House of Delegates

Board of Directors Report: Policy Recommendations for the June 2024 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. Prehospital Management of Medications

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 encourage the pharmacy workforce to assume responsibility for medication-related aspects of ensuring the continuity of care as patients transition from prehospital care to other care settings; further,

To collaborate with stakeholders involved in prehospital medication-use cycle 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 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. That expertise could 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 would optimize medication use, improving prehospital care and patient safety during emergent situations and patient transfers.

Background

The Council examined this topic in response to a recommendation from the 2023 House of Delegates. Council members noted that a similar gap in ASHP policy led to the development of ASHP policy 2317, Emergency Medical Kits, and agreed that an ASHP policy position was needed to fill this gap.

2. Role of Artificial Intelligence in Pharmacy Practice

To recognize artificial intelligence (AI) as a tool with tremendous potential to improve patient care and the medication-use process, which should be implemented with caution due to potential unforeseen risks; further,

To encourage healthcare organizations to develop policies, procedures, and guidelines to determine which care settings, medications, and patient populations are appropriate candidates for the use of AI; further,

To advocate for pharmacy workforce involvement and transparency in the decision-making, design, implementation, and ongoing evaluation of AI-related applications and technologies that affect medication-use processes and tasks; further,

To oppose any use of AI that compromises human interaction or replaces ethical decision-making, professional judgment, or critical thinking or is implemented solely to reduce healthcare staffing and resources; further,

To advocate for regulations and standards that permit the use of AI in circumstances in which it has proven safe and effective.

Rationale

Artificial intelligence (AI) is an emerging technology described as intelligent computer programs or software capable of learning human cognition and processes. AI falls under two categories: machine learning (ML) for data set analysis and natural learning processes for information extraction from existing data. In recent years, AI technology has evolved at an immense speed, and healthcare has been increasingly digitizing data, raising two questions: how to best use both 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 and compassion) of the interprofessional care team.

The healthcare community recognizes the potential benefit and risk of AI in patient care. Examples of opportunities include but are not limited to optimizing patient health, reducing variation in patient care services, translating evidence to practice, streamlining workflows and creating efficiencies, and reducing cognitive load on the interprofessional care team. Risks 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, widening health disparities in undeserved or underrepresented patient populations. Given these risks, pharmacists and other healthcare professionals must retain oversight of AI applications and their implementation. Even if there comes a time when AI technology can account for every possible variable, the healthcare team must retain the right to make the final decisions on patient care to mitigate its inherent risks.

Pharmacy should take a leading role on the interprofessional healthcare team to research, develop, implement, and improve the quality of AI/ML-based clinical models that affect medication-use processes and tasks. The potential for improvement of care, lower costs, and comprehensive medication management could significantly impact healthcare, but healthcare providers must recognize the need for sufficient purview and monitoring to guarantee patient safety and effective therapy. Pharmacists, as leaders in AI health technology, can guide healthcare professionals and future generations on the implementation of AI in healthcare.

Background

The Council discussed AI following the Joint Council and Commission Meeting on the Role of Artificial Intelligence in Pharmacy. Their initial focus was on the ethical considerations in AI; however, the Council felt there was a need to discuss how AI impacts pharmacy practice more broadly. The Council agreed on the need for new ASHP policy. The Council also agreed that the ASHP Statement on the Use of Artificial Intelligence in Pharmacy should be revised to address ethical considerations for AI in healthcare and pharmacy practice, such as what tasks should always be performed by a human and never be replaced by AI, and what ethical considerations are needed for initial evaluation, implementation, and ongoing quality assurance of AI technologies.

3. 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 (underscore 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]**
>
> 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, **[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.

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.

Vivian Bradley Johnson, *Board Liaison*

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.

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.

1. Testing for Pregnancy Status

To affirm that pregnancy testing should occur only with informed consent 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 and as a result are key stakeholders.

It is important to note that this policy pertains to testing without informed consent 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 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.

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."

Background

The Council reviewed and discussed ASHP policy positions 2315, Responsible Medication-Related Clinical Testing and Monitoring; 0013, Patient's Right to Choose; and 2320, Pharmacoequity, in their discussion about this topic, and concluded that a standalone policy is needed.

2. 5-HT_2 Agonist, Entactogen, and Empathogen (Psychedelic) Assisted Therapy

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 code 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 this use is falls within indigenous cultural and religious traditions and is not intended as a medical treatment, this policy does not address those uses.

Background

The Council reviewed the current evidence supporting the use of psychedelics along with the federal and state laws surrounding their use. Council members also discussed the trend of state law circumventing federal law for Schedule I substances and acknowledged that, despite promising results, the state approach to permitting use is concerning. The Council also recognized that although the ideal approach to PAT would be through controlled studies, PAT outside of investigational studies is already expanding, so the policy is written to reflect this reality and to encourage the presence of a medical professional at sites where PAT is provided. The Council also suggested that since more states are enacting legislation permitting the use of psychedelics, ASHP could provide resources on drug-drug interactions, toxicology, and education on PAT.

3. 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.

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
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Michelle Estevez, *Vice Chair* (Florida)
Aliyah Cruz (Wisconsin)
Stacy Dalpoas (North Carolina)
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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. Opposition to Pharmacy Jurisprudence Examination Requirement

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

To advocate that employers provide initial and ongoing education of the pharmacy workforce on pertinent federal and state pharmacy laws; further,

To acknowledge that it is a professional obligation of a pharmacist 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.

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 employers should provide training on pertinent federal and state pharmacy laws. Even absent the state law exams, continuing education requirements and professional responsibility require pharmacists to know the laws in the state(s) in which they are licensed.

Background

The Council reviewed licensing requirements across states and professions, the relevance of continued law examination for pharmacists, and potential outcomes of eliminating the MPJE, and determined that ASHP needs a policy advocating the removal of a standalone examination of federal or state pharmacy law as a requirement for licensure. The Council felt eliminating this requirement would allow for greater flexibility regarding interstate movement and practice and align pharmacy with other healthcare professions.

2. Pharmacy Technician Education Requirements

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-accredited training program, be certified by the Pharmacy Technician Certification Board, and be licensed by state boards of pharmacy; further,

To advocate that beyond those requirements, pharmacy technicians working in advanced roles should complete at a minimum an associate of science degree and demonstrate ongoing competencies specific to the tasks to be performed; further,

To advocate that expansion of pharmacy technician duties into expanded, advanced roles should include consideration of potential risk to patients and that ongoing quality assurance metrics should be established to assure patient safety.

Note: This policy would supersede 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 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 of science 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 therapist, 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. In addition, these measures would promote recruitment and retention of the pharmacy technician workforce within hospitals and health systems.

Background

The Council reviewed ASHP policy 1203, Qualifications of Pharmacy Technicians in Advanced Roles, as part of the discussion of pharmacy technician formal education requirements for health systems. The Council voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> 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-accredited training program, be certified by the Pharmacy Technician Certification Board, and be licensed by state boards of pharmacy; further,
>
> To advocate that beyond those requirements, pharmacy technicians working in

advanced roles should ~~have additional training~~ complete at a minimum an associate of science degree and ~~should~~ demonstrate ongoing competencies specific to the tasks to be performed; further,

To advocate that expansion of pharmacy technician duties into expanded, advanced roles should include consideration of potential risk to patients and that ongoing quality assurance metrics should be established to assure patient safety.

3. Implications of Artificial Intelligence for Professional Integrity

To encourage hospitals, health systems, and colleges of pharmacy to adopt policies regarding the appropriate use of artificial intelligence and ongoing surveillance of these tools.

Rationale

The rapid advancement of generative artificial intelligence (AI) technologies, such as ChatGPT, has introduced new possibilities and challenges across society, particularly in the realm of education. These technologies appear to offer innovative ways to assist learners, enhance educational experiences, and streamline administrative processes. However, the integration of AI tools 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.

AI tools require extensive education and ongoing surveillance about their potential utility and limitations. Ethical and regulatory implications must be considered, as AI is increasingly incorporated into practice, education, and training. Furthermore, pharmacists must be prepared to engage in the development, validation, and implementation of AI to ensure such tools are being leveraged appropriately to support optimal patient care.

Background

At its Policy Week meeting, the Council reflected on the implications of ChatGPT and AI for academic integrity and guidance to student pharmacists, pharmacy residents, educators, and preceptors. The Council identified a need for ASHP policy on this issue.

4. 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*

Council Members
Christy Norman, *Chair* (Georgia)
Jennifer Miles, *Vice Chair* (Florida)
Thomas Achey (South Carolina)
Timmi Anne Boesken, *Pharmacy Technician* (Ohio)
Elissa Chung, *Student* (Washington)
Rox Gatia (Michigan)
Davey Legendre (Georgia)
Ryan Naseman (Kentucky)
Rebecca Ohrmund, *Pharmacy Technician* (Illinois)
Daniel O'Neil (West Virginia)
Joseph Pinto (New York)
Ellen Revak (Wisconsin)
Kate Schaafsma (Wisconsin)
Tara Vlasimsky (Colorado)
Jason Wong (Oregon)
Eric Maroyka, *Secretary*

1. Documentation of Patient-Care Services in the Permanent Health Record

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 promote inclusion of the pharmacy workforce in organization-based credentialing and privileging processes and in collaboration with an organization's clinical informatics team to ensure accurate and complete documentation of the care provided to patients and to validate the impact of patient care provided by the pharmacy workforce on patient outcomes and cost of care; further,

To advocate that electronic health records be designed with a common documentation space to accommodate all healthcare team members and support the communication needs of pharmacy.

Note: This policy would supersede 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). Organization-based privileging is the process used by a healthcare organization, after evaluating a practitioner's credentials, to assure stakeholders that the healthcare professional has the competencies and experience to provide certain direct patient care services. Privileging grants that individual practitioner permission to deliver those patient care services and document the rendering of those services in the permanent health record. ASHP supports the use of 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 (see 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.

Background

The Council reviewed ASHP policy 1419, Documentation of Patient-Care Services in the Permanent Health Record, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To advocate for public ~~and organizational~~ policies that support ~~pharmacist~~ documentation of patient-care services provided by the pharmacy workforce in the permanent patient health record; further,
>
> To promote inclusion of the pharmacy workforce in organization-based credentialing and privileging processes and in collaboration with an organization's clinical informatics team to ensure accurate and complete documentation of the care provided to patients and to validate the impact of ~~pharmacist~~ patient care provided by the pharmacy workforce on patient outcomes and ~~total~~ cost of care; further,
>
> To advocate that electronic health records be designed with a common documentation space to accommodate all healthcare team members and support the communication needs of pharmacy.

The Council discussed the lengthy first clause in the existing policy and felt advocating for public policies seems reasonable but not so for organizational policies. Promoting incorporation in an organization-based credentialing and privileging process and in collaboration with an organization's clinical informatics team seem practical and actionable. There is some crossover with ASHP policy 2137, Documentation of Pharmacist Patient Care, but that policy focuses more on documentation, billing, and attribution for services rendered. There was some discussion

about a need for advocacy to support documentation of activities by pharmacy technicians within their scope of practice (e.g., medication history documentation) as part of team-based care documentation.

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

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

Note: This policy would supersede ASHP policy 1914.

Rationale

Globally, health spending as a share of the overall economy has been steadily increasing since the 1980s, as spending growth has outpaced economic growth across all high-income countries, the United States included. This growth is multifactorial but is largely due to advances in medical technologies, including specialty medications; exponential and disparate price increases in the health sector across all markets; and higher demand for services, especially from a growing, aging population (Commonwealth Fund, Peterson-KFF). Based on data from 2021, the United States spent 18.3% of gross domestic product (GDP) on healthcare, nearly twice as much as the average country in the Organisation for Economic Co-operation and Development (Peterson-KFF, CMS). Over 2022-2031, average growth in national health expenditures (5.4%) is projected to outpace that of average GDP growth (4.6%), resulting in an increase in the health spending share of GDP, from 18.3% in 2021 to 19.6% in 2031 (CMS). This increasing cost of healthcare in the United States has motivated stakeholders across the care paradigm to search for strategies to curtail costs. Over the last decade, 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 (see 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. These newer 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, physician's 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 (see 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 Chapters 797 and 800, 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.

Background

The Council reviewed ASHP policy 1914, Safe Medication Preparation, Compounding, and Administration in All Sites of Care, as part of sunset review and in response to recommendations made by an ASHP member advisory panel and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

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

The Council discussed opportunities to make the policy recommendation and associated rationale reflective of current practice, healthcare trends, and pharmacy opportunities to ensure optimal patient care. The Council proposed ASHP continue advocacy in opposition to specific payer strategies that restrict access points, interfere with shared provider-patient decision-making, and jeopardize patient care.