities of HIT providers, regulators, and providers to ensure the necessary product development and assessments are made before implementation of new HIT.

ASHP advocates that the pharmacy department be part of the implementation team for any medication-related technology within an institution. Technology assessment tools should be applied by the pharmacy workforce to proactively determine gaps in function prior to implementation, during upgrades, and as part of the continuous evaluation of HIT performance. The use of failure modes effects analysis (FMEA) and other resources should be considered. Organizations selecting or upgrading HIT should work closely with implementation partners or vendors to ensure the following: (1) products are suited to the organization's needs; (2) HIT will be usable by clinicians and staff; and (3) accurate estimates of resources needed are identified to implement and support new or upgraded HIT. These processes also provide opportunities to examine and optimize care delivery processes. Tailoring both technology and processes around care pathways takes advantage of the technology's potential to support safer care, inclusive of patient goals, while reducing burdens on healthcare professionals. Risk assessment should also be considered when implementing any new technology to ensure that unintended consequences are minimized. Regulatory and accreditation organizations include components of risk assessment and quality improvement within their criteria, but hospitals need to incorporate these into their overall plans. Such risk assessments could result in less attention on some HIT implementations. Finally, federal law needs to recognize vendors' accountability for the safety of their products as implemented.

2407

Unit Dose Packaging Availability

Source: Council on Pharmacy Management

To advocate that pharmaceutical manufacturers provide all medications used in health systems in unit dose packages or, when applicable, in packaging that optimizes medication safety, improves operational efficiency, and reduces medication waste; further,

To urge that the Food and Drug Administration require pharmaceutical manufacturers to provide stability data to support the repackaging of medications outside of their original manufacturer bulk containers in the interest of public health, healthcare worker and patient safety, and reduced waste.

This policy supersedes ASHP policy 2253.

Rationale

The benefits of unit dose drug administration were well established in the 1960s. Despite these benefits, some drugs are not available from manufacturers in unit dose packages. One reason sometimes cited for this lack of availability is that because unit dose packages make up a relatively small portion of business for many manufacturers, some manufacturers are making a business decision to discontinue this form of packaging. When manufacturers do not provide drugs in unit dose form, the pharmacy must repackage them, introducing opportunities for error and healthcare worker or patient harm. Increasingly, however, pharmaceutical manufacturers are including verbiage on bulk medication bottles and within package inserts that state "dispense in original container" or similar language. These statements are typically declared without any rationale, studies, or analytical support. The statements and the lack of external

data regarding stability of medications when repackaged have created hardships for health-system pharmacies trying to provide medications in a ready-to-use form for timely administration. This practice may perpetuate drug shortages and lead to avoidable and costly medication and packaging waste. Although it may not be practical for FDA to mandate unit dose packaging to optimize medication and patient safety, improve operational efficiency, and support the interest of public health, FDA could encourage such packaging in other ways, such as by developing packaging guidelines for the pharmaceutical industry. In cases in which unit dose packaging is not practical, manufacturers should at a minimum provide package sizes or medication stability data that would reduce waste.

2408
Supporting High Reliability in Pharmacy Practice
Source: Council on Pharmacy Management
To state that a commitment to the principles and science of high reliability, with the goals of zero medication errors and zero harm, are foundational to pharmacy excellence; further,

To encourage hospitals and health systems to commit to high-reliability principles; further,

To encourage research that informs the creation of best practices in high reliability and progress toward implementation of high-reliability principles in all pharmacy services.

Rationale
High reliability is an ongoing process or an organizational frame of mind, not a specific structure. The Agency for Healthcare Research and Quality has outlined practical strategies for healthcare organizations aiming to become highly reliable in their report of practices employed by hospitals in the High Reliability Organization Learning Network. This mindset is supported by five characteristic ways of thinking: preoccupation with failure; reluctance to simplify explanations for operations, successes, and failures; sensitivity to operations (situation awareness); deference to frontline expertise; and commitment to resilience. High-reliability organizations work to create an environment in which potential problems are anticipated, detected early, and virtually always responded to early enough to prevent catastrophic consequences. The Joint Commission suggests that hospitals and healthcare organizations work to create a strong foundation before they can begin to mature as high-reliability organizations. Such foundational work includes developing a leadership commitment to zero-harm goals, establishing a positive safety culture, and instituting a robust process improvement culture. The Joint Commission also provides metrics and tools for assessing the maturity of an organization's leadership, safety culture, and process improvement culture as preconditions to high reliability. Structured analysis of work processes can eliminate inefficiencies, increase value-added time spent with patients, reduce staff stress, and optimize the use of supplies and other resources.

Reliable information technology systems are critical to ensure care quality and improve efficiency in administrative and process measures. ASHP's PAI 2030 includes a recommendation that states: "C9. Pharmacy should employ high-reliability principles when designing and selecting health information technology." Given the rising cost of healthcare and internal competition for finite capital dollars, it is important to identify solutions that will improve quality and safety

while being fiscally responsible. Research is needed to evaluate tasks and processes to identify better approaches that will reduce waste, improve outcomes, and yield significant savings. Continuous improvement on the delivery of high-value care requires healthcare institutions to continually monitor and improve reliability and performance (see ASHP policy 2206, Continuous Performance Improvement).

2409
ASHP Statement on the Community Pharmacist's Role in the Care Continuum
Source: Section of Community Pharmacy Practitioners
To approve the ASHP Statement on the Community Pharmacist's Role in the Care Continuum.

2410
5-HT$_2$ Agonist, Entactogen, and Empathogen (Psychedelic) Assisted Therapy
Source: Council on Therapeutics
To recognize that psychedelic-assisted therapy (PAT) has demonstrated therapeutic potential and should be further researched; further,

To recognize that in PAT there is not a standardized product subject to the same regulations as a prescription drug product, and to support the development of standardized formulations of psychedelics that would provide consistent potency and quality; further,

To encourage state boards of pharmacy, regulatory agencies, and safety bodies with an interest in PAT to promote research best practices and regulatory standards for medication preparation, compounding, and administration to ensure safety and quality; further,

To advocate that when psychedelics are used for PAT, healthcare providers, including pharmacists, should assess patients for medical, pharmacologic, and psychosocial contraindications prior to use and provide medical assistance as needed.

Rationale
There has been growing interest in the therapeutic potential of psychedelic drugs for use in the treatment of conditions such as depression, posttraumatic stress disorder, substance use disorders, and other conditions. The U.S. Food and Drug Administration (FDA) includes among these psychedelic drugs the "classic psychedelics," typically understood to be 5-HT$_2$ agonists such as psilocybin and lysergic acid diethylamide (LSD), as well as entactogens or empathogens such as 3,4 methylenedioxymethamphetamine (MDMA). As a result of the growing interest, the FDA issued guidance that provides general considerations to sponsors developing psychedelic drugs for treatment of medical conditions.

Many studies report that psychedelic compounds are associated with few adverse events in trials, but the populations studied are not generalizable to the larger population. Psychological safety is a potential concern, and psychological distress is common, though not necessarily harmful in the long term. Increased blood pressure and heart rate due to the distress experienced during the administration session may put individuals with uncontrolled blood pressure or coronary artery disease at risk of ischemic events and may be considered a

relative contraindication. Psychiatric illnesses, including schizophrenia, psychosis, and bipolar disorder, are considered a likely contraindication to psychedelic therapy. Drug-drug interactions of psilocybin, including tricyclic antidepressants, monoamine oxidase inhibitors, selective serotonin reuptake inhibitors, and QT interval-prolonging medications, are of concern and underscore the importance of pharmacists in the management of policies and practices related to the use of psychedelic compounds. Small sample sizes, a lack of diversity in enrollment, a lack of effective blinding, varied doses studied, and selective enrollment are just some of the critiques of trials assessing the use of psychedelic compounds. Psilocybin has been studied mainly in the treatment of psychological distress associated with life-threatening illnesses and major depressive disorder, while MDMA has been studied most extensively in the treatment of posttraumatic stress disorder. Despite promising results of some of the studies, the limitations of the studies prevent firm conclusions from being drawn.

In 2023, the American Medical Association also released new Current Procedural Terminology (CPT) III codes for Continuous In-Person Monitoring and Intervention During Psychedelic Medication Therapy. The codes will provide a mechanism to track and report on the delivery of psychedelic treatments and will cover multiple psychedelic compounds with psychological support models, if approved, as well as various staffing structures, and numbers and credentials of qualified healthcare professionals.

Currently, psychedelic compounds with proposed therapeutic benefit, including psilocybin and MDMA, remain Schedule I substances, with no recognized therapeutic uses. Two states, Oregon and Colorado, have passed laws allowing the legal consumption of psychedelic compounds. Medical organizations have expressed concern about state efforts to circumvent federal laws through this approach, particularly when in the guise of medical treatment. In Oregon, for example, the administration of psychedelics is accompanied by assisted psychotherapy to maximize the possible therapeutic benefits. Prior to administration of the psychedelic compound, the individual will meet with a facilitator in a “preparation” session to review safety and support planning, transportation, and expectations for the administration of the psychedelic compound. The individual is then administered the dose under the supervision of the facilitator. Although these individuals are encouraged to share their past medical histories with the facilitator, it is not required, and the screening needed to ensure an appropriately selected client may fail to detect contraindications or significant drug-drug interactions. Furthermore, facilitators are required to have only a high school diploma and are not required to undergo medical training. This lack of training is of particular concern because individuals who are not trained medical professionals are likely unable to distinguish between medical emergencies and the side effects of the psychedelic compounds.

ASHP policy also aligns with the American Psychiatric Association position that recognizes the emerging scientific evidence for using psychedelic drugs within the context of approved investigational studies and that “clinical treatments should be determined by scientific evidence in accordance with applicable regulatory standards and not by ballot initiatives or popular opinion.”

It is important to recognize that mushrooms containing psilocybin have long been used for rituals and religious ceremonies around the world. As those uses fall within indigenous cultural and religious traditions and are not intended as medical treatment, this policy does not address those uses.

2411
Pharmacy Residency Training
Source: Council on Education and Workforce Development
To continue efforts to increase the number of ASHP-accredited pharmacy residency training programs and positions available; further,

To promote efforts to increase recruitment and retention of residents in ASHP-accredited pharmacy residency programs; further,

To encourage stakeholders to evaluate priority areas within pharmacy for future residency training needs.

This policy supersedes ASHP policy 0917.

Rationale
ASHP is committed to achieving the goal that "pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience" and advocates that "the completion of an ASHP-accredited postgraduate year one residency be required for all new college or school of pharmacy graduates who will be providing direct patient care" (ASHP policy 2027). Furthermore, recommendation B4 of the Practice Advancement Initiative (PAI) 2030 states, "Health systems should require completion of ASHP-accredited residency training as a minimum credential for new pharmacist practitioners." There are opportunities to evaluate recruitment and retention of residents to increase the number of successfully completed residency training programs. In addition, key stakeholders (e.g., colleges of pharmacy, academic medical centers, healthcare organizations, and government agencies) should evaluate priority areas within pharmacy for future training needs, which may include health-system pharmacy administration and leadership, population health management and data analytics, pain and palliative care, medication-use safety and policy, pharmacy informatics, and others.

2412
Prehospital Management of Medications
Source: Council on Pharmacy Practice
To assert that variation in the prehospital management and use of medications is a risk to patient safety and continuity of care; further,

To advocate for pharmacy workforce involvement in clinical and operational decision-making for prehospital management and utilization of medications; further,

To collaborate with stakeholders involved in prehospital medication-use decisions to improve patient safety, minimize variation, and reduce inefficiencies.

Rationale

ASHP advocates that the pharmacy workforce "assume responsibility for medication-related aspects of ensuring the continuity of care as patients move from one care setting to another" (ASHP policy 2205). Prehospital management and utilization of medications is within the continuum of care of patients and varies greatly through patient emergency services, transport, and transfers. The pharmacy workforce has established clinical and operational expertise across the spectrum of medication use, which would add value and safety measures to the prehospital management and utilization of medications. Leveraging that expertise will inform decision-making regarding standardization, management of medication shortages, and prevention of medication errors, among other things. Ensuring pharmacy workforce involvement in these medication-related activities and decisions will optimize medication use and thereby improve prehospital care and patient safety during emergent situations and patient transfers.

2413

Role of Artificial Intelligence in Pharmacy Practice

Source: Council on Pharmacy Practice

To embrace artificial intelligence (AI) as a tool with tremendous potential to improve patient care and the medication-use process through the enhancement of pharmacy practice; further,

To recognize that AI technologies offer innovative ways to gather clinical knowledge, assist learners, enhance educational experiences, and streamline administrative processes; further,

To advocate for standards, policies, and procedures that permit the use of AI in circumstances in which it has proven safe and effective as an augmentation of pharmacy services and to ensure safeguards along with its implementation; further,

To encourage the adoption of policies regarding the use of AI and ongoing surveillance of these tools to maintain professional integrity; further,

To advocate for pharmacy workforce involvement and transparency in the decision-making, design, validation, implementation, and ongoing evaluation of AI-related applications and technologies; further,

To recognize that ethical considerations must guide the development and use of AI in pharmacy practice, and to oppose any use of AI that compromises human interaction or replaces ethical decision-making, professional judgment, critical thinking, or the safety and effectiveness of pharmacy services.

Rationale

Artificial intelligence (AI) is an emerging technology described as intelligent computer programs or software capable of learning human cognition and processes. AI is a valuable tool for hospitals and health systems that can improve healthcare outcomes for the benefit of patients and augment capabilities of the pharmacy workforce. AI falls under two categories: machine learning (ML) for data set analysis and natural learning processes for information extraction from existing

data. AI technology has evolved at an immense speed, and healthcare organizations have been increasingly digitizing data. Therefore, organizations must determine AI's use to improve patient-specific care on a grand scale without compromising patient safety and outcomes, and how to retain the expertise, autonomy, and humanity (e.g., empathy, compassion, and ethical decision making) of the interprofessional care team.

The potential benefits of AI in patient care include, but are not limited to, optimizing patient outcomes, improving implementation of high reliability principles, decreasing process variability, increasing evidence-based practices, streamlining Non-Relative Value Unit (RVU) generating processes, and re-focusing providers on clinical functions. The rapid advancement of generative AI technologies, such as ChatGPT, has also introduced new possibilities in the realm of education. These technologies appear to offer innovative ways to assist learners, enhance educational experiences, and streamline administrative processes.

The pharmacy workforce should collaborate with other healthcare professionals, professional organizations, and stakeholders to research, develop, implement, and improve the quality of AI/ML-based clinical models that affect medication-use processes and tasks. This collaborative team should ensure seamless integration of AI into the broader healthcare ecosystem, promoting the sharing of best practices and knowledge. The pharmacy workforce should maintain competence and continuing education in AI-related technologies that will advance pharmacy practice. Healthcare providers must recognize the need for sufficient purview and monitoring to guarantee patient safety and effective therapy. Risk should be formally assessed and mitigated as necessary. AI vendors and the pharmacy workforce independently have the responsibility to understand how AI solutions are functioning, impacting pharmacy clinical workflows, protecting patient data privacy and security standards, maintaining compliance with all relevant legal statutes, and identifying limitations in supporting practice and clinical services. Additional and applicable expectations for vendors can also be found in ASHP policy 1418, Risk Assessment of Health Information Technology.

Risks of AI use in patient care may include potential for breaches in patient privacy and safety, failure to incorporate ethical and moral decision-making, lack of transparency, automation biases, and narrow algorithm development that does not account for diverse populations and threatens to widen health disparities in underrepresented patient populations. Given these risks, the pharmacy workforce and other healthcare professionals must retain oversight of AI applications and their implementation. The pharmacy workforce should have access to mechanisms to report AI-caused errors or adverse events. Healthcare organizations, hospitals, and colleges of pharmacy should develop policies, procedures, and guidelines to determine which care settings, medications, and patient populations are appropriate candidates for the use of AI. Even if AI technology eventually accounts for every possible variable, final decision-making should be left to the healthcare team to mitigate its inherent risks and biases. Integration of AI tools also raises concerns about academic integrity, plagiarism, and the potential for unethical use that could undermine the educational process.
As such, hospitals, health systems, and colleges of pharmacy should adopt policies regarding the appropriate use of AI across the continuum of learning, from didactic to experiential, and within the clinical learning environment.

The pharmacy workforce should consider the transformative potential of AI in pharmacy practice, but also the ethical, professional, and practical considerations associated with its

integration. These principles provide the pharmacy workforce a roadmap to navigate the evolving landscape of AI while upholding the highest standards of patient care and professional responsibilities.

2414
Pharmacist's Role on Ethics Committees
Source: Council on Pharmacy Practice
To advocate that pharmacists should be included as members of hospital and health-system ethics committees; further,

To encourage pharmacists to actively seek ethics consultations as appropriate; further,

To support continued inclusion of ethics in pharmacy education and encourage pharmacists serving on ethics committees to seek advanced training in healthcare ethics.

This policy supersedes ASHP policy 1403.

Rationale
Many hospitals have a committee or other process by which they consider ethical decisions related to patient care. Many issues that face these committees involve medications, yet often pharmacists do not serve on the committee or are not directly involved in the decision-making process related to ethical issues. The number of ethical issues involving medications is expected to increase, given many new and unique drug products coming into the market. These include patient access to high-cost medications, considerations during medication shortages, and other ethical considerations that surface as part of the formulary process. Pharmacist involvement would better inform these committees and consultations. To effectively contribute to decision-making on ethics, pharmacists will require advanced education on the subject.

2415
Enhancing the Safety of Hazardous Drug Product Handling
Source: Council on Pharmacy Practice
To advocate that pharmaceutical manufacturers and wholesale distributors employ decontamination practices to eliminate surface contamination on packages of hazardous drugs (HDs); further,

To advocate that pharmaceutical manufacturers develop closed-system transfer device compatible, ready-to-administer HD products; further,

To advocate for standardized labeling and package design for HDs that would alert handlers to the potential presence of surface contamination; further,

To advocate for pharmacist involvement in the development of policies, procedures, and operational assessments regarding administration of HDs.

This policy supersedes ASHP policies 1615 and 1902.

Rationale

Hazardous drugs (HDs) present well-known risks to healthcare workers who handle them. Most HDs are administered orally or intravenously; however, other routes of administration are sometimes used, such as intrathecal, intraventricular, or intravesicular administration, or perfusion into a vessel or organ cavity. The protective precautions required for administration through these routes is well described in United States Pharmacopeia (USP) General Chapter <800>, the ASHP Guidelines on Handling Hazardous Drugs, the Oncology Nursing Society's *Safe Handling of Hazardous Drugs*, and other sources.

Healthcare providers are required to use personal protective equipment and other protective devices, such as closed-system transfer devices (CSTDs), when the dosage form allows. To reduce the risks to healthcare providers, ASHP encourages device and pharmaceutical manufacturers and the Food and Drug Administration (FDA) to deploy new production and processing standards to mitigate exposures, including label and package design that alerts handlers to the possibility of contamination. In addition, manufacturers and the FDA should develop CSTD-compatible, ready-to-administer HD drug products with the goal that CSTDs be utilized for all routes of administration of HD products as a best practice.

HDs are sometimes administered through other routes (e.g., Ommaya reservoirs, intraperitoneal infusion) for which protective precautions are not as well described or CSTD use is not possible. However, when such use is not possible, an assessment of risk will identify gaps and ensure there are pharmacy-guided policies to address the handling, compounding, and administration for all healthcare staff coming into contact with HDs during administration via nontraditional routes. Such policies should also address any specialized training for staff in procedural areas, or the availability of a staff member with HD-specialized training to assist in the administration of the drug (e.g., a "chemo nurse").

ASHP encourages all healthcare settings to conduct an interprofessional, proactive assessment of the risk of such procedures to evaluate the potential exposure risks for healthcare providers and identify mitigating measures. Given their depth of knowledge regarding the handling of HDs, the pharmacy workforce should be involved in the development of policies, procedures, and operational assessments regarding administration of HDs in such circumstances.

The outer surfaces of vials of HDs have been shown to be contaminated, unwittingly exposing pharmacy and other personnel handling those vials to hazardous substances. ASHP advocates that individuals involved in drug distribution, receiving, and inventory control adhere to safe handling guidelines, including ASHP guidelines and USP General Chapter <800>, to avoid undue exposure to hazardous substances. Recognizing the limits of these best practices, pharmaceutical manufacturers have a responsibility to provide vials that are devoid of surface contamination by ensuring adequate vial-cleaning procedures such as using decontamination equipment and protective sleeves during the manufacturing process.

2416
Independent Double Checks for Single Practitioners
Source: Council on Public Policy
To advocate for implementation of independent double checks, when feasible, to reduce the risk of error when a single practitioner is solely responsible for ordering, dispensing, administering, and monitoring medication therapy.

Rationale
As pharmacy practice has evolved to include more direct patient care services, oversight of these services has not kept pace. This trend was exacerbated by the COVID-19 pandemic, which ushered in new test-to-treat models for pharmacy teams and introduced new flexibilities into telehealth. As care has shifted, pharmacists may be placed in situations in which they are overseeing many aspects of medication use, from independent prescribing to dispensing, without any additional verification checks. Other clinicians, including physicians and nurse practitioners, may also be in similar positions. Regardless of setting, without adequate patient safety safeguards (e.g., high-reliability process, technology and/or human review), placing one clinician in charge of the elements of the medication-use process related to ordering, dispensing and administration, as well as any patient evaluation and monitoring, increases the risk for errors and adverse outcomes. While human checks are preferable for high-risk drugs, nothing in this policy should be considered to oppose appropriate autoverification of orders.

2417
State Prescription Drug Monitoring Programs
Source: Council on Public Policy
To support continued state implementation of prescription drug monitoring programs that collect real-time, relevant, and standard information from all dispensing outpatient entities about controlled substances and monitored prescriptions; further,

To advocate that such programs and states seek adoption into health information exchanges to best integrate into electronic health records and to allow prescribers, the pharmacy workforce, and other practitioners to proactively monitor data for appropriate assessment and dispensing; further,

To advocate that such programs improve their interstate data integration to enhance clinical decision-making and end-user satisfaction; further,

To advocate against unilateral use of these systems that may lead to patient stigmatization or prevent them from seeking appropriate medical care; further,

To encourage policies that allow the pharmacy workforce to gain access to databases without holding licensure in each state; further,

To promote research on the effects of prescription drug monitoring programs and electronic health record programs on prescribing, dispensing, misuse, morbidity, and mortality.

This policy supersedes ASHP policy 1408.

Rationale

ASHP recognizes the important contributions to public health made by state prescription drug monitoring programs (PDMPs). To be effective, these programs need to be mandatory; must collect standardized, relevant, and real-time information for analysis and comparison among states; and need to be universal and accessible by the pharmacy workforce. However, reporting of information to the PDMP should not be used for the purposes of stigmatizing patients or criminalizing the provision of necessary patient care (e.g., requiring reporting of mifepristone prescriptions).

All states have implemented PDMPs, with the final state, Missouri, implementing its PDMP on January 20, 2023. While this is a great step forward, continued improvement of PDMP utilization is required. A recent review of PDMP reviews by Tay et al. in the *Journal of Drug and Alcohol Dependence* identified the following still-existing barriers: PDMP system-related functionality (i.e., usability, data quality), end-user-related experience (i.e., satisfaction, workflow efficiency), and broader issues (i.e., electronic health record [EHR] integration, data sharing). More importantly, not all states mandate provider use of PDMP prior to controlled substance prescribing, and states that do mandate its use are slow to hold providers/pharmacists accountable for not using it. Due to these factors, it is difficult for practitioners to make relevant clinical decisions.

Improved data sharing between different jurisdictions, enhanced interoperability with EHRs and information exchanges, and increased evidence of PDMPs' impacts on patient outcomes are needed to increase utilization and augment states' PDMPs. Finally, adequate state and federal funding is essential to sustain the viability of these programs and to encourage research, education, and implementation of best practices in PDMPs.

2418

Testing for Pregnancy Status

Source: Council on Therapeutics

To affirm that pregnancy testing should occur only with the patient's informed consent or assent, when feasible, and only when the test results would change medical management; further,

To affirm that a positive pregnancy test should not compromise the integrity of evidence-based, patient-centered care.

Rationale

Screening and testing for the pregnancy status of patients prior to admission to a hospital or surgical center or before initiation of a teratogenic drug therapy has long been a routine practice, as the pregnancy status of a patient has many ethical and legal considerations when medical management is considered for patient care. Chief pharmacy officers often oversee laboratory medicine departments, and pharmacists are often involved in creating protocols and

order sets in which pregnancy testing and screenings are embedded. As a result, pharmacists are key stakeholders in this practice.

It is important to note that this policy pertains to testing without informed consent or assent when therapy may need to be changed due to a positive test. The balance between unnecessary testing and testing when initiating a medication therapy is supported by a 2015 study that found that pregnancy assessment was underutilized in the emergency department when patients were prescribed a pregnancy category D or X drug. This policy does not advocate that healthcare professionals should not include pregnancy screening as a part of a patient history, only that pregnancy testing should occur only with informed consent or assent and not be a requirement for care. The incidence of unknown pregnancy in adult women presenting to a hospital for surgical procedures varies from 0.125 to 1.2%, depending on the procedure. It is important to note that testing should occur when feasible, as care should not be delayed in emergent or urgent scenarios.

This policy also aligns ASHP with the American Society of Anesthesiologists statement that recommends "pregnancy testing may be offered to female sex patients of childbearing age and for whom the result would alter the patient's management, but testing should not be mandatory. Informed consent or assent of the risks, benefits, and alternatives related to preoperative pregnancy testing should ideally be obtained. Best practice may employ shared decision-making between patients and providers."

2419

Nonprescription Status of Rescue and Reversal Medications

Source: Council on Therapeutics

To support the nonprescription status of medications intended for evidence-based rescue use or reversal of potentially fatal events, in delivery systems appropriate for administration by lay persons; further,

To promote practices and policies that ensure affordable and equitable access to rescue and reversal medications; further,

To support and foster standardized education and training on the role of rescue and reversal medications and their proper storage, proper administration, safe use, and appropriate follow-up care.

Rationale

As part of public health initiatives, certain medications used for rescue and reversal have moved from prescription to nonprescription status. The opioid reversal agent naloxone is the most recent approval, with naloxone nasal spray approved in March of 2023 to help combat the opioid epidemic in the United States. Rescue and reversal medications such as naloxone and epinephrine require an additional level of action from patients and caregivers because they are used to initially treat life-threatening conditions, in contrast to other nonprescription agents. These patients will often require an additional level of care to monitor for safety and potential adverse events in the event of an opioid overdose or anaphylactic reaction. Therefore, it is important that rescue and reversal medications considered for nonprescription status have

evidence that supports their use.

As barriers to access are removed, patient demand for these life-saving agents will almost certainly skyrocket, aligning with the intended purpose of such initiatives. To forestall the possibility of counterproductive market shortages, efforts to support and enhance manufacturing processes should be bolstered, with the U.S. Food and Drug Administration (FDA) likely being the most effective entity for these interventions.

Similarly, pricing for rescue and reversal medications should be minimized as much as possible, including efforts to eliminate patient cost entirely. Nonprescription status often results in loss of third-party payer coverage, although there are notable exceptions to this trend (e.g., aspirin, vitamin D). The Affordable Care Act established a precedent for requiring insurer coverage of preventive drugs, and similar provisions could be made for rescue and reversal agents. Government efforts could include other related strategies, such as developing manufacturing cost subsidies, supporting tax-exempt status designations, and augmenting the wholesale distribution process and related infrastructure.

Finally, because the use of rescue and reversal medications often occurs in an emergency situation, proper storage and easy-to-understand instructions on how to use these drugs and how to escalate if a person does not respond should be encouraged by all manufacturers. These instructions should be designed, tested, and validated in a similar design to the Drug Fact Label created by the FDA, which is designed to assess whether all the components of the product with which a user would interact could be used safely and effectively as intended.

2420

Opposition to Pharmacy Jurisprudence Examination Requirement

Source: Council on Education and Workforce Development

To advocate for the removal of standalone examination of federal or state pharmacy law as a requirement for licensure to increase interstate practice flexibility; further,

To support ongoing education of the pharmacy workforce on pertinent federal and state pharmacy laws; further,

To acknowledge that it is a professional obligation of the pharmacy workforce to practice in compliance with federal and state laws.

Rationale

National pharmacy associations have recently joined in advocacy for a more portable pharmacist license. Pharmacist interstate movement and practice are inhibited by the state-specific nature of the pharmacy jurisprudence examination. The pharmacist's licensing process includes one clinical knowledge exam (the NAPLEX), and in 48 states a jurisprudence exam is required, typically the Multistate Pharmacy Jurisprudence Examination (MPJE) — a 2.5-hour adaptive and proctored test. In contrast, physicians take three clinical knowledge exams, and only Texas, Oklahoma, Maine, and Oregon require a jurisprudence exam, which is taken online and is open-resource. Nurses are required to take one clinical knowledge exam (the NCLEX), and only Texas and Kentucky require a jurisprudence exam, which is also online and open-

resource. A 2017 working paper from the National Bureau of Economic Research found that pharmacists ranked among the lowest in terms of between-state migration, at -47%, compared to nurses (+5.5%) and physicians (+33%). While licensure in multiple states has always been almost a prerequisite for practitioners whose systems are in multi-state areas (e.g., VA, MD, DC), the advances in telehealth have made multistate licensure compulsory for many more pharmacists. Removal of standalone examinations would inevitably increase interstate practice flexibility.

Accreditation Council for Pharmacy Education accreditation standards require pharmacy law as part of the curriculum, but student pharmacists may not practice in the state in which they receive their education, and support of ongoing education on pertinent federal and state pharmacy laws should be provided to the pharmacy workforce. Even absent the state law exams, continuing education requirements and professional responsibility require the pharmacy workforce to know the laws in the state(s) in which they are licensed.

2421

Documentation of Patient-Care Services in the Permanent Health Record

Source: Council on Pharmacy Management

To advocate for public policies that support documentation of patient-care services provided by the pharmacy workforce in the permanent patient health record; further,

To advocate for the design and use of electronic health records with a common documentation space to accommodate all healthcare team members.

This policy supersedes ASHP policy 1419.

Rationale

Documentation in the patient record is critical for a complete record for patient care and communication among members of the healthcare team. Documentation should be done within an electronic health record (EHR) to the fullest extent possible. ASHP supports the use of post-licensure credentialing, privileging, and competency assessment, in a manner consistent with other healthcare professionals, to practice pharmacy as a direct patient-care practitioner (ASHP policies 2011, Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice, and 1415, Credentialing, Privileging, and Competency Assessment).

Pharmacy technicians, within their scope of practice, have documented activities (e.g., medication history documentation) in the record as part of team-based care documentation. When documenting electronically, use of standardized and coded formats allows for improved measurement of patient outcomes.

2422

Safe Medication Sourcing, Storage, Preparation, and Administration in All Sites of Care

Source: Council on Pharmacy Management

To advocate that all sites of care be required to meet the same regulatory standards for medication sourcing, storage, preparation, and administration to ensure safety and quality.

This policy supersedes ASHP policy 1914.

Rationale

Payers have implemented strategies that fragment providers' comprehensive care management of the patient. These strategies include but are not limited to site-of-care (SOC) optimization, which shifts care away from hospitals, and payer-directed drug distribution models (ASHP policy 2309, Payer-Directed Drug Distribution Models), which undermine hospitals' patient safety protections and jeopardize patient care. The payers' overarching goal is cost containment, while maintaining access to the prescribed therapy. Cost containment efforts have shifted beyond the traditional pharmacy point-of-sale management intended for self- administered medications under the pharmacy benefit, such as formulary tiering, prior authorization requirements, drug exclusions, and step therapy implementation. Payer strategies targeting provider-administered medications under the medical benefit present risks to patient care and safety. Patients are increasingly being required to receive care at lower-cost nonhospital SOCs, rather than at traditional venues, such as hospital outpatient infusion centers. Alternative or nonhospital SOCs include nonhospital-affiliated outpatient infusion centers, physicians' offices, ambulatory infusion centers, or patients' homes. Payer-imposed SOC restrictions and policies jeopardize the continuity of care for the patient by introducing incongruent providers and systems (ASHP policy 2031, Continuity of Care in Insurance Payer Networks). These same policies also create additional logistical challenges for the patient to navigate and can impede timely access to care for patients who require additional special assistance or services, such as access to emergency staff in the event of an adverse reaction.

Further, the level of infrastructure required to adequately address regulatory and accreditation requirements focused on quality and safety (e.g., United States Pharmacopeia General Chapters
<797> and <800>, Drug Supply Chain Security Act, state board of pharmacy regulations, and the standards of accreditors such as The Joint Commission and Det Norske Veritas Healthcare) varies across SOCs, with hospitals carrying the greatest administrative burden and costs. As a result, health systems should collaborate with pharmacy leadership when exploring ways to optimize medication access and appropriate utilization in nonhospital SOCs.

2423

Independent Prescribing Authority

Source: Council on Pharmacy Practice

To affirm that pharmacists are highly trained medication experts on the interprofessional care team who make evidence-based decisions; further,

To advocate that pharmacists have independent authority to initiate, monitor, modify, and deprescribe all schedules and classes of medications, commensurate with the pharmacist's training and in accordance with the standard of care; further,

To encourage healthcare delivery organizations to establish credentialing and privileging processes for pharmacists that delineate scope of practice, support pharmacist prescribing, and

ensure that pharmacists who prescribe are accountable, competent, and qualified to do so; further,

To advocate that pharmacists be recognized as authorized providers by payers, pharmacies, and industry.

This policy supersedes ASHP policies 2236 and 2251.

Rationale

Pharmacists are highly trained medication experts skilled in providing comprehensive medication management (CMM) services across the continuum of care. As such, pharmacists are core members of the healthcare team, well-positioned to provide high-quality, cost-effective care that increases patient access and reduces the burden on other healthcare providers. Hundreds of studies published in peer-reviewed literature, conducted throughout a variety of organizations and health systems, have consistently demonstrated the benefits of pharmacist-directed patient care across a variety of clinical practice settings.

Independent, or autonomous, prescribing allows pharmacists to be responsible and accountable and fully execute CMM treatment plans. Independent medication therapy decision-making by pharmacists is already common and accepted by other licensed practitioners (e.g., physicians, physician assistants, and nurse practitioners). Practitioners participating in interprofessional teams that include pharmacists rely on the knowledge, demonstrated competency, and expertise of those pharmacists for CMM. Pharmacists in specialty practice areas such as anticoagulation management, solid organ transplant, and nutrition support have long functioned in roles in which independent prescriptive authority has improved clinical outcomes in the management and monitoring of medication therapy. In settings such as the Indian Health Service and Veterans Health Administration systems, prescriptive authority for pharmacists providing CMM services has been in place for over 40 years and has demonstrated positive clinical impact and increased patient access across the continuum of care.

Enabling state and institutional policy are critical in ensuring that pharmacists can seamlessly provide CMM services as members of the interprofessional team and at the top of their training and education. States authorize pharmacists to independently or collaboratively prescribe or initiate medications at varying degrees. Many health systems authorize pharmacists to manage medication therapy by enacting pharmacy and therapeutics committee policies that require use of medical staff delegation protocols and physician oversight for pharmacist-initiated orders. Pharmacist autonomous prescriptive authority should be the gold standard for practice, especially when appropriate credentialing and privileging is in place and there is a separation of duties to ensure that a prescribing pharmacist is not responsible for the processing and dispensing of that medication order, except during extenuating circumstances.

Credentialing and privileging of individual healthcare providers is essential for determining who is authorized to prescribe and should ensure the appropriate evaluation of the quality of care provided. The credentialing procedures used to establish pharmacists' competency to prescribe must ensure that patients receive treatment from highly qualified caregivers. In addition to verifying appropriate education, licensure, and certification, the

process should include:

- the same transparency and rigor applied to other prescribers,
- criteria used to measure patient care quality, and
- peer review by similar or higher-level peers (i.e., pharmacist prescribers or other licensed practitioners who are authorized to prescribe).

Healthcare organizations should use privileging methods that establish the scope of practice and clinical services that pharmacists are authorized to provide commensurate with their demonstrated competency within an area or areas of clinical expertise. The practice of credentialing and privileging should be consistent between hospitals, health systems, accountable care organizations, and other organizations where pharmacists function as a part of the interprofessional team.

ASHP Policy 2011, Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice, stipulates that pharmacists who prescribe must be recognized by payers and receive equitable payment for performing these advanced practice services. All pharmacist prescribers must possess a National Provider Identifier to monitor the care provided and should be reimbursed for services rendered. Finally, interprofessional education and training programs should incorporate the standard of pharmacist prescribing to ensure consistency and acceptance of pharmacist prescribing in similar practice settings and with similar levels of responsibilities.

2424

Additional Education Requirements for Pharmacy Technicians in Advanced Roles

Source: Council on Education and Workforce Development

To recognize that highly trained and skilled pharmacy technicians working in advanced roles regularly perform complex and critical medication-use procedures, and that a safe and effective medication-use process depends significantly on the skills, knowledge, and competency of those pharmacy technicians to perform those tasks; further,

To reaffirm that all pharmacy technicians should complete an ASHP/ACPE-accredited training program, be certified by the Pharmacy Technician Certification Board, and be licensed by state boards of pharmacy; further,

To advocate that pharmacy technicians working in advanced roles have additional training, such as an associate degree, and demonstrate ongoing competencies specific to the tasks to be performed, to ensure patient safety.

This policy supersedes ASHP policy 1203.

Rationale

Pharmacy technician roles have undergone a significant transformation within health systems throughout the years. In today's intricate healthcare landscape, these pharmacy technicians take on advanced responsibilities beyond their traditional duties. These extended roles include managing information systems, sterile product preparation, handling logistics, and

implementing cutting-edge technology. According to the 2022 ASHP National Survey, more advanced pharmacy technician roles are emerging, including 340B Drug Pricing Program management, responsibility for USP General Chapter <797> (USP <797>) compliance, initiation of medication reconciliation, and supervision of other technicians. Pharmacy administrators have also reported a range of functions that health-system technicians perform, including sterile and nonsterile compounding, inventory management, purchasing, hazardous drug handling, controlled substance system management, medication order distribution, supervisory responsibilities, billing and reimbursement, and technician education and training. These advanced roles will require different skills and competencies, and pharmacy technicians should demonstrate competency before being allowed to perform such tasks, which will require additional, task-specific training.

The advancement of the pharmacy technician workforce includes credentialing, licensing, and on-the-job training. Moreover, engaging in formal education such as an associate degree equips pharmacy technicians with the necessary skill set to excel in these multifaceted roles, aids human resources departments in assigning an appropriate job code and pay grade, and elevates the pharmacy profession more broadly. Furthermore, other technical personnel in the healthcare sector (e.g., radiology technicians, respiratory therapists, laboratory technicians) are moving towards requiring a minimum of an associate degree and completion of an accredited training program, and aligning pharmacy technician requirements with other professions provides another pathway for enhanced remuneration. It is recognized that these measures are synergistic with, and should not replace, existing educational requirements for pharmacy technicians working in advanced roles including the ASHP/ACPE-accredited training program, certification by the Pharmacy Technician Certification Board, state board of pharmacy licensure, professional certificate programs, and institution-based programs such as those from the military and armed services. It is the intent that these collective measures would promote recruitment and retention of the pharmacy technician workforce within hospitals and health systems.

2425
Liability Protection
Source: Council on Public Policy
To advocate that the pharmacy workforce be able to provide services consistent with the standard of care to patients without fear of legal consequences, harassment, or liability; further,

To advocate that protection against liability extend to referrals for out-of-state care and for providing services consistent with the standard of care to patients from another state.

Rationale
In some states, pharmacists face potential civil or criminal liability for providing certain patient care services consistent with the standard of care, including services related to reproductive health, gender-affirming care, and prevention and post-prophylaxis for HIV. Subjecting pharmacists to such liability for providing patient services consistent with the standard of care not only inappropriately infringes on the practice of pharmacy, it increases risks to patients. Given the chilling effect of the laws impeding certain patient care services, patient access to

services may be reduced or eliminated. Treatment delays, particularly for time-sensitive care related to reproductive health and provision of post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP), adversely impact patient care and outcomes and may result in patient or fetal mortality. Further, fear of prosecution could not only unduly limit the number of pharmacists willing or able to provide these services, but also significantly hinder training and specialization in these areas in the next generation of clinicians, damaging our nation's clinical pipeline. This policy is meant to apply only to care provided consistent with the standard of care and would not extend to protect against liability associated with negligence or malpractice.

2426
Access to Reproductive Health Services
Source: House of Delegates
To recognize that reproductive healthcare includes access to and safe use of medications; further,

To recognize that reproductive health services include pre-conception, conception, post-conception, and termination of pregnancies; further,

To advocate for access to safe, comprehensive reproductive healthcare for all patients, including historically underserved patient groups such as patients of color, those with limited means, and those living in rural areas; further,

To advocate that medications related to reproductive health not be reclassified as controlled substances and that dispensing of those medications not be required to be reported to prescription drug monitoring programs; further,

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

This policy supersedes ASHP policy 2250.

Rationale
Reproductive health has been defined as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes," and reproductive healthcare has been defined as "the constellation of methods, techniques and services that contribute to reproductive health and well-being by preventing and solving reproductive health problems." (International Conference on Population and Development Programme of Action, Twentieth Anniversary Edition, United Nations Population Fund, Sep 2014). In the U.S., the term "reproductive health services" is defined in 18 USC § 248(e)(5) as "medical, surgical, counselling or referral services relating to the human reproductive system, including services relating to pregnancy or the termination of a pregnancy." Reproductive health services include pre-

conception, conception, post-conception care, including termination of pregnancies, and reproductive healthcare includes access to and safe use of medications.

ASHP advocates for access to safe, comprehensive reproductive healthcare for all patients, including historically underserved patient groups. Studies show that there have been longstanding disparities in access to and outcomes from reproductive health services in the U.S., especially for racial and ethnic minorities. For example, black women have the highest maternal morbidity and mortality rates in the country. These disparities include contraceptive use, reproductive cancers, preterm deliveries, and maternal morbidity and mortality. (Sutton MY, Anachebe NF, Lee R et al. Racial and ethnic disparities in reproductive health services and outcomes, 2020. *Obstet Gynecol.* 2021; 137:225–33.)

The reproductive health medications misoprostol and mifepristone have been reclassified as Schedule IV controlled substances in Louisiana, effective October 1, 2024 (Louisiana Act 246, 2024). The classification of controlled substance is typically reserved for medications with potential for abuse that may lead to physical or psychological dependence and safety liability. There is no evidence suggesting that misoprostol and mifepristone have a likelihood for abuse or physiological dependence, despite decades of approved use in the U.S. The improper classification of reproductive health medications burdens providers and patients and can lead to a dangerous stigma for patients prescribed the medications for purposes other than abortion, such as mifepristone for managing the effects of miscarriage or misoprostol for treating or preventing stomach ulcers. Prescription drug monitoring programs require reporting of dispensed controlled substances, often across state lines, which could increase risks of prosecution for both providers and patients who seek or provide these medications.

On June 24, 2022, the Supreme Court of the United States overturned *Roe v. Wade*, freeing states to restrict or outlaw abortion. Thirteen states had implemented trigger laws that would outlaw abortion almost immediately, and 26 states were expected to ban or severely restrict access to abortion. These state laws are likely to impact patient access to necessary treatments, including medications, and the practice of pharmacy, in the following ways:

- *Access to necessary treatments:* Pharmacists are involved in treating patients with ectopic pregnancy or pregnant patients with cancer diagnoses. These laws could limit patient access to lifesaving treatments because of the risk of legal liability for providers. Pharmacists have a role in providing medications for these treatments as well as supporting patients' mental health and well-being related to reproductive health.
- *Access to medications:* A number of companies have formed that provide telehealth access to medications used to induce abortion. There are likely to be challenges to interstate mail order of these medications. In addition, some overseas companies also provide these medications, which raises questions about foreign importation of medications. ASHP opposes wholesale importation of medications from other countries due to supply chain security concerns but does not object to patients ordering from legitimate foreign pharmacies for their personal needs. Further, medications (e.g., misoprostol) that are used off-label as abortifacients but have other clinical uses may become harder for patients to access because providers fear the legal liability for prescribing or dispensing these medications. Finally, access to medications is a national security issue. For examples, the Department of Defense is required by law to make contraceptive services available to all female active-duty servicemembers.

- *Clinician judgment:* Restrictions on medication abortion function as limitations on clinicians' professional judgment. As noted above, because some medications can be used off-label as abortifacients, it is possible that there will be increased scrutiny of the prescribing and dispensing of certain medications. Further, some states are pursuing laws that would allow citizens a private right of action against a clinician who assists in an abortion (i.e., "bounty laws"). These laws could create civil and/or criminal liability against clinicians who prescribe or dispense abortion medications.

In addition to these concerns, other procedures that are not abortion but might result in destruction of an embryo (e.g., in vitro fertilization therapy) could fall into an uncertain legal zone. Medications used to induce labor to protect a pregnant patient could be restricted. Because the decision in *Roe v. Wade* was based on a constitutional right to privacy, other privacy-related rulings are now in question, including *Griswold v. Connecticut*, which allowed access to contraception.

The decision to terminate a pregnancy is a complicated, difficult, and often extremely emotional choice for patients and healthcare providers, and it often involves weighing the risks to the pregnant patient. Under some state laws, pregnant patients could be prosecuted for seeking lifesaving treatment, and healthcare providers involved in these difficult decisions and providing necessary treatments could be subject to unjust criminal prosecution. ASHP believes that healthcare workers should be able to provide reproductive healthcare per their clinical judgment and their conscience without fear of legal consequence, workplace sanctions, social stigmatization, harassment, or harm.

2427
Use of Two Patient Identifiers in the Provision of Patient Care
Source: Council on Pharmacy Practice

To encourage the use of two unique identifiers during the provision of patient care.

This policy supersedes ASHP policy 2010.

Rationale
Errors caused by dispensing or administering medications to the wrong patient are largely preventable. The Institute for Safe Medication Practices reports that dispensing a correctly prepared prescription to the wrong patient in community pharmacies is the most common complaint reported to the National Consumer Medication Errors Reporting Program, with approximately 25% of events resulting in patient ingestion of the wrong medication. The Joint Commission (TJC) recognizes that wrong-patient errors occur in all stages of diagnosis and treatment in hospitals and health systems. Both organizations call for a standard approach to verify a patient's identity using at least two patient identifiers.

TJC defines a patient identifier as "Information directly associated with an individual that reliably identifies the individual as the person for whom the service or treatment is intended. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, date of birth, or other person-specific identifier." ASHP supports the consistent use of

two patient identifiers in the dispensing and administration of medications during the provision of care in all care settings. ASHP also believes that bar code medication administration is important for verification of medication use, however, should not be a replacement for verifying a patient's identity with two patient identifiers.

2428
ASHP Statement on Artificial Intelligence in Pharmacy
Source: Section of Pharmacy Informatics and Technology
To approve the ASHP Statement on Artificial Intelligence in Pharmacy.

This statement supersedes the ASHP Statement on the Use of Artificial Intelligence in Pharmacy dated May 20, 2020.