House of Delegates

Board of Directors Report: Policy Recommendations for the March 2024 Virtual House of Delegates

COUNCIL ON PHARMACY PRACTICE POLICY RECOMMENDATIONS

The Council on Pharmacy Practice is concerned with ASHP professional policies related to the responsibilities of pharmacy practitioners. Within the Council's purview are (1) practitioner care for individual patients, (2) practitioner activities in public health, (3) pharmacy practice standards and quality, (4) professional ethics, (5) interprofessional and public relations, and (6) related matters.

Jennifer Tryon, *Board Liaison*

1. Role of the Pharmacy Workforce in Improving Mental Health

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.

Background

The Council examined this topic in response to a recommendation from the 2023 House of Delegates. Council members felt that ASHP policy was needed to raise awareness of the importance of mental health for patients and healthcare workers, advocate for improved

access to pharmacist services, and to leverage the entire pharmacy workforce in screening for and triaging mental health conditions. The Council discussed use of the term *mental health* versus *behavioral health* and decided to use the former to be consistent with the World Health Organization and to use less stigmatizing terminology.

The Council also recommended that the Council on Education and Workforce Development consider adding language emphasizing the importance of ensuring members of the pharmacy workforce are able to access to mental health services and the risk of moral injury to pharmacy workforce mental health in ASHP policy 2329, Well-Being and Resilience of the Pharmacy Workforce.

2. Independent Prescribing Authority

To affirm that prescribing is a collaborative process that includes patient assessment, understanding of the patient's diagnoses, evaluation and selection of available treatment options, monitoring to achieve therapeutic outcomes, patient education, and adherence to safe and cost-effective prescribing practices; further,

To recognize that pharmacists are highly trained medication experts on the interprofessional care team capable of making independent and autonomous evidence-based decisions on medication therapy management; further,

To advocate that pharmacists have independent and autonomous authority to initiate, modify, and deprescribe all schedules and classes of medications; further,

To advocate that healthcare delivery organizations 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 all pharmacists have a National Provider Identifier that is recognized by payers.

Note: This policy would supersede 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. Nearly all states include pharmacist prescribing authority within their state practice acts, although those acts differ in how pharmacist prescribing authority is described, terminology used, and the degree of prescribing autonomy (i.e., autonomous or collaborative). Regulations at the state level are critical to ensuring that pharmacists can seamlessly provide CMM services within the

interprofessional team and to the top of their skills and abilities. Pharmacists are a core healthcare team member, 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. A 2010 comprehensive systematic review of 298 studies of U.S. pharmacists' effect as a member of the patient care team found positive results on therapeutic and safety metrics (Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. *Med Care.* 2010; 48:923-33).

Autonomous prescribing allows pharmacists to be fully optimized as a part of the interprofessional healthcare team and ensures that their skills are used to the fullest potential to allow them to be responsible and accountable and fully execute CMM treatment plans. Pharmacist prescribing is implicit to interprofessional care delivery, but the form and manner of pharmacist prescribing varies among health systems and organizations. Independent and autonomous drug 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 autonomous prescribing 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, prescribing 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.

Many health systems authorize pharmacists to manage drug therapy by enacting pharmacy and therapeutics committee policies that require use of medical staff protocols and physician oversight for pharmacist-initiated orders. While this model works effectively for specific scenarios (e.g., management of population-specific patients), it does not allow the pharmacist to fully function and fulfill the CMM needs of their patients. Depending on the patient, medication, and degree of trust with the pharmacist, physicians often delegate therapeutic decision-making and medication treatment planning to pharmacists, based on the trust relationship developed through the interprofessional team and shared experiences in successfully dealing with challenging clinical situations, rather than through formal collaborative practice agreements. Common examples of pharmacist prescribing include independently managing symptoms and adverse events in oncology patients, identifying and resolving drug-induced disease or problems, managing anticoagulant therapy for patients whose clinical status falls outside specified parameters, and responding to general directives to simply "fix the problem" when medication therapy is indicated. Further, there are settings of care and pharmacy practice models that allow for autonomous and accountable prescribing authority by pharmacist practitioners as core component of CMM, without the need for collaborative practice authority for specific patients or populations. Pharmacist autonomous prescribing 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.

Pharmacists who prescribe must be recognized by payers and receive equitable payment for performing these advanced practice services. All pharmacist prescribers on the interprofessional team must possess a National Provider Identifier to monitor the care provided as well as reimburse for services rendered. 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 the pharmacists function as a part of the interprofessional team. Finally, interdisciplinary health professional training programs should incorporate the concept of pharmacist prescribing in a standard way to ensure consistency amongst pharmacists practicing in similar practice settings and with similar levels of responsibilities.

Background

The Council examined this topic in response to a recommendation from the 2023 House of Delegates to consolidate and harmonize ASHP policies related to pharmacist prescribing authority. The Council consolidated ASHP policies 2251, Qualifications and Competencies Required to Prescribe Medications, and 2236, Pharmacist Prescribing in Interprofessional Patient Care, and updated them for readability and consistency as follows (<u>underscore</u> indicates new text; ~~strikethrough~~ indicates deletions):

> To affirm that prescribing is a collaborative process that includes patient assessment, understanding of the patient's diagnoses, evaluation and selection of available treatment options, monitoring to achieve therapeutic outcomes, patient education, and adherence to safe and cost-effective prescribing practices; further, **[from policy 2251]**
>
> ~~To affirm that safe prescribing of medications, performed independently or collaboratively, requires competent professionals who complement each others' strengths at each step.~~ **[from policy 2251]**
>
> <u>To recognize that pharmacists are highly trained medication experts on the</u>

interprofessional care team capable of making independent and autonomous evidence-based decisions on medication therapy management; further,

To advocate that pharmacists have independent and autonomous authority to initiate, modify, and deprescribe all schedules and classes of medications; further,

To advocate that healthcare delivery organizations 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, **[from policy 2236]**

~~To advocate for comprehensive medication management that includes autonomous prescribing authority for pharmacists as part of optimal interprofessional care; further,~~ **[from policy 2236]**

To advocate that all pharmacists ~~on the interprofessional team~~ have a National Provider Identifier ~~(NPI); further,~~ that is recognized by payers. **[from policy 2236]**

~~To advocate that payers recognize pharmacist NPIs~~. **[from policy 2236]**

The Council drafted the new second clause ("To recognize that pharmacists are highly trained medication experts…") to emphasize that pharmacists have the skills to make decisions regarding medication therapy management, including prescribing. The Council drafted the new third clause ("To advocate that pharmacists have independent and autonomous authority…") to capture the intent of the clause struck from policy 2236 and to more clearly define the scope of pharmacists' prescribing authority.

3. Suicide Awareness, Prevention, and Response

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.

Note: This policy would supersede 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.

Background

The Council reviewed ASHP policy 1901, Suicide Awareness and Prevention, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To support the goal of zero suicides; further,

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

To acknowledge that optimal suicide awareness, ~~and~~ 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 ~~providers on the patient care team~~, are integral to suicide awareness, ~~and~~ 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 provide education that assists the pharmacy workforce in their continuing professional development efforts related to suicide awareness and prevention; further,~~

~~To support the inclusion of suicide awareness and prevention principles throughout pharmacy curricula and postgraduate educational and training programs; further,~~

~~To encourage efforts that support universal education and training of healthcare providers in suicide awareness and prevention; further,~~

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

To enhance awareness of local, state, ~~and~~ national, and global suicide awareness, ~~and~~ prevention, and response resources~~, including the National Suicide Prevention Lifeline funded by the Substance Abuse and Mental Health Services Administration; further,~~

~~To foster education and research on suicide awareness and prevention~~.

The Council suggested the amendments to acknowledge the importance of suicide postvention efforts, in addition to improving awareness and prevention of death by suicide. The Council felt that the education and research clauses are better captured in the rationale, since there are broader ASHP policies that call for education and research to ensure the pharmacy workforce is competent and informed. Lastly, the Council called for the reference to the 988 Suicide & Crisis Lifeline be added to the rationale and any specific mention to national hotlines be removed from the policy clause. In their discussions, the Council felt that ASHP policy 2329, Clinician Well-Being and Resilience, or its rationale, be updated to include information about moral injury and trauma response considering the exposure to loss, illness and injury, and death in the healthcare work environment.

4. Pharmacist's Role on Ethics Committees

To advocate that pharmacists should be included as members of, or identified as a resource to, hospital and health-system ethics committees; further,

To encourage pharmacists to actively seek ethics consultations or solicit input from their institution's ethics committee, as appropriate; further,

To encourage pharmacists serving on ethics committees to seek advanced training in healthcare ethics.

Note: This policy would supersede 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. 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.

Background

The Council reviewed ASHP policy 1403, Pharmacist's Role on Ethics Committees, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To advocate that pharmacists should be included as members of, or identified as a resource to, hospital and health-system ethics committees; further,
>
> To encourage pharmacists to actively seek ethics consultations or solicit input from their institution's ethics committee, as appropriate; further,
>
> To encourage pharmacists serving on ethics committees to seek advanced training in healthcare ethics.

This policy was last reviewed in 2019 by the Council on Pharmacy Practice. The Council determined the policy needed to be revised to capture pharmacists serving as an expert or resource to ethics committees. Council members also indicated that ASHP needs to offer more education and resources in ethics and ethical decision-making. In particular, the Council felt more programming is needed related to ethical decisions specific to medication use, medication shortages, and high-cost medications.

5. Safe Handling and Administration of Hazardous Drugs

To advocate that pharmaceutical manufacturers eliminate surface contamination on packages and vials of hazardous drugs (HDs); further,

To inform pharmacists and other personnel of the potential presence of surface contamination on the packages and vials of HDs; further,

To advocate that all healthcare settings proactively conduct an interprofessional assessment of risk for exposure to HDs during handling and administration, including the use of closed-system transfer devices (CSTDs); further,

To advocate for pharmacist involvement in the development of policies, procedures, and operational assessments regarding administration of HDs, including when CSTDs cannot be used; further,

To advocate that the Food and Drug Administration require standardized labeling and package design for HDs that would alert handlers to the potential presence of surface contamination, including development of CSTD-compatible, ready-to-administer HD products; further,

To encourage healthcare organizations, wholesalers, and other trading partners in the drug supply chain to adhere to published standards and regulations.

Note: This policy would supersede 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. These procedures are becoming more common. 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. 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.

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. ASHP encourages all healthcare settings to conduct an interprofessional, proactive assessment of the risk of such procedures to assess the potential exposure risks for healthcare providers and identify mitigating measures. Given their depth of knowledge

regarding the handling of HDs, pharmacists should be involved in the development of policies, procedures, and operational assessments regarding administration of HDs in such circumstances. 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 labeling 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. However, when such use is not possible, an assessment of risk could 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 could also address any specialized training for staff in procedural areas, or the availability of a HD-specialized trained staff member to assist in the administration of the drug (e.g., a "chemo nurse").

The outer surfaces of vials of hazardous drugs have been shown to be contaminated with hazardous substances, and pharmacy and other personnel handling those vials may unknowingly be exposed. ASHP advocates that individuals involved in drug distribution, receiving, and inventory control adhere to safe handling guidelines, including ASHP guidelines and United States Pharmacopeia Chapter 800, to avoid undue exposure to hazardous substances but recognizes 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.

Background

The Council reviewed ASHP policy 1902, Safe Administration of Hazardous Drugs, as part of sunset review, and voted to recommend consolidating it with ASHP policy 1615, Protecting Workers from Exposure to Hazardous Drugs, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To advocate that pharmaceutical manufacturers eliminate surface contamination on packages and vials of hazardous drugs (HDs); further, **[from policy 1615]**
>
> To inform pharmacists and other personnel of the potential presence of surface contamination on the packages and vials of HDs ~~hazardous drugs~~; further, **[from policy 1615]**
>
> To advocate that all healthcare settings proactively conduct an interprofessional assessment of risk for exposure to ~~hazardous drugs (~~HDs~~)~~ during handling and administration, including the use of ~~when~~ closed-system transfer devices (CSTDs)~~ cannot be used~~; further, **[from policy 1902]**
>
> To advocate for pharmacist involvement in the development of policies, procedures, and operational assessments regarding administration of HDs, including when CSTDs

cannot be used; further, **[from policy 1902]**

To advocate that the Food and Drug Administration require standardized labeling and package design for HDs ~~hazardous drugs~~ that would alert handlers to the potential presence of surface contamination~~; further~~, **[from policy 1615]**

~~To encourage device and pharmaceutical manufacturers and the Food and Drug Administration to foster~~ including development of CSTD-compatible, ready-to-administer HD products; further, **[from policy 1902]**

To encourage healthcare organizations, wholesalers, and other trading partners in the drug supply chain to adhere to published standards and regulations~~, such as ASHP guidelines and United States Pharmacopeia Chapter 800, to protect workers from undue exposure to hazardous drugs~~. **[from policy 1902]**

COUNCIL ON PUBLIC POLICY
POLICY RECOMMENDATION

The Council on Public Policy is concerned with ASHP professional policies related to laws and regulations that have a bearing on pharmacy practice. Within the Council's purview are (1) federal laws and regulations, (2) state laws and regulations, (3) analysis of public policy proposals that are designed to address important health issues, (4) professional liability as defined by the courts, and (5) related matters.

Sam Calabrese, *Board Liaison*

1. Order Verification

To advocate that a prescriber should not be solely responsible for medication ordering, dispensing, and administration as well as any patient monitoring and evaluation, except when a double check would limit patient access to care.

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 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.

Background

The Council discussed how independent prescribing authority has shifted pharmacy practice, resulting in situations in which a single pharmacist is responsible for all patient-focused elements of the medication-use process (e.g., ordering, administration, dispensing, and evaluation and/or monitoring). The Council noted that this is also the case for physicians and certain nonphysician practitioners, but agreed that regardless of clinician type, checks are needed to ensure patient safety. The Council reviewed both ASHP policies 2133, Optimal Pharmacy Staffing Levels, and 2246, Autoverification of Medication Orders, and concluded that this issue merited its own policy rather than inclusion in an existing policy.

The Council discussed the Board's recommended edits to the policy, but felt that they did not fully capture the Council's intent. Specifically, the Council reiterated its concerns that no clinician, including pharmacists, should be placed in a position in which they maintain responsibility for the entire medication-use process without any checks. The Council agreed that checks could be provided by technology and should not be the basis for limiting patient access to treatment when such checks were unavailable (particularly in rural and/or underserved areas). The Council reworked the original policy language to incorporate the last portion of the Board's revisions and suggested some edits to the rationale, as indicated above. The Council felt strongly that this policy would not impede uptake of test-to-treat models, given that the language is inclusive of all providers and makes allowances for situations in which additional checks are not feasible.

COUNCIL ON PUBLIC POLICY
POLICY RECOMMENDATIONS

The Council on Public Policy is concerned with ASHP professional policies related to laws and regulations that have a bearing on pharmacy practice. Within the Council's purview are (1) federal laws and regulations, (2) state laws and regulations, (3) analysis of public policy proposals that are designed to address important health issues, (4) professional liability as defined by the courts, and (5) related matters.

2. Liability Protection

To advocate that pharmacists be able to provide evidence-based dispensing and care to patients without fear of criminal or civil legal consequences, harassment, or liability; further,

To advocate that protection against liability extend to referrals for out-of-state care and for dispensing to patients from another state.

Rationale

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

Background

The Council reviewed ASHP policy 2250, Access to Reproductive Health Services, to ensure that no changes were needed to address state law shifts following the Dobbs decision. The Council felt that no changes to policy 2250 were needed, but voiced concern about the growing threat of prosecution or civil liability for pharmacists providing evidence-based reproductive health, gender-affirming care, and PEP and PrEP. The Council felt that ASHP should provide education and analysis of new state laws to avoid chilling effects related to fear of prosecution or liability. Further, the Council recommended some edits to the rationale of policy 2250 to note the need for education related to potential areas of liability (e.g., reproductive health, PEP and PrEP, and gender-affirming care).

3. State Prescription Drug Monitoring Programs

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 seek adoption into health information exchanges to best integrate into electronic health records and to allow prescribers, pharmacists, 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 encourage policies that allow practicing pharmacists 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 opioid prescribing, dispensing, misuse, morbidity, and mortality.

Note: This policy would supersede 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.

All states have implemented PDMPs, with the final state, Missouri, implementing its 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 barriers still exist: PDMP system-related (i.e., usability, data quality), end-user related (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 due 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.

For states to see improvement in PDMP~~s~~ there needs to be improved data sharing between different jurisdictions, enhanced interoperability with EHRs and information exchanges, and increased evidence of PDMPs' impacts on patient outcomes to increase utilization. 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.

Background

The Council reviewed ASHP policy 1408, State Prescription Drug Monitoring Programs as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To ~~advocate for mandatory, uniform~~ 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 the design of these programs should balance the need for appropriate therapeutic management with safeguards against fraud, misuse, abuse, and diversion; further,~~
>
> To advocate that such programs seek adoption into health information exchanges to best integrate into ~~be structured as part of~~ electronic health records and ~~exchanges~~ to allow prescribers, pharmacists, and other practitioners to proactively monitor data for appropriate assessment and dispensing; further,
>
> ~~To advocate for full interstate integration to allow for access by prescribers, pharmacists, and other qualified designees across state lines; further,~~
>
> ~~To advocate for federal and state funding to establish and administer these programs; further,~~
>
> ~~To promote research, education, and implementation of best practices in prescription drug monitoring programs.~~

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

To encourage policies that allow practicing pharmacists 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 opioid prescribing, dispensing, misuse, morbidity, and mortality.

The Council updated the wording of the policy to reflect the fact that all states have now adopted PDMPs. It also updated language around integration of PDMP usage into EHRs and information exchanges to better reflect current technology and usage.

4. Emergency Supplies of Drug Products

To discontinue ASHP policy 1906, Emergency Supplies of Drug Products, which reads:

To advocate for states to allow any pharmacist, during a declared emergency, to dispense without a prescription an emergency supply of a drug product in quantities that meet the needs of patients.

Background

The Council felt that with some modifications to the rationale for policy 2142, Pharmacy Services in a State of Emergency, policy 1906 was no longer necessary. Specifically, the Council noted that policy 1906 effectively restates the third clause of the 2142, which is broad enough to allow for any additional authorities beyond dispensing emergency supplies.

The Council recommended that for policy 2142, some of the language focusing on COVID-19 should be removed to make it general to all emergencies. Further, the Council suggested that the language in policy 1906 regarding dispensing without a prescription and dosage quantities should be added to the rationale for policy 2142.

5. Drug Nomenclature

To discontinue ASHP policy 9011, Drug Nomenclature, which reads:

To work with the FDA, USP, and pharmaceutical industry to assure that drug products are named in a manner that clearly and without confusion permits identification of ingredients' strengths and changes.

Background

The Council felt that the language was already adequately addressed by ASHP policy 2044, Drug Names, Labeling, and Packaging Associated with Medication Errors. Because policy 9011 does not have a rationale, the Council also felt there was not enough context to suggest any differentiation from policy 2044. To avoid having duplicative policy, the Council voted to recommend discontinuing 9011.

COUNCIL ON THERAPEUTICS
POLICY RECOMMENDATIONS

The Council on Therapeutics is concerned with ASHP professional policies related to medication therapy. Within the Council's purview are (1) the benefits and risks of drug products, (2) evidence-based use of medicines, (3) the application of drug information in practice, and (4) related matters.

Vickie L. Powell, *Board Liaison*

1. Medication Stewardship Programs

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.

Background

The Council discussed the goals of stewardship programs and the role of the pharmacy workforce in those programs. Patient management is becoming more complex as value-based care expands, so it is only natural that more healthcare organizations are looking to stewardship approaches, as they have demonstrated their worth as an approach to patient care. The Council noted that there was a need for this policy to contain separate clauses for pharmacists as both foundational members of stewardship programs as well as leaders within those programs. The Council shared personal experiences when pharmacy was brought in after a stewardship program was started, or when they were included initially as a member of the

program but sidelined when the program was up and running. By highlighting these two distinct and important roles in the policy, the Council hopes to demonstrate that these are unique but equally important roles that pharmacists need to fill. The Council also recommended that ASHP create a statement that outlines the essential elements of all hospital and health-system stewardship programs to serve as a foundation for all future programs, including best practices, data analytics, infrastructure, core measures, outcomes, and recommendations for advocacy within their organization.

2. Nonprescription Status of Rescue and Reversal Medications

To support the over-the-counter (OTC) status of medications intended for evidence-based rescue use or reversal of potentially fatal events; further,

To work with federal, state, and local governments and others to improve the rescue and reversal medication development and supply system to ensure an adequate and equitably distributed supply of these medications; further,

To advocate that all insurers and manufacturers maintain coverage and limits on out-of-pocket expenditure so that patient access to rescue and reversal medications is not compromised; further,

To support and foster standardized education and training on the role of rescue and reversal medications and their 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 over-the-counter (OTC) 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 OTC 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 OTC 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. These interventions may include new drug application (NDA) provisions that require a certain threshold of product availability prior to OTC approval or a mandate that all manufacturers of an approved product transition their agent-specific supply chain to OTC distribution. Further, the FDA should optimize the NDA process itself, which may include a fast track for rescue and reversal medications, subsidies for all or part of the process, or standardized product labeling — which may serve the dual purpose of also supporting patient education initiatives — and other such measures.

Similarly, pricing for rescue and reversal medications should be minimized as much as possible, including efforts to eliminate patient cost entirely. OTC 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 efforts, 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, 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.

Background

The Council discussed the approval of naloxone spray as an OTC agent and the potential for other rescue and reversal medications to become OTC. In light of the FDA announcement of naloxone's change to OTC status, the Council reviewed ASHP policy position 2211, Naloxone Availability, for potential updates and found that, even with the recent change to OTC status, the policy language is still relevant and did not require updating. When discussing other drugs, injectable epinephrine was the next drug that was considered. OTC inhaled epinephrine is OTC as the branded Primatene Mist HFA, which is indicated for treatment of mild to intermittent asthma but is not a part of any treatment guideline. Its approval in 2018 was the cause of much concern in the medical community. Due to this experience, the Council expressed a desire to ensure that FDA approvals for rescue and reversal medication are evidence-based and guideline-driven, given the emergent nature of their use. Council members also noted that in Massachusetts there is a push to change albuterol to OTC, which reinforced the need for a clause that speaks to evidenced-based and guideline-driven approvals. The Council also discussed their concern of supply chain shortages, as occurred with prescription epinephrine in 2018, and therefore included language about ensuring that supply can keep up with demand for rescue and reversal medications.

3. Research on Drug Use in Obese Patients

To discontinue ASHP policy 1920, Research on Drug Use in Obese Patients, which reads:

To encourage drug product manufacturers to conduct and publish pharmacokinetic and pharmacodynamic research in obese patients to facilitate safe and effective dosing of medications in this patient population, especially for medications most likely to be affected by obesity; further,

To encourage manufacturers to include in the Food and Drug Administration (FDA)–approved labeling detailed information on characteristics of individuals enrolled in drug dosing studies; further,

To advocate that the FDA develop guidance for the design and reporting of studies that support dosing recommendations in obese patients; further,

To advocate for increased enrollment and outcomes reporting of obese patients in clinical trials of medications; further,

To encourage independent research on the clinical significance of obesity on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

To recognize that pharmacists are medication therapy experts who should provide guidance on appropriate drug dosing for obese patients.

Background

The Council reviewed ASHP policy position 1920, Research on Drug Use in Obese Patients, as part of sunset review and voted to recommend discontinuation. The Council noted that obese patients are still an underrepresented population for which more research is needed, but that these needs are addressed in ASHP policy positions 1804, Drug Dosing in Conditions That Modify Pharmacokinetics or Pharmacodynamics, and 2243, Enrollment of Underrepresented Populations in Clinical Trials.

4. Therapeutic Interchange

To discontinue ASHP policy 8708, Therapeutic Interchange, which reads:

To support the concept of therapeutic interchange of various drug products by pharmacists under arrangements where pharmacists and authorized prescribers interrelate on the behalf of patient care.

Background

The Council reviewed ASHP policy position 8708, Therapeutic Interchange, as part of sunset review and voted to recommend discontinuation because therapeutic interchange is now an established part of formulary management, as noted in the ASHP Guidelines on the Pharmacy and Therapeutics Committee and Formulary System.

COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATIONS

The Council on Education and Workforce Development is concerned with ASHP professional policies, related to the quality and quantity of pharmacy practitioners. Within the Council's purview are (1) student education, (2) postgraduate education and training, (3) specialization, (4) assessment and maintenance of competence, (5) credentialing, (6) balance between workforce supply and demand, (7) development of technicians, and (8) related matters.

Kristi Gullickson, *Board Liaison*

Council Members
Joshua Blackwell, *Chair* (Texas)
Michelle Estevez, *Vice Chair* (Florida)
Aliyah Cruz (Wisconsin)
Stacy Dalpoas (North Carolina)
Sandeep Devabhakthuni (Maryland)
Johnnie Early II (Florida)
Glen Gard, *Pharmacy Technician* (Illinois)
Devon Hess, *Student* (North Carolina)
Tera Moore (Federal Service)
Vipul Patel (California)
Jennifer Robertson (Tennessee)
Kate Taucher (Colorado)
Ted Walton (Georgia)
Sophia Chhay, *Secretary*

1. Flexible Workforce Models

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.

Background

The Council reviewed pharmacy workforce-related survey data, including the American Academy of Colleges of Pharmacy's 2023 Graduating Student Survey, Pharmacy Career Information Center Updates, ASHP's 2022 National Survey of Pharmacy Practice in Hospital Settings: Workforce, and discussed the trend toward more flexible workforce models across not only healthcare but all industries. The Council also reviewed related ASHP policies, including 2133, Optimal Pharmacy Staffing, and felt that a broader policy encompassing the entire pharmacy workforce, regulatory bodies, and legislative bodies on flexible workforce models is needed to support institutions' ability to transform recruitment and retention strategies, address current workforce supply and demand, and positively impact the future of pharmacy.

2. Pharmacy Residency Training

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.

Note: This policy would supersede 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 position 2027) Furthermore, in the Practice Advancement Initiative (PAI) 2030, recommendation B4 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 who successfully complete 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.

Background

The Council reviewed ASHP policy 0917, Pharmacy Residency Training, as part of the discussion

of pharmacy residency trends. The Council voted to recommend amending it as follows (underscore indicates new text):

> 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.

COUNCIL ON PHARMACY MANAGEMENT POLICY RECOMMENDATIONS

The Council on Pharmacy Management is concerned with ASHP professional policies related to the leadership and management of pharmacy practice. Within the Council's purview are (1) development and deployment of resources, (2) fostering cost-effective use of medicines, (3) payment for services and products, (4) applications of technology in the medication-use process, (5) efficiency and safety of medication-use systems, (6) continuity of care, and (7) related matters.

Kim Benner, *Board Liaison*

1. Pharmacist Access to Provider Networks

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.

Note: This policy would supersede 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.

Background

The Council reviewed ASHP policy 2134, Patient Access to Pharmacist Care within Provider Networks, in response to recommendations made by an ASHP member advisory panel. During previous Council discussions and at subsequent House of Delegates meetings, members were challenged to define broad-based policy and recommendations related to pharmacist patient care delivery within payer networks, pharmacy access to networks, and how to best advance payer reimbursement. The Council considered some of the recommendations suggested by the member advisory panel and voted to recommend amending the policy as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

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

~~To advocate 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; further,~~

~~To acknowledge that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality and viability of healthcare services provided; further,~~

~~To advocate for laws and regulations that would help ensure the same level of patient care within a payer network by requiring healthcare payers to (1) disclose to participating providers and those applying to participate the criteria used to include, retain, or exclude providers; (2) ensure that those criteria are standardized across all network providers; and (3) collect data on how well providers meet those criteria and report that data to providers; further~~,

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

The Council acknowledged that numerous challenges and marketplace changes are making it increasingly difficult for ASHP members to manage budgets. The difficulty of ensuring that hospital leadership understands the complexity and impact of insurance carve-outs, network access, and the responsibility to patients across the continuum of care required an assessment of existing ASHP policies. Council discussion focused on pharmacist scope of practice being highly variable from state to state and the need for ASHP policy to be broad and flexible enough to meet the needs of most states yet serve as a roadmap for other states earlier in their journey. The Council highlighted key considerations ASHP could address through education and resource development to orient members on aspects of this topic. Some of these key considerations include variation in state pharmacy practice laws and level of provider recognition, reimbursement methodology, terminology and definitions, scope of practice and credentialing, and pharmacy access to networks. More specifically, a resource on sample contract language, who to work with, and negotiating with payers regarding qualified pharmacist access to provider networks is desired. An additional area of member need is education and resources on billing and reimbursement for pharmacist-provided patient care services (e.g., comprehensive medication management). Lastly, the Council discussed the different interpretations of the term “network” (i.e., pharmacy network vs. provider network), which they identified as a key factor in successful payer communications and a potential future policy topic.

2. Risk Assessment of Health Information Technology

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.

Note: This policy would supersede 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.

Background

The Council reviewed ASHP policy 1418, Risk Assessment of Health Information Technology, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text):

> 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.

The Council emphasized the importance of the usability of new or upgraded HIT by clinicians and staff and of HIT vendors providing reliable estimates of the resources required to implement and support new or upgraded HIT.

3. Unit Dose Packaging Availability

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.

Note: This policy would supersede 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.

Background

The Council reviewed ASHP policy 2253, Unit Dose Packaging Availability, at the request of an ASHP delegate recommendation, to discuss a policy-related member concern expressed during the 2023 House of Delegates meetings, and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

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 ~~to support~~ require pharmaceutical manufacturers to provide stability data to support the repackaging of medications outside of their original manufacturer bulk containers ~~this goal~~ in the interest of public health, ~~and~~ healthcare worker and patient safety, and reduced waste.

The Council discussed the ASHP delegate recommendation voiced during the 2023 House of Delegate meetings and agreed the request was reasonable despite a sunset review of the policy the previous year. The Council sensed the new policy recommendation could be part of the ASHP advocacy narrative to improve the quality and resilience of the healthcare supply chain.

4. Optimizing the Medication-Use Process

To discontinue ASHP policy 9903, Optimizing the Medication-Use Process, which reads:

To urge health-system pharmacists to assume leadership, responsibility, and accountability for the quality, effectiveness, and efficiency of the entire medication-use process (including prescribing, dispensing, administration, monitoring, and education) across the continuum of care; further,

To urge health-system pharmacists to work in collaboration with patients, prescribers, nurses, and other health care providers in improving the medication-use process.

Background

The Council found the compilation of ASHP best practice and guidance documents adequately covers all aspects of this policy, making its continued existence unnecessary. Some of the documents taken into consideration include ASHP policies 2206, Continuous Performance Improvement; and 2208, Pharmacist's Role in Team-Based Care; the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive; and the ASHP Guidelines on Preventing Medication Errors in Hospitals.