Board of Directors Report: Policy Recommendations for the May 2020 Virtual House of Delegates

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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.

Julie A. Groppi, Board Liaison

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1. Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice

To recommend the use of credentialing and privileging in a manner consistent with other healthcare professionals to assess a pharmacist’s competence to engage in patient care services.

Note: This policy would supersede ASHP policy 1907.

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

Background
The Council reviewed ASHP policy 1907, Credentialing and Privileging by Regulators, Payers, and Providers For Collaborative Practice, upon the suggestion of the ASHP House of Delegates.
and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deleted text):

To advocate expansion of collaborative practice agreements in which the prescriber and pharmacist agree upon the conditions under which the pharmacist initiates, monitors, and adjusts a patient’s drug and non-drug therapy; further,

To support (1) the development (as a professional initiative by pharmacist associations rather than as a government activity) of national standards for determining a pharmacist’s competence to provide medication management services and (2) the appropriate use of these standards by clinical privileging systems, government authorities, and public or third-party payers; further,

To advocate pharmacists be included as providers in medical staff bylaws; further,

To support recommend the use of credentialing and/or clinical privileging by hospitals, health systems, and payers in a manner that is consistent with other healthcare professionals to assess a pharmacist’s competence to engage in medication management services within the hospital or health system patient care services.

ASHP policy 0905, the predecessor to policy 1907, was slated for sunset review during the 2018-2019 Council year. The Council recommended changes to update the policy’s terminology, namely to replace references to collaborative drug therapy management with more recent terminology, collaborative practice agreements. The policy recommendation was the subject of intense discussion at the June 2019 House of Delegates and was passed with significant amendments.

Given that the Council initially undertook a relatively narrow discussion of the policy for the purposes of the 2018 sunset review, they felt the revised policy merited more robust discussion to ensure it met the Council’s intent. The Council removed the collaborative practice references because ASHP policies 1715, 1415, and 1907 adequately address the collaborative practice issue. The Council further recommended that ASHP policies 1715, 1415, and 1907 be reviewed and harmonized, as necessary.

The new language in the policy is meant to ensure that the policy is expansive enough to reflect everything that should be considered when credentialing and privileging a pharmacist. Specifically, the Council agreed that having a concise policy would facilitate more productive discussions with administrators than asking them to review several related policies.

2. Importation of Drug Products

1. To oppose wholesale importation of drug products as a method to lower drug costs.

Note: This policy would supersede ASHP policy 0413.
**Rationale**

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

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

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

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

**Background**

In response to recent White House and Congressional proposals, the Council reviewed ASHP policy 0413, Importation of Drug Products, which reads:

To advocate for the continuation and application of laws and regulations enforced by the Food and Drug Administration (FDA) and state boards of pharmacy with respect to the importation of pharmaceuticals in order to (1) maintain the integrity of the pharmaceutical supply chain and avoid the introduction of counterfeit products into the United States; (2) provide for continued patient access to pharmacist review of all medications and preserve the patient-pharmacist-prescriber relationship; and (3) provide adequate patient counseling and education, particularly to patients taking multiple high-risk medications; further,

To urge the FDA and state boards of pharmacy to vigorously enforce federal and state laws in relation to importation of pharmaceuticals by individuals, distributors (including wholesalers), and pharmacies that bypass a safe and secure regulatory framework.

The Council recommended replacing that language with a more direct statement of opposition (“To oppose wholesale importation of drug products as a method to lower drug costs”). Following the introduction of the current administration’s *Safe Importation Action Plan*, the
Council felt that ASHP policy 0413 did not sufficiently address the issue. Although the Council recognized the pressing need for drug pricing solutions, Council members determined that the integrity of the drug supply is paramount and that importation on a broad scale presents unacceptable risks. Further, the Council felt that relying on importation to reduce costs would result in significant expenditures that are unlikely to produce meaningful cost savings.

The Council discussed Canada’s opposition to importation and its representations that its current purchasing levels would not be sufficient to supply the United States. Discussion also focused on the potential dangers importation poses to patient safety and supply chain integrity, including disruption of implementation of/compliance with the Drug Supply Chain Security Act (i.e., track and trace). Additionally, the Council agreed that even if drugs could be purchased at a lower cost from a foreign country, the pharmaceutical manufacturers were likely to adjust to the supply/demand curve quickly, wiping out any savings for the U.S. The Council stated that other policy options, including increased transparency and insurance coverage protections for seniors and uninsured or underinsured individuals are more likely to produce significant cost savings for patients and the healthcare system without the attendant risks of importation.

Based on these factors, the Council felt that policy 0413 should be replaced with a blanket statement opposing wholesale importation and that the detailed specifications for safe importation from the previous policy should be moved into the rationale. The Council also recommended a note that the new policy is not meant to stop FDA from importing drugs to address shortages or to impact personal importation of pharmaceuticals in states that allow it.

3. Public Quality Standards for Biologic Products

1. To oppose federal or state legislation that would remove the requirement for biologic products to adhere to public quality standards; further,
2. To review and evaluate current public standards to ensure that they are relevant and appropriate to biologic products.

Rationale

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

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

**4. New Categories of Licensed Pharmacy Personnel**

1. To oppose the creation of new categories of licensed pharmacy personnel.

**Background**
This issue arose after several states (e.g., New Hampshire, Ohio) introduced laws allowing the creation of a “pharmacist assistant.” The Council discussed the background of the pharmacist assistant term, including the proposed role the pharmacist assistant would fill in practice. Discussion then turned to how the pharmacist assistant role would intersect with that of the pharmacy technician and lead to potential confusion related to different roles of pharmacy technicians that already exist. For instance, the intent by the laws in New Hampshire and Ohio was to shift non-clinical tasks to the pharmacist assistant. However, the law does not specify requirements for licensure or outline scope of practice, but instead instructs that the board of pharmacy develop rules to address them, which may or may not be consistent with pharmacy technician professional standards currently in place. Further, the pharmacist assistant, rather than the supervising pharmacist, will be accountable to the board of pharmacy for tasks performed within the pharmacist assistant’s allowed scope of practice. Janet Silvester joined the Council to provide additional relevant details from the Consensus Conference of 2018 and the Pharmacy Technician Certification Board (PTCB) job analysis. The Council questioned the need for any new midlevel role and reinforced the importance of the pharmacy technician. The Council noted that the statement was not meant to in any way impede the use of current licensed personnel, including pharmacy technicians and students.
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.

Nish Kasbekar, Board Liaison

1. Naloxone Availability

1. To recognize the public health benefits of naloxone for opioid reversal; further,

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

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

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

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

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

Note: This policy would supersede ASHP policy 1510.
Rationale
According to the Centers for Disease Control and Prevention (CDC), prescription drug abuse is a national epidemic. Deaths from prescription opioid overdose number 10,000 per year; in contrast, deaths from heroin overdose number 2000. People at risk for opioid overdose include not only substance abusers, but also opioid-naive patients, such as those being admitted for or discharged from ambulatory surgery.

Naloxone is a reversal agent that rapidly rescues patients from narcotic overdose by displacing mu2 opioid receptors in the brain. Naloxone has an excellent safety profile. The World Health Organization includes naloxone on its model list of essential medicines.

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

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

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

Background
The Council reviewed ASHP policy 1510, Naloxone Availability, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To recognize the potential public health benefits of naloxone for opioid reversal; further,

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

To advocate that individuals other than licensed healthcare professionals be permitted access to naloxone after receiving education; further,

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

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

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

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

These changes reflect the evolution of naloxone use since the policy was first written, including needs for additional, affordable formulations; recognizing that access has a public health benefit; the role of the pharmacy technician; and the need for standardized education and protection for those administering and providing aid to those requiring opioid reversal.
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.

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1. Network Connectivity and Interoperability for Continuity of Care

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

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

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

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

13. To strongly encourage health-system administrators, regulatory bodies, and other appropriate groups to provide health-system pharmacists with full access to patient-specific clinical data; further,
Rationale
For the past two decades, the U.S. health system has been racing to take advantage of the potential that digital health information offers for improved patient care. Each institution and practice has invested in information systems that work for its specific situation. These systems were developed by multiple vendors, each with their own proprietary structures and labels. Information was and continues to be found in silos, within health systems, within institutions, even within departments.

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

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

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

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

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

Note: This policy would supersede ASHP policy 0507.

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

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

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

Council on Pharmacy Management: Policy Recommendations
**Background**

The Council reviewed ASHP policy 0507, Electronic Information Systems, as part of sunset review, and voted to recommend amending it as follows (underscore indicates new text):

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

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

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

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

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

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

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

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

The Council discussed the need for providers of care having seamless ability to securely access and use health information from different sources to ensure patient-centered continuity of care. The Council indicated a desire for the Section of Pharmacy Informatics and Technology (SOPIT) to provide member education and resources on interoperability progress and barriers. Consideration should be given to an update on recent ONC efforts to see where the policy opportunities lie and the types of questions to ask to guide vendor selection. The Council sees this as a way to help members scope the problem and increase the likelihood for interoperability across sites of care to mitigate risk points and process inefficiencies.

### 2. Medication Formulary System Management

1. To declare that decisions on the management of a medication formulary system, including criteria for use, (1) should be based on clinical, ethical, legal, social,
Rationale
A formulary is a continually updated list of medications and related information, representing the clinical judgment of pharmacists, physicians, and other experts in the diagnosis and treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications, standardized medication concentrations, and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The multiplicity of medications available, the complexities surrounding their safe and effective use, and differences in their relative value make it necessary for healthcare organizations to have medication-use policies that promote rational, evidence-based, clinically appropriate, safe, and cost-effective medication therapy. The formulary system is the ongoing process through which a healthcare organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

As described in more detail in the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System, a fundamental characteristic of the formulary system is that all decisions are made based on factors that result in optimal patient care, include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals; and (3) should not be based solely on economic factors; further,

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

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

Note: This policy would supersede ASHP policies 9601 and 1805.
therapeutically equivalent, but the current Food and Drug Administration (FDA) approval process does not include a determination of interchangeability between reference and biosimilar products. Because the substitution of a biosimilar for a reference product is a decision outside the FDA regulatory process, it is therefore a matter of state pharmacy law. The obligation to have a specific payer-preferred biosimilar results in hospitals and health systems devoting significant resources to procure, store, label, and dispense payer-preferred biosimilars. This duplication adds complexity to the medication-use process, and as more biosimilars become available, the potential for harmful medication errors will increase. The use of biosimilars was a key cost-reduction concept in the Affordable Care Act. However, in May 2018, the price linkage cost-reduction concept within Medicare Part B was rescinded. Going forward, reimbursement will be based on the specific biosimilar product pricing. The full impact of this change for individual healthcare organizations will depend on patient and payer mix. Biosimilars that are priced at a lower acquisition cost compared to the innovator product are likely to stagnate or lose market share due to a low reimbursement margin. As a result, pricing of biosimilars may increase to make the reimbursement margin competitive with the innovator product, leaving healthcare organizations in search of other cost reduction opportunities.

**Background**

The Council reviewed ASHP policy 9601, Standardization of Medication Formulary Systems, as part of sunset review and voted to recommend consolidating it with ASHP policy 1805, Medication Formulary System Management, by amending it as follows (underscore indicates new text; strikethrough indicates deletion; first clause is from ASHP policy 1805):

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

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

To include in the formulary standardization process the direct involvement of the health system’s physicians, pharmacists, and other appropriate healthcare professionals; further,

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

Linda S. Tyler, Board Liaison

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1. Role of the Pharmacy Workforce in Preventing Accidental and Intentional Firearm Injury and Death

To recognize that accidental and intentional firearm injury and death in the U.S. is a public health crisis; further,

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

Rationale
Firearm-related injury is a leading cause of death in the U.S. Over 39,000 people succumbed to death by firearm-related injuries in 2017 (60% by suicide, 37% from homicide, 1% unintentional, and 1% related to legal intervention), which translates to 12.2 deaths per 100,000 population. For perspective, there were 14.9 drug overdose deaths involving any opioid and 11.9 motor vehicle traffic deaths per 100,000 population. Over 67,000 people receive medical care in an emergency department or are hospitalized (approximately 46% and 54%, respectively) as a result of a firearm-related injury inflicted by assault, self-harm, or unintentional action. According to the American College of Surgeons, in 2016 a firearm was involved in 51% of suicides and 75% of homicides, and while there has been 22% decrease in traffic-related deaths since 1999, there has been a 17% increase in firearm-related intentional injury death rates over the same period.
Firearm-related injury is a medical and public health problem that hospitals and health systems play an important role in preventing and treating. Evidence-based public health strategies can be employed when violence and firearm-related injury are framed as a complex disease. This approach enables identification of primary, secondary, and tertiary levels of prevention and intervention strategies. Primary prevention, measures taken before the onset of injury (i.e., before the gun is fired), seek to interrupt the transmission of violence and improve the safety of communities. Examples of primary prevention include surveillance to gain insight into causes and determine the impact of interventions of firearm-related injury and violence; identification of risk factors associated with violence from firearms; and development, dissemination, and implementation of prevention strategies. Secondary prevention begins when the firearm causes injury and includes strategies for early response to triage care and minimize morbidity and mortality through emergency and inpatient medical care. Lastly, tertiary prevention provides long-term strategies aimed at caring for the victim following injury. It offers opportunities to not only provide acute care for the injured but to deploy services such as hospital-based violence intervention programs (HVIPs), screening and treatment for post-traumatic stress disorder, and case management aimed at preventing firearm-related violence and injury recidivism.

In February 2019, the American College of Surgeons hosted a summit of 44 major medical and injury prevention organizations and the American Bar Association with the goal of building consensus around ways to address the growing problem of firearm injury and death in the U.S. The participants arrived at the following consensus positions.

1. Firearm injury in the US is a public health crisis.
2. A comprehensive public health and medical approach is required to reduce death and disability from firearm injury.
3. Research is needed to better understand the root causes of violence, identify people at risk, and determine the most effective strategies for firearm injury prevention.
4. Federal and philanthropic research funding must be provided to match the burden of disease.
5. Engaging firearm owners and populations at risk is critical in developing programs and policies for firearm injury prevention.
6. Healthcare providers should be encouraged to counsel patients and families about firearm safety and safe storage. Educational and research efforts are needed to support appropriate culturally competent messaging.
7. Screening for the risk of depression, suicide, intimate partner violence, and interpersonal violence should be conducted across all healthcare settings and in certain high-risk populations (such as those with dementia). Comprehensive resources and interventions are needed to support patients and families identified as high risk for firearm injury and who have access to a firearm.
8. Hospitals and healthcare systems must genuinely engage the community in addressing the social determinants of disease, which contribute to structural violence in underserved communities.
9. Our professional organizations commit to working together and continuing to meet to ensure these statements lead to constructive actions that improve the health and well-being of our fellow Americans.
ASHP recognizes that these consensus positions provide one example of a comprehensive public health and medical approach to reducing death and disability from firearm injury and that the pharmacy workforce has important roles in implementing the interventions needed to reduce death and disability from firearms.

**Background**
The Council considered the topic of firearm-related injury and death after participating in the Joint Meeting on Violence and Firearm-related Injury and Death. The Council recognized that firearm-related injury and death is on the spectrum of violence but determined that a separate policy dedicated to the topic is necessary. The intent of the policy is to affirm the pharmacy workforce’s role in addressing firearm-related injury and death. In doing so, pharmacy personnel can leverage the policy to seek inclusion in public health intervention programs in their communities and institutions. In addition, the Council is requesting the Board to consider endorsing the Consensus Statements from the Medical Summit on Firearm Injury Prevention (see Voted 10). The Council agreed with each of the 9 Consensus Statements and believe that pharmacy personnel should be aware of them and aspire to take action on them in their communities and institutions. Over 40 medical and injury prevention organizations unanimously agreed to endorse the Consensus Statements, and Council members felt strongly that a national pharmacy presence was missing from the list of organizations.

### 2. Safe Use of Transdermal System Patches

1. To encourage hospitals and health systems to implement policies and procedures to ensure safe use of transdermal system patches; further,

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

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

*Note: This policy would supersede ASHP policy 1404.*

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

**Background**

The Council reviewed ASHP policy position 1404, Safe Use of Fentanyl Transdermal Patches, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To encourage hospitals and health systems to implement policies and procedures to ensure safe use of transdermal system patches; further,

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

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

The Council’s intent in its recommended revisions is to broaden the scope of policy position 1404 to include other transdermal system patches. The Council recognized that the best practices needed to ensure safe use of fentanyl transdermal system patches should also be applied to other transdermal system patches that present similar risks. The Council also recognized that although hospitals and health systems have an important role in ensuring safe use of transdermal patches through implementation of best practices, manufacturers share that responsibility and could improve safe use through improved packaging, labeling, formulation, and consumer education.
The Section of Pharmacy Informatics and Technology supports the mission of ASHP by being the professional home for all members who are dedicated to advancing medication use and health outcomes through the use of health information technology.

Kristina L. Butler, Board Liaison

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1. **ASHP Statement on the Use of Artificial Intelligence in Pharmacy**

   1. To approve the ASHP Statement on the Use of Artificial Intelligence in Pharmacy (Appendix).
Position
Pharmacists are responsible for determining which aspects of medication use and management are best handled by pharmacists, by artificial intelligence (AI), or by pharmacists who receive advice from AI-based systems. Pharmacists should use scientific approaches to determine the degree to which AI is used to automate specific medication-use tasks. Full automation using AI should be reserved for algorithmic tasks for which it is demonstrated that AI performs as well or better than pharmacists. AI of proven value should be adopted and used so that pharmacists can make better decisions and focus their expertise on solving new and confounding problems for patients, families, and organizations.

Pharmacists are uniquely positioned to be key contributors and domain experts in the advancement of AI in healthcare. Pharmacists should lead the design, implementation, and ongoing evaluation of AI-related applications and technologies that affect medication-use processes and tasks. Pharmacists should define appropriate medication-related use cases for AI-enabled technology and provide foresight for anticipated future applications. It is also important for pharmacists to assist in validating AI for clinical use. At a minimum, AI should be evaluated for accuracy and interpretability. In addition, pharmacists should be prepared to adapt to AI through education and continued engagement.

Background
The U.S. healthcare landscape is rapidly evolving, driven by rising costs, an aging population, and an increased emphasis on personalized medicine. As healthcare becomes increasingly
digitized, unprecedented amounts of data offer valuable opportunities to better understand and thus improve patient care and pharmacy practice. The increasing digitization of healthcare data further accelerates the need for increased automation and scalability. Pharmacy must be prepared to embrace and lead efforts in making efficient use of advanced technologies to address all aspects of the quadruple aim (improving access, reducing costs, improving outcomes, and optimizing clinician satisfaction).\(^1\)

AI is the theory and development of computer systems to perform tasks normally requiring human intelligence, such as visual perception, language processing, learning, and problem solving.\(^2\) AI, when deployed optimally, has the ability to “augment human intelligence and improve decision-making and operational processes.”\(^3\) As the ASHP Commission on Goals noted at its 2019 meeting, AI capabilities are rapidly evolving within healthcare, with both clinical and operational implications for pharmacy.\(^4\) This technology allows for automation of routine and manual tasks and provides a higher level of clinical decision support for the clinician across every aspect of medication management, including procurement, storage, ordering, verifying, dispensing, administering, and monitoring. As this technology advances, its deployment in the healthcare system has the potential to create new roles for pharmacists and alter the scope of pharmacist care.\(^5\)

ASHP has developed this statement to define the role and position of pharmacists and pharmacy technicians in the advancement of AI in the care of patients. This statement was developed not simply to consider potential applications of AI within the current practice of pharmacy but also to plan for how this technology will need to be developed and implemented in coming years. Although this position is similar to the positions of other health professional organizations contemplating how AI will drive change in their practices, it is uniquely focused on identifying opportunities specific to the practice of pharmacy. This statement is based on consensus opinion and professional judgment among experts on AI in pharmacy. Pharmacy practice settings impacted by this policy include informatics, acute care, ambulatory, community, education, public health, policy, industry, research, and development.
Responsibilities of pharmacists in AI

For AI implementation, pharmacists should actively seek to address the following three key questions:

1. Which medication- or therapy-related tasks are appropriate for AI to address?
2. How should AI models be evaluated?
3. For each type of use case, which AI learning approach(es) is (are) most appropriate?

As AI methodology and techniques evolve, pharmacists should define appropriate medication-related clinical-use cases for AI-enabled technology based on AI’s current capabilities, providing foresight for anticipated future applications. Every health system should include an AI integration roadmap as an important part of strategic planning. Any clinical AI platform implemented in the health system related to medication use or monitoring should be validated by a pharmacist prior to implementation and receive continual evaluation by a pharmacist for its contextual accuracy and interpretability. As new techniques and methodologies come into practice, establishing best practices for clinical validation and bias reduction will be a critical component in AI optimization. Pharmacists should develop and maintain clinical validation standards for AI at the local and national levels, outlining the varying levels of required evidence for safety and efficacy before deploying AI-enabled technology. Clinical validation standards should

- take into account the level of risk involved in the AI activity and its level of autonomy,
- balance stringency with the need for rapid innovation, and
- include definitions and requirements for interpretability for any model used in the medication-use process.

Impact on pharmacy

As AI automates routine, manual, and repeatable tasks, pharmacists’ time and focus can shift to complex clinical tasks that provide direct, empathetic patient care in a high-touch and humanistic way. AI systems have the potential to offload time-consuming tasks, such as routine monitoring, patient and medication safety surveillance, and data processing. AI technology can run in the background to provide information in a visually digestible and
easily interpretable way, at the appropriate time to aid the pharmacist in patient care decisions. AI also has the potential to synthesize and become a new source of evidence-based data with which pharmacists will need to be actively engaged. As AI capacity develops further into the diagnostic space, it has the potential to shift healthcare paradigms, with some diagnoses being confirmed independently through AI-enabled devices and applications.\textsuperscript{8,9} Eventually, patients may receive continuous diagnostic surveillance. Pharmacy leadership should focus on improving access to care through scalable models centered on AI-enabled diagnostic surveillance and pharmacy medication management, especially for underserved patient populations. Given the novelty of this technology, systems should be designed with a functional level of autonomy that corresponds to the level of trust users can confidently place in the system.\textsuperscript{10}

In addition to its impact on care delivery models, AI is expanding the medication armamentarium. Advances in AI capabilities are enabling the emergence of software platforms designed for patients with chronic disease states, to be used with, or in place of, medication therapy.\textsuperscript{11} Given the anticipated trend of increasing development and use of digital therapeutics and a blend between chemical, biological, and digital therapies,\textsuperscript{12,13} pharmacists should be involved in the design of AI-enabled digital therapeutics. Pharmacists should have access to the summarized data from AI-enabled digital therapeutics for safety and efficacy monitoring. Pharmacy organizations should seek out opportunities to collaborate with other healthcare organizations to be involved in creating guidance and standards on how to incorporate AI-enabled digital therapeutics into patient care.

**Informatics**

Pursuant to the rigor applied to clinical trial design and the practice of evidence-based medicine, AI models need to be trained, evaluated, corrected, and applied to data that match clinical practice. AI models run on poorly sourced data, data with disproportionate representation, or correlated data assumed to be causal, could unintentionally magnify systemic bias or discrimination.\textsuperscript{14-16} In addition, AI models require maintenance and
monitoring as clinical practice and data inputs or data distributions change over time. With their background in experimental design, research methodology, and problem-solving, pharmacists (especially pharmacists specialized in informatics) have ideal baseline skill sets for AI development and implementation. Pharmacists can further specialize in AI and data science, or develop partnerships with data scientists to develop, test, and validate new AI models related to medication management, and should promote development of interdisciplinary teams or dedicated positions for integrating AI solutions within the health system.

**Clinical applications**

Pharmacists should be open and willing to make changes to traditional clinical workflows by leveraging AI and AI-enabled clinical decision support systems to improve patient care. AI applications are expanding from diagnostics to therapy recommendations. Since medications are a central focus of therapy recommendation models, pharmacists should take a central role in leading the research, development, implementation, and quality improvement of these models. Pharmacy departments should work with healthcare systems to leverage pharmacists and future emerging AI-enabled diagnostic tools and decision support tools to evaluate models, improve care, lower costs, and provide comprehensive medication management for patients.

**Pharmacy operations**

From an operational standpoint, AI platforms can be used to tighten inventory management, facilitate product verification, and help pharmacists perform at the top of their skill set. As AI becomes more reliable, standard pharmacy operations will become increasingly automated, allowing pharmacists to focus more on high-value patient care activities. Rather than merely adopting AI, it is important that pharmacy executives lead the effort to define the future of pharmacy and the role of the pharmacist in an environment where AI is pervasive. As pharmacy departmental leadership looks at operational AI systems to develop and deploy, they should prioritize systems and applications that promote
personalized, continuous, and preventive care.\textsuperscript{20}

\textbf{Education and engagement}

Education about and exposure to AI is necessary throughout all domains of pharmacy practice.\textsuperscript{4} Pharmacy students should be introduced to the essentials of data science and fundamentals of AI through a health informatics curriculum during their Pharm.D. education. Pharmacists must also be given the opportunity to develop an understanding of AI through continuing education. Data science courses or pharmacy residencies with a focus on AI topics should be made available for pharmacists seeking more hands-on involvement in AI development, governance, and use. As these technologies rapidly evolve, the pharmacy education system must remain agile to ensure our profession is equipped to steward these transformations of care.

\textbf{Conclusion}

Advances in technology through AI stand to substantially change how care is delivered to patients. In all aspects of the medication-use process there are opportunities to refine and augment existing pharmacy workflows to improve both safety and efficiency. Pharmacists will be necessary in leading innovation on how AI models and technologies are developed, validated, and activated to enact change. Further, pharmacists must be poised to capitalize on the operational gains and enhanced clinical guidance made possible by AI technology to enhance patient care. To carry this out, pharmacy needs to continue to build on education that will enable current and future generations of pharmacists and pharmacy technicians to shape the evolution of AI technology. The scope and impact of changes to come will cross into all aspects of pharmacy practice, requiring continued engagement by all in the field.

\textbf{References}


12. Farr C. Digital treatments can be real medicine (April 7, 2017). *MIT Tech Rev.*


   https://www.forbes.com/sites/forbestechcouncil/2018/05/10/how-data-analytics-

Suggested Readings and Other Resources


