AGENDA

2020 ASHP
Virtual Regional Delegate Conferences

Note: The Regional Delegate Conferences (RDCs) run from 1:00 to 5:30 p.m. EDT each day from April 25 to April 28.

A. Welcome and Ground Rules

B. RDC Objectives

C. Review of RDC Agenda

D. Review of Policy Recommendations and Resolution(s)

E. How to Follow Up on RDCs

COUNCIL ON PUBLIC POLICY POLICY RECOMMENDATIONS

1. Credentialing and Privileging by Regulators, Payers, and Providers of Collaborative Practice
2. Access to Affordable Healthcare
3. Care-Commensurate Reimbursement
4. Importation of Drug Products
5. Public Quality Standards for Biologic Products
6. New Categories of Licensed Pharmacy Personnel
7. Funding, Expertise, and Oversight of State Boards of Pharmacy
8. Dispensing by Nonpharmacists and Nonprescribers

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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

Council Members
Jeff Little, Chair (Kansas)
Steve Riddle, Vice Chair (Washington)
Roy Guharoy (Alabama)
Charzetta James (Florida)
Rusol Karralli (Texas)
Janet Lee (Maryland)
Luke Miller (Texas)
Adam Porath (Nevada)
Elizabeth Rodman, New Practitioner (Wisconsin)
Jeffrey Schnoor (Vermont)
Elizabeth Shlom (New York)
Jennifer Wang Tomlinson, Student (Colorado)
Jillanne Schulte Wall, Secretary

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 1207 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. Access to Affordable Healthcare

1. To advocate for access to affordable healthcare for all residents of the United States, including coverage of medications and related pharmacist patient care services; further,

2. To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective healthcare services; (2) optimize treatment
Rationale
This policy expresses ASHP’s stance on access to healthcare in the United States. The policy emanated from ASHP policies dealing with affordability and accessibility of pharmaceuticals. ASHP believes that it is important to address the larger issue of healthcare access, particularly due to the impact of the cost of medications on the nation’s overall healthcare budget as well as pharmacy budgets in hospitals and health systems. Healthcare should be affordable, but also sufficient to ensure patient access to services.

Background
The Council reviewed ASHP policy 1001, Health Insurance Coverage for U.S. Residents, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To advocate for health insurance access to affordable healthcare for all residents of the United States, including coverage of medications and related pharmacist patient care services; further,

To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective healthcare services; (2) optimize treatment outcomes; and (3) minimize overall costs without compromising quality; and (4) ensure patient choice of healthcare providers, including pharmacy services; further,

To advocate that health insurers healthcare payers seek to optimize continuity of care in their design of benefit plans.

Note: This policy would supersede ASHP policy 1001.

During the Council’s June 2019 call, healthcare reform was slated as a topic for Policy Week discussion. Healthcare reform, which includes the entire spectrum of policy proposals from repeal of the Affordable Care Act to the creation of a public option (e.g., Medicare for All), continues to be a political hot topic. Thus, the Council undertook a review of relevant policies to ensure that ASHP can advocate for, and respond to, health reform proposals that impact pharmacy practice and patient care.

To center the discussion, the Council reviewed relevant policies as well as ASHP’s Principles of Healthcare Reform. The Council then conducted a mini gap analysis of federal policy proposals since 2017, when the Principles were drafted, to determine if any policies were needed to address new developments. After talking through some recent proposals, including Medicare for All, the Council was not comfortable crafting policy responsive to any specific
proposal. Instead, they determined that a flexible policy focused on coverage strength and patient access protections would be more effective.

Rather than drafting an entirely new policy, the Council reworked policy 1001, Health Insurance Coverage for U.S. Residents, which was up for sunset review. The new language in the proposed policy is designed to emphasize both access to, and affordability of, coverage. The Council also recommended updates to the policy’s rationale. Specifically, the Council suggested the rationale note that the policy applies to all health insurance coverage and state that the “cost-effectiveness” of the language is meant to apply to both patients and systems (e.g., patients should pay for meaningful coverage and systems shouldn’t have to pay for unnecessary interventions, etc.). Finally, the Council expressed concern as to whether the title should refer to U.S. residents or whether it should be more general (i.e., “Access to Health Insurance Coverage”).

3. Care-Commensurate Reimbursement

To advocate that reimbursement for healthcare services be commensurate with the level of care provided, based on the needs of the patient.

Rationale
As a means to reduce costs for federal programs, the Centers for Medicare & Medicaid Services (CMS) has been aggressively expanding efforts to reduce reimbursement at certain sites of care. Specifically, CMS has cut reimbursement for care services provided at hospital outpatient departments to match the rate paid physicians’ offices. CMS refers to this policy as “site-neutral payment.” On the basis of site neutrality, CMS also extended cuts to hospital reimbursement for drugs purchased under the 340B drug discount program to hospital outpatient departments. Private payers have also sought to impose site-neutral payment policies.

Reimbursement for services should reflect unique factors associated with a site of care. Hospital outpatient departments are held to higher quality standards with more oversight than what is often required for alternate sites of care. In addition to the Medicare Conditions of Participation, hospital outpatient departments must meet accreditation, United States Pharmacopeia (USP), and even Food and Drug Administration requirements. These standards result in high-quality patient care, but at a higher cost than what can be accomplished without the oversight.

Patients may also derive benefits from receiving care at a hospital outpatient department. Hospital care delivery models are crafted to ensure that patients receive the highest quality care possible. For hospitals that belong to an accountable care organization or are otherwise part of an integrated network, seeing patients at the outpatient department allows providers to better coordinate care, resulting in improved patient outcomes. Care provided in this setting is often highly complex and complementary to acute care that the patient receives from the hospital. Drastic cuts to hospital outpatient reimbursement could endanger the long-term viability of these care delivery models – if services are cut or outpatient departments are closed, patient access will suffer.
**Background**
The Council discussed this issue against a backdrop of ongoing CMS efforts (i.e., the CMS Hospital Outpatient Prospective Payment System proposed rule) to institute payment cuts in settings where ASHP members provide services. Although the Council recognized that the reimbursement in question might not be for medication in all cases, the clinical reimbursement that is the target for current cuts often supports pharmacist services. In theory, there was support for equal payment for equal services, but the Council agreed that the context of the services had the potential to impact quality and outcomes. Discussion also focused on the potential unanticipated consequences of reducing reimbursement, including potential incentives for certain settings to cherry-pick patients or to reduce emphasis on ambulatory care services. The Council also felt that reimbursement should differentiate between care settings unless all settings of care are held to the same regulatory and oversight standards, as advocated in ASHP policy position 1914, Safe Medication Preparation, Compounding, and Administration in All Sites of Care.

**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

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**4. 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.*
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.
5. Public Quality Standards for Biologic Products

To oppose federal or state legislation that would remove the requirement for biologic products to adhere to public quality standards; further,

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.

6. New Categories of Licensed Pharmacy Personnel

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

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.
**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.

### 7. Funding, Expertise, and Oversight of State Boards of Pharmacy

1. To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,
2. To advocate representation on state boards of pharmacy and related agencies by pharmacists and pharmacy technicians; further,
3. To advocate that health systems are adequately represented on state boards of pharmacy; further,
4. To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies including funding for the training of state board of pharmacy inspectors and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the pharmaceutical supply chain, and protection of the public; further,
5. To advocate that inspections be performed only by pharmacists competent about the applicable area of practice.

*Note: This policy would supersede ASHP policy 1507.*
Rationale
In recent years, the regulatory scope of boards of pharmacy has grown to address new and expanded scopes of practice and healthcare while fulfilling its mission of protecting the public health. In addition, coordination with federal agencies (e.g., Food and Drug Administration, Drug Enforcement Administration) and related state agencies add to the complexity of a state board’s mission. With this expanded scope and mission comes the need for additional resources, both financial and human. Specific knowledge acquired by pharmacists and pharmacy technicians is essential to the safe regulation of practice. Thus, inspectors need to have that knowledge and training in order to assure the health and safety of the public.

Background
The Council reviewed ASHP policy 1507, Funding, Expertise, and Oversight of State Boards of Pharmacy, as part of sunset review and voted to recommend amending it as follows to simplify the language related to health-system representation on state boards of pharmacy (underscore indicates new text; strikethrough indicates deletions):

To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,

To advocate adequate representation on state boards of pharmacy and related agencies by pharmacists and pharmacy technicians knowledgeable about who represent various areas of pharmacy practice (e.g., hospitals, health systems, clinics, and nontraditional settings) to ensure appropriate oversight; further,

To advocate that health systems are adequately represented on state boards of pharmacy; further,

To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies including funding for the training of state board of pharmacy inspectors and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the pharmaceutical supply chain, and protection of the public; further,

To advocate that inspections be performed only by pharmacists competent about the applicable area of practice.

8. Dispensing by Nonpharmacists and Nonprescribers

To reaffirm the position that to ensure optimal patient outcomes all medication dispensing functions must be performed by, or under the supervision of, a pharmacist; further,
To reaffirm the position that any relationships that are established between a pharmacist and other individuals in order to carry out the dispensing function should preserve the role of the pharmacist in (a) maintaining appropriate patient protection and safety, (b) complying with regulatory and legal requirements, and (c) providing individualized patient care; further,

To advocate that all medication dispensing be held to the same regulatory standards that apply to dispensing by a pharmacist; further,

To urge pharmacists to assume a leadership role in medication dispensing in all settings to ensure adherence to best practices.

Note: This policy would supersede ASHP policy 0010.

Rationale
The Council recognizes the reality of limited pharmacist availability and lack of comprehensive pharmacy services in many settings, including public health clinics, rural and urban outreach clinics, and hospital emergency departments. However, the Council believes that responsibility and services of pharmacists are critical to safe medication use and that all dispensing should meet the same standards that apply to pharmacies and pharmacists. The Council believes that the current ASHP Minimum Standard for Pharmaceutical Services in Ambulatory Care is explicit and pertinent to the practice of dispensing by nonpharmacists and nonprescribers. The Council also noted that this type of drug delivery and dispensing arrangement does not constitute collaborative drug therapy management as defined in ASHP policy 9903.

Background
The Council reviewed ASHP policy 0010, Dispensing by Nonpharmacists and Nonprescribers, as part of sunset review and voted to recommend amending it as follows to strengthen the primacy of pharmacists in dispensing functions and to emphasize that patients are at risk when pharmacists do not maintain oversight of dispensing (underscore indicates new text):

To reaffirm the position that to ensure optimal patient outcomes all medication dispensing functions must be performed by, or under the supervision of, a pharmacist; further,

To reaffirm the position that any relationships that are established between a pharmacist and other individuals in order to carry out the dispensing function should preserve the role of the pharmacist in (a) maintaining appropriate patient protection and safety, (b) complying with regulatory and legal requirements, and (c) providing individualized patient care; further,

To advocate that all medication dispensing be held to the same regulatory standards that apply to dispensing by a pharmacist; further,
To urge pharmacists to assume a leadership role in medication dispensing in all settings to ensure adherence to best practices.

Board Actions

Sunset Review of Professional Policies
As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Pharmacist Participation in Health Policy Development (1501)
- Pharmacist Recognition as a Healthcare Provider (1502)
- Expedited Pathways for FDA Drug Approval (1411)
- Medicare Prescription Drug Benefit (0813)
- Medication Therapy Management (1005)
- FDA Authority on Recalls (1003)
- FDA’s Public Health Mission (0012)
- Nonproprietary Naming of Biological Products (1535)
- Patient Adherence Programs as Part of Health Insurance Coverage (1504)
- Statutory Protection for Medication-Error Reporting (1505)
- Regulation of Home Medical Equipment Medication Products and Devices (1007)

Other Council Activity

Joint Meeting on Violence and Firearm-related Injury and Death
On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Sheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law enforcement to identify security gaps and described workplace programs that help hospital
staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council on Pharmacy Practice developed proposed policy based on the discussion.

**Drug Pricing Recommendation**

The Council voted to explore options for having ASHP convene a workshop of pharmacists with relevant expertise to examine proposed drug pricing policy solutions and create a report with policy recommendations.

During discussions regarding drug pricing proposals related to healthcare reform and site neutrality, the Council felt that even with the background reading, the ramifications and parameters of the various policies (e.g., the International Pricing Index Model) remained unclear. An ASHP report breaking down various drug pricing proposals could be used to inform future policymaking and advocacy on the topic.

**Impact of Tariffs on U.S. Drug Supply**

The Council discussed a recommendation to consider policy related to the impact of tariffs on the national drug supply, particularly active pharmaceutical ingredient (API) produced in China. Although the Council recognized the potential impact of tariffs on pricing and availability of finished pharmaceuticals, they felt that our current policies on drug pricing and shortages would be sufficient to address the issue. Further, the Council was concerned that policy specific to tariffs would be perceived as overtly political and potentially divisive.

**Pharmaceutical Quality**

Although the Council had a robust discussion on pharmaceutical manufacturing quality, which arose from concerns about oversight of foreign manufacturing of generics, the Council did not propose new policy on the topic. The Council considered our current quality-related policies and deemed them robust enough to cover a range of quality issues. However, the Council did indicate that they have ongoing concerns related to the consistency of inspections of facilities as well as the application of the FDA’s quality ratings program. The Council recommended that the Council on Pharmacy Management review policy 1602, Drug Product Supply Chain Integrity, to determine whether it should include stronger language regarding inspections. Further, the Council suggested that ASHP should create goals related to manufacturing quality and work them into a longer-term advocacy strategy.
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.

Nish Kasbekar, Board Liaison

 Council Members
Snehal Bhatt, Chair (Massachusetts)
Christi Jen, Vice Chair (Arizona)
Sarah Anderson (Colorado)
Amie Blaszczyk (Texas)
Rena Gosser (Washington)
Cyrine Haidar (Tennessee)
Calvin Ice (Michigan)
Matthew Kostoff (Ohio)
Wesley Kufel, New Practitioner (New York)
H. Henry Le, Student (Oregon)
Andrew Mays (Mississippi)
Carolyn Oxencis (Wisconsin)
Vicki Basalyga, Secretary

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
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.

### 2. Safety and Efficacy of Compounded Topical Formulations

1. To advocate for the development of processes that would ensure potency, quality, and standardization of compounded topical formulations; further,

2. To advocate that public and private entities establish a process to evaluate and regulate the safety, efficacy, and composition of compounded topical formulations; further,

3. To advocate that public and private payers and healthcare providers collaborate to create standardized and efficient methods for authorizing payment for medically necessary compounded topical formulations; further,

4. To encourage hospitals and health systems to develop policies and procedures to guide clinicians in making informed decisions regarding the prescribing and use of compounded topical formulations; further,

5. To encourage pharmacists to take a leadership role in developing and providing education on the safety and efficacy of compounded topical formulations to providers and consumers.
Rationale
Compounded topical formulations are meant to be customized for individuals whose needs cannot be met by commercially available drugs. Unlike the drugs made by conventional manufacturers that require Food and Drug Administration (FDA) approval, compounded drugs such as various topical formulations are not evaluated by the FDA for safety, effectiveness, or quality, and many are exempt from the new-drug approval process, current good manufacturing practice, and other FDA requirements. In addition, quality standards for compounded drugs are generally lower than those for FDA-approved drugs; therefore, compounded drugs can pose increased safety risks (e.g., being contaminated or having the wrong potency) or lack efficacy.

Because some drugs do have FDA approval for topical application, clinicians and patients may not be aware of potential safety risks or potential lack of effectiveness associated with certain ingredients and combinations of ingredients in compounded topical pain creams. When these agents are compounded, at least one of the ingredients is an active ingredient in an FDA-approved topical pain cream (e.g., lidocaine), while the remaining ingredients may be active ingredients in drugs approved by the FDA for non-topical administration to treat non-pain-related indications (e.g., antidepressants, anticonvulsants, antivirals, narcotics). In addition, the literature supporting the use of the additional agents outside their normal vehicle of administration is often not well designed and are not sufficiently powered to demonstrate efficacy. A study published by the U.S. Department of Defense found that these combination-compounded pain creams were no better than placebo creams, and with their higher costs, which had escalated to cost of $6 million per day, should no longer be used.

Issues of fraud are also well known with compounded topical formulations. In August 2018, the Department of Health and Human Services Office of Inspector General (OIG) found that from 2006 to 2015, spending for these drugs increased 625%, and spending for compounded topical drugs—such as creams, gels, and ointments— grew at an even faster pace. Medicare Part D sponsors cover these drugs under certain circumstances. The OIG also found that Part D spending for compounded topical drugs increased 2353% from 2010 to 2016, rising from $13.2 million to $323.5 million. Much of this growth occurred from 2014 to 2016, when spending increased by more than $200 million and raised concerns that the drugs that were billed to Part D were not always dispensed or medically necessary. Upon investigation, the OIG found that many of the parties charging Part D were located in a handful cities, with thousands of prescriptions written by a single provider and filled by a limited number of pharmacies. This led HHS to conclude that the prescribers may not have had legitimate doctor-patient relationships with the beneficiaries.

Background
The Council discussed the increase in prevalence of compounded topical agents now being seen in hospitals and health-systems, particularly in long-term care facilities. Council members noted that there is a notable lack of standardization in the creation of these formulations, often to the point where some providers have developed their own “brand” of topical formulation, with ingredients and strengths that may have evidenced-based
Council members also expressed concerns about safety and efficacy, as pharmacokinetic and pharmacodynamics data are not known with these agents, which could put patients at high risk for adverse events, particularly the elderly, who use these products most frequently. Council members also shared experiences in which colleagues were arrested, fined, and jailed as a part of fraud schemes involving compounded topical formulations. Finally, the Council expressed concerns surrounding questionable evidence on safety and efficacy, concerns around USP Chapter 795 compounding, and undermining the use of legitimate topical compounds that have evidence for use (e.g., estrogen for fertility).

### 3. Postmarketing Studies

1. To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest and to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

2. To advocate that Congress provide adequate funding to FDA and other agencies to fulfill this expanded mission related to postmarketing surveillance and studies; further,

3. To advocate that such studies compare a particular approved drug product or licensed biologic product with (as appropriate) other approved drug products, licensed biologic products, medical devices, or procedures used to treat specific diseases; further,

4. To advocate expansion of studies of approved drug products or licensed biologic products to improve safety and therapeutic outcomes and promote cost-effective use; further,

5. To encourage impartial private-sector entities to also conduct such studies.

*Note: This policy would supersede ASHP policies 1004 and 0515.*

### Rationale

Pharmacists, other members of the healthcare team, patients, and private and public payers need objective, authoritative, and reliable evidence to make the best treatment decisions. Since the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Agency for Healthcare Research and Quality (AHRQ) has been tasked with studying the outcomes, comparative clinical effectiveness, and appropriateness of healthcare items and services. For such research to contribute to the practice of evidence-based patient care, good clinical decision-making, and rational drug use, AHRQ must evaluate devices, invasive procedures, and prescription and nonprescription medications, including both labeled and unlabeled uses of prescription drugs. Since prescription drugs represent a significant and growing portion of healthcare costs, the need for such research is increasingly important.
Although impartial private sector entities can supplement the research efforts of government agencies such as AHRQ, only the federal government has the ability to support such independent research, provide oversight to safeguard the integrity of the research process, and disseminate the findings.

Furthermore, to ensure safety, the Food and Drug Administration (FDA) has several requirements for manufacturers and programs in place to monitor postmarket adverse events. These requirements and programs include the Division of Medication Error Prevention and Analysis, which is responsible for monitoring and preventing medication errors related to the naming, labeling, packaging, and design for CDER-regulated drugs and therapeutic biological products; the Risk Evaluation and Mitigation Strategy (REMS) program, which is designed to help reduce the occurrence and severity of certain serious risks; by informing and supporting the execution of the safe use conditions described in the medication’s FDA-approved prescribing information; the Safe Use Initiative, a program that aims to reduce preventable harm by identifying specific, preventable medication risks and developing, implementing, and evaluating cross-sector interventions with partners who are committed to safe medication use. Other programs include the FDA Adverse Event Reporting System (FAERS), which is a database that contains adverse event reports, medication error reports, and product quality complaints resulting in adverse events that were submitted to FDA, and MedWatch, the FDA Safety Information and Adverse Event Reporting Program, which permits voluntary reporting by consumers and healthcare professionals and mandatory reporting for regulated industry and user facilities. Additionally, the FDA requires that adverse drug events (ADEs) must be reported in accordance with the requirements of 21 CFR 310.305 and 314.80, which require three types of ADE reports: (1) 15-day reports of serious, unlabeled events; (2) 15-day narrative increased frequency reports of serious, labeled events; and (3) periodic reports.

**Background**

The Council reviewed ASHP policies 1004, Postmarketing Comparative Clinical and Pharmacoeconomic Studies, and 0515, Postmarketing Safety Studies, as a part of sunset review and concluded that, although there is still a need for both of these policies, the essential elements should be consolidated into a single new policy. ASHP policy 0515, Postmarketing Safety Studies, reads:

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,

To advocate that Congress grant FDA broader authority to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA to fulfill this expanded mission related to postmarketing surveillance.

ASHP policy 1004, Postmarketing Comparative Clinical and Pharmacoeconomic Studies, reads:

To advocate that Congress grant the Food and Drug Administration (FDA) authority to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,
To advocate expansion of comparative clinical and pharmacoeconomic studies on the effectiveness, safety, and cost comparison of marketed medications in order to improve therapeutic outcomes and promote cost-effective medication use; further,

To advocate that such studies compare a particular medication with (as appropriate) other medications, medical devices, or procedures used to treat specific diseases; further,

To advocate adequate funding for the Agency for Healthcare Research and Quality and other federal agencies to carry out such studies; further,

To encourage impartial private-sector entities to also conduct such studies.

The Council voted to recommend amending the two policies as follows (underscore indicates new text; strikethrough indicates deletions):

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest; further,

To advocate that Congress grant FDA broader authority and to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA and other agencies to fulfill this expanded mission related to postmarketing surveillance and studies; further,

[CLAUSE MOVED] To advocate that such studies compare a particular medication approved drug product or licensed biologic product with (as appropriate) other medications approved drug products, licensed biologic products, medical devices, or procedures used to treat specific diseases; further,

To advocate expansion of comparative clinical and pharmacoeconomic studies of approved drug products or licensed biologic products on the effectiveness, safety, and cost comparison of marketed medications to improve safety and therapeutic outcomes and promote cost-effective use; further,

To advocate adequate funding for the Agency for Healthcare Research and Quality and other federal agencies to carry out such studies; further,

To encourage impartial private-sector entities to also conduct such studies.
4. Gabapentin as a Controlled Substance

To advocate that the Drug Enforcement Administration reschedule gabapentin to Schedule V due to its low potential for abuse and patient harm.

**Rationale**

Gabapentin is a structural analog of gamma-aminobutyric acid that is approved by the Food and Drug Administration (FDA) for post-herpetic neuralgia and as an adjunctive therapy for partial seizures. Gabapentin has been identified as an opportunistic drug of abuse which, when used in conjunction with other medications, particularly opioids, may result in serious adverse events such as respiratory depression and even death. Gabapentin is used due to its low cost, classification as a noncontrolled substance, and increasing rates of on- and off-label prescribing attributable to clinicians’ desire for an alternative to opioids for pain management. In the U.S., gabapentin is and remains a noncontrolled substance at the federal level despite evidence suggestive of diversion and abuse with opioids. Most recently, several states have made an effort to combat the diversion and abuse of gabapentin by examining various regulatory approaches, such as reclassification of gabapentin as controlled substance or mandating the reporting of the prescribing and/or dispensing of gabapentin to a state-level prescription drug monitoring programs (PDMPs). As recently as April 2019, the United Kingdom reclassified gabapentin as a Class C controlled substance, which required similar dispensing and monitoring as controlled substances in the U.S., due to the increase in abuse they have seen in this drug.

As defined by the Drug Enforcement Administration (DEA), Schedule V controlled substances “are defined as drugs with lower potential for abuse than Schedule IV” substances. Schedule IV substances “are defined as drugs with a low potential for abuse and low risk of dependence.” Recent data from multiple sources have shown a significant increase in gabapentin misuse, abuse, and diversion over the past 10 years, and one study found that 22% of a sample of 162 opioid-dependent patients had a prescription for gabapentin, of which 40% indicated they used more than prescribed to augment and enhance their opioid experiences.

The criteria used by DEA to determine whether to control or reschedule a drug include (a) the drug’s actual or relative potential for abuse; (b) scientific evidence of its pharmacological effect, if known; (c) the state of current scientific knowledge regarding the abuse of the drug or other substance; (d) its history or current pattern of abuse; (e) the scope, duration, and significance of abuse; (f) what, if any, risk there is to public health; (g) its psychic or physiological dependence liability; and (e) whether the substance is a precursor of a substance already controlled under the law. Based on an assessment using these criteria, gabapentin is similar to other controlled substances found in Schedule V and should therefore be assigned to Schedule V. Because some states have already taken steps to reschedule gabapentin as Schedule V or have added it to their PDMPs, the DEA should take steps to change the schedule status of gabapentin to ensure continuity of care and monitoring.

While it is difficult to predict the impact rescheduling may have on abuse, the current extent of abuse is likely exacerbated by easy access to and excessive supply of these therapies. However, the potential public health benefit of rescheduling must be weighed against concerns
about restricting patients’ access to treatment and increasing administrative and other burdens on pharmacists and other clinicians. The proposed change to a more restrictive schedule would require stricter recordkeeping and security processes, which could in turn make providers reluctant to prescribe these therapies for patients who need pain management. In balancing these concerns, it should be noted that increased control of drugs with abuse potential is in the best interests of patients and public health. DEA and other stakeholders should monitor the impact of this scheduling change on patient access and practice, as well as monitor the impact of other strategies that have been implemented to minimize the abuse and diversion of these therapies.

Background
The Council discussed the need to reschedule gabapentin from a nonscheduled drug to Schedule V under the Controlled Substance Act. The Council’s assessment included the review of the DEA criteria for drugs in Schedule V, the schedule status of the structurally similar drug pregabalin, and the reports from entities concerning the extent of abuse and patient harm. The Council discussed the necessity of the rescheduling of gabapentin to a Schedule V designation. Council members shared that they often see inappropriate prescribing in the outpatient setting in both the dose and frequency, which they believe may also be contributing to the cycle of abuse, as well as lack of an antidote. Furthermore, the Council discussed their concerns about patient access, noting that although the number of states making such a schedule change is increasing, scheduling is inconsistent across the U.S., which could lead to access and diversion issues. The Council believed that encouraging the DEA to change gabapentin’s schedule status would permit a uniform approach to monitoring and metrics.

Board Actions

Sunset Review of Professional Policies
As part of sunset review of existing ASHP policies, the following policy was reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue this policy.)

- Generic Substitution of Narrow Therapeutic Index Drugs (0817)

Other Council Activity

Joint Meeting on Violence and Firearm-related Injury and Death
On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in
November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law enforcement to identify security gaps and described workplace programs that help hospital staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council on Pharmacy Practice developed proposed policy based on the discussion.

**ASHP Statement on Over-The-Counter Availability of Statins**
The Council reviewed the ASHP Statement on Over-The-Counter Availability of Statins as part of sunset review. The Council believes that there is still a need for this statement but that it should be updated, since it has remained unchanged since drafted and approved in 2005. The Council recommends that content matter experts update this statement to include considerations for newer classes of statins; pharmacogenomics considerations and other areas not articulated in the current statement, including concerns for duplicate therapy; picking the most appropriate statin; omission from medication histories, as many patients do not consider over-the-counter medications as a part of their regimen; the Affordable Care Act increasing access to statins; and the role of statins as a significant part of quality measures now seen in healthcare. The Council agreed that while the updates are written, the statement should remain accessible and notice should be posted to indicate that that statement is currently under revision.

**Continuous and Extended Interval Antibiotic Dosing**
The Council discussed the practices of extending interval, continuous, and intravenous (IV) push administration of antibiotics and their role in practice. The Council reviewed how these treatment strategies, particularly extended internal and continuous infusions, have shown to increase the time an antimicrobial’s concentrations in the blood, mostly beta-lactams, are above the minimum inhibitory concentration, and the impact this has on critically ill patients, patients with impaired renal function, and outpatient strategies. The Council also discussed how new beta-lactams are only being studied as prolonged infusions. Members shared their institutions’ practices, which were variable across the country and depended on the antimicrobial. The Council also discussed the strategies that were employed during the small volume parenteral shortage, which consisted of administration of antimicrobials over IV push. The Council considered the data and operational considerations around these strategies and
believed that the best approach for ASHP would be to provide education on the impact of these administration approaches on morbidity, mortality, cost savings, and operational considerations.

**Clinical Utility of Drug-Specific Reversal Agents for Direct Oral Anticoagulants**

The Council discussed the current clinical, cost, and ethical issues surrounding the use of drug-specific reversal agents for direct oral anticoagulants. During the discussion, it was noted that most large academic medical centers will carry most of the drug-specific reversal agents, as the cost is not a barrier, whereas small and rural institutions will carry only one brand, use means of reversal that were available prior to the development of these drug-specific agents, or transport the patient to an institution that carries the agents. The Council also noted the need for research on dosing strategies, as these drug-specific reversal agents can be administered on a fixed-dose or weight-based strategy, and approaches vary widely across the country. The Council also discussed the pressure of keeping multiple agents on formulary, as practitioners are prescribing the direct oral anticoagulants more frequently and are assuring patients that all hospitals will have the required reversal agent, and the need for protocol-based management if the agent is on formulary, as use should be restricted to certain clinical cases. When reviewing existing policies, they believed that ASHP policy 1703, Pharmacist’s Leadership Role in Anticoagulation Therapy Management, addressed most of the concerns discussed but was missing the reversal component in the clauses and therefore recommended that the policy be updated to reflect this.

**Safety and Clinical Considerations for IV Fluid Lounges and Blood Bars**

A recent practice emerging on the consumer side of healthcare is the option to receive IV fluids or blood transfusions when it’s not considered medically necessary or specifically recommended as part of an established doctor-patient relationship. These sites often advertise their services as options for recovering from jetlag, hangovers, or food poisoning, or to improve a person’s appearance, and treatments are paid for out of pocket. The Federal Trade Commission has already investigated several of these companies that have claimed to be able to treat a variety of maladies and cited them for these infractions. Council members discussed the impact these facilities have on patient safety and hospitals and health systems, including cases of patient death due to sepsis, driving up the price of drugs in shortage, lack of medications and ingredients essential to patients who require them, and potential violations of USP Chapter 797. Council members also cited knowledge of other organizations, including A.S.P.E.N. and the Academy of Dietetics, who also view these sites as a threat to patient safety and well-being. Interestingly, many Council members were unaware how prolific these IV lounges where within their communities and suggested that ASHP provide education on the rising prevalence and risk these unique operations pose. Ultimately, the Council did not feel strongly that this warrants creation of an ASHP policy but suggested ASHP should collaborate with outside organizations such as A.S.P.E.N. and the Academy of Dietetics to write a statement or commentary on the impact these lounges are having on patient care to reach a broader audience and increase visibility of the potential dangers of this growing niche industry.
Intravenous Lidocaine for Pain Management

Lidocaine is a class 1B antiarrhythmic agent, which is mainly used for the treatment of ventricular arrhythmias and most commonly used as a local anesthetic in the outpatient setting. Intravenous (IV) lidocaine has become an increasingly popular alternative for acute pain management in post-operative settings, cancer pain management, and as a treatment strategy in the emergency department, as practitioners seek alternatives to opioids, particularly as it is an agent used in the alternatives to opioids (ALTO) approach to pain management. The Council discussed the patient safety and practice issues around using lidocaine for pain management, including the following:

- different dosing strategies (it is infused as mg/min as an antiarrhythmic but mg/kg/hr for pain management),
- the need for cardiac monitoring,
- lack of data for safety and efficacy after 24 hours, and
- electrolyte and serum monitoring, and no conclusive correlation between serum levels and pain relief.

Despite these potential barriers, there is still promise that lidocaine could be an appropriate medication in certain clinical situations. Therefore, the Council recommends that there be more information available to pharmacists, including education, resources, and potentially a review article on the available safety, efficacy, and operational considerations for using this agent for the management of pain.
COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATION

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.

Paul C. Walker, Board Liaison

Council Members
Seena Haines, Chair (Mississippi)
Garrett Schramm, Vice Chair (Minnesota)
Angela Bingham (Pennsylvania)
Christopher Edwards (Arizona)
David Gregory (Tennessee)
Chelsea Gresham, New Practitioner (West Virginia)
Carol Heunisch (Illinois)
Jesse Hogue (Michigan)
Norman Hooten (Florida)
Denise Kelley (Florida)
Ann Lloyd (Oklahoma)
Jenna Summerlin, Student, (Tennessee)
Erika Thomas, Secretary

1. Residency Training for Pharmacists Who Provide Direct Patient Care

To recognize that optimal direct patient care by a pharmacist requires the development of clinical judgment, which can be acquired only through experience and reflection on that experience; further,

Pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience; further,

To support the position 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.

Note: This policy would supersede ASHP policies 0701 and 0005.

Rationale
Pharmacists who engage in direct patient care can improve patient outcomes and significantly decrease the overall costs of the healthcare system. Completion of a postgraduate pharmacy residency enables a pharmacist to maximize the provision of these direct patient care services.
The use of well-trained pharmacy technicians and technological advances will minimize pharmacists’ dispensing roles. Based on the assumption that in the next 20-30 years most pharmacists will be providing direct patient care, it is incumbent upon the pharmacy profession to ensure that pharmacists are in a position to make the most effective interventions when selecting, modifying, and monitoring patients’ drug therapy regimens.

Pharmacy students who graduate meet the minimum competency requirements based on pharmacy licensing examinations; however, pharmacists who have completed a residency are better equipped to provide direct patient care due to advanced training based on repetitive practice, preceptor guidance, and the additional interdisciplinary training they receive. This direction is consistent with ASHP’s Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems.

Similar to the medical model in which medical school graduates complete a residency that allows for the standardization of physician training and the attainment of an appropriate level of competency, the profession of pharmacy would benefit from a similar standardization of training. The value of pharmacy residency programs has been demonstrated over time and has stimulated a significant increase in accredited residency programs as well as employer demand for residency-trained pharmacists. An increasing number of pharmacy graduates are completing one or two years of residency training after graduating in order to bolster their clinical skills and develop clinical judgement, which is acquired only through experience and reflection on that experience.

The number of PGY1 residencies continues to grow with the number of available residencies in the U.S. is now nearly 2600 programs. The growth in the number of pharmacy school graduates has begun to plateau while PGY1 residency positions has grown 11% in the last three years.

**Background**

The Council reviewed ASHP policy 0005, Residency Training for Pharmacists Who Provide Direct Patient Care, and ASHP policy 0701, Requirement for a Residency, as part of sunset review and voted to recommend consolidating the two policies and amending them as follows (underscore indicates new text; strikethrough indicates deletions; first two clauses are from policy 0005 and the final one is from policy 0701):

To recognize that optimal direct patient care by a pharmacist requires the development of clinical judgment, which can be acquired only through experience and reflection on that experience; further,

Establish as a goal that Pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience; further,

To support the position that by the year 2020, the completion of an ASHP-accredited postgraduate-year-one residency should be a requirement for all new college or school of pharmacy graduates who will be providing direct patient care.
Board Actions

Sunset Review of Professional Policies
As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Communication Among Health-System Pharmacy Practitioners, Patients, and Other Healthcare Providers (0510)
- Employment Classification and Duty Hours of Pharmacy Residents (1008)

Other Council Activity

Joint Meeting on Violence and Firearm-related Injury and Death
On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law enforcement to identify security gaps and described workplace programs that help hospital staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council on Pharmacy Practice developed proposed policy based on the discussion.

ASHP Statement on Professionalism
The Council reviewed the current ASHP Statement on Professionalism, approved by the ASHP Board of Directors in 2007, and discussed the relevance of the document in light of
contemporary practice. Council members believed that the statement is still necessary and relevant, but suggested that the scope of the statement be expanded to include the pharmacy workforce. Members also discussed how social media is prevalent in practice and our personal lives and should be addressed in the statement. As contemporary practice extends patient care beyond the hospital and into areas such as ambulatory care, transitions of care, and other areas, the Council felt that these new practices should be considered when updating the statement. Additional facets of contemporary professionalism that the Council felt should be addressed include the concept of continuous professional development, credentialing and privileging, and board certification. The Council also discussed how professionalism is an important characteristic of leadership and as pharmacists and pharmacy technicians continue to evolve into leadership roles, both formal and informal roles, professionalism is an important foundation for the pharmacy workforce. A writing group will develop an updated statement and bring the statement back to Council.

**Mental Health Resources and Training Programs**

Council discussed the fact that one in five Americans suffers from a mental illness or substance use disorder. Members also agreed that recognizing mental health and substance use challenges can be difficult, which is why it is so important for everyone, including pharmacists, to understand the warning signs and risk factors. Mental health resources available for the general public as well as healthcare practitioner-level training resources were discussed. Council acknowledged that mental health training and awareness is an important component of ASHP policy 1825, Clinician Well-being and Resilience that Council drafted in 2018, as well as the ASHP Clinician Well-Being and Resilience Initiative. The fact that the level of mental health training in the pharmacy curriculum varies widely was addressed, but overall the Council felt that most student pharmacists currently have minimal education in this area. However, many schools and colleges of pharmacy are currently developing further pharmacy-specific education on mental health based on programs such as the Mental Health First Aid program offered through the National Council for Behavioral Health. Council members also acknowledged that pharmacists are in a unique position to recognize selected warning signs of mental health issues based on the patient’s medication therapy and that training pharmacists on targeted patient education on mental health is an important component of effective patient counseling. Sharing of best practices in this area is also important. Further, making additional resources available on the Workforce Well-Being and Resilience Resource Center and the State Affiliate Well-Being and Resilience Toolkit, will further disseminated this important information. The Council addressed this topic to determine the need for an ASHP policy advocating for mental health training and education for the pharmacy workforce. Members were in agreement that this issue is most appropriately addressed through education and raising awareness among the pharmacy workforce instead of a new policy. Members also felt that ASHP policy 1901, Suicide Awareness and Prevention, also advocates for education and training of the pharmacy workforce on mental health.

**Pharmacists in the Gig Economy**

The Council discussed the new roles for pharmacists as temporary or contract workers in the
“gig economy,” which is becoming more commonplace due to smartphone technology. As stated in the 2014 National Pharmacist Workforce Survey, “the pharmacy profession currently has, and will continue to build, capacity for contributing to the U.S. healthcare system. However, as shifts in professional roles occur, deployment of capacity must meet the requirements of changing service models.” Examples of contract work facilitated by digital platforms were reviewed. The Council discussed implications of new roles for these temporary or contract workers, including the following: educational training, professional training and redeployment, updates to practice acts and regulations, new documentation and billing systems, enhanced information exchange, collaborative practice models, infrastructure, technology, policy, and new business models. Council felt that with the increase in mail-order pharmacies and closing of community pharmacies (especially rural pharmacies), patients are further away from personal interaction with pharmacists, and the gig economy model has the potential to deploy pharmacists to meet with patients on demand. This could be especially beneficial in rural communities, where access to a pharmacist may not be available through primary or ambulatory care.

New models of temporary and contract work may provide an innovative model for expanding patient care and additional income to pharmacists. The Council will continue to monitor these new roles in the gig economy and the potential impact on the pharmacy workforce.

**Essential Elements for Core Advanced Pharmacy Practice Experiences:**

**Hospital and Health-System Pharmacy Essential Elements**

The Council discussed the American Association of Colleges of Pharmacy (AACP) new Hospital/Health System (HS) Pharmacy Essential Elements and implications for hospital and health-system practice. In February 2015, the Accreditation Council for Pharmacy Education (ACPE) published the 2016 accreditation standards and key elements for professional programs in pharmacy leading to the doctor of pharmacy degree. The standards outlined principles for both the didactic and experiential curriculum. ACPE’s standards focus on key elements that should be incorporated in experiential rotations to help students become practice-ready upon graduation. Although the hour allotment is specified, definitions of each of the required practice settings is not provided. Due to the lack of definitions regarding each required practice setting, inconsistencies have been found in how colleges and schools of pharmacy interpret the core advanced pharmacy practice experiences (APPEs). In an effort to bring uniformity to the expectations of student learning in each practice area, AACP formed a task force charged with developing a set of essential elements describing the minimum competencies for each setting. After the initial AACP task force draft in 2016, essential elements were approved for all practice settings, with the exception of the HS APPE. In 2019, the AACP task force finalized the essential elements for HS APPEs.

Council members discussed the HS APPE essential elements, taking into consideration the inpatient general medicine patient care APPE essential elements; the ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals, which outlines critical pharmacy service elements that are essential to successful patient care outcomes; and the ASHP/ACPE Entry Level Competencies Needed for Pharmacy Practice in Hospital and Health Systems, which
describes the competencies needed for entry-level practice in hospitals and health systems and helps identify gaps in the readiness of new pharmacy graduates were also considered in the discussion. Council members acknowledged that the HS APPE essential elements were new and colleges and schools of pharmacy will be determining how this would be implemented. Council members also acknowledged the fact that residency programs may be impacted because some residents may require additional training in compounding sterile preparations since students may not have the necessary training or certification to compound sterile preparations upon graduation.

Recent Pharmacy Workforce-Related Survey Results
The Council discussed several recent pharmacy workforce-related survey results, including the AACP New Graduate Surveys, HRSA Allied Health Workforce Projections, 2016-2030: Pharmacists, and ASHP National Survey of Pharmacy Practice in Hospital Settings: Workforce—2018 to determine whether there are implications for ASHP policy.

Dr. Bradley-Baker provided Council with an update on the Pharmacy Career Information Center (PCIC) and the recent 2019 National Pharmacist Workforce Study - Preliminary Results of Main Survey.

The Council discussed the importance of communicating to ASHP members that the profession is changing and pharmacists need to be proactive about its future. The Council discussed how the profession should take this opportunity to highlight what pharmacists are trained to do and how we can continue to expand the scope of currently provided services. The Council also suggested that ASHP continue to explore collaborations with other organizations that advocate for expanded pharmacist participation in patient care.

Clinician Well-Being and Resilience – Residency Standards
The Council discussed incorporating the requirements for well-being and resilience into pharmacy residency standards and the issue of pharmacy residency preceptor resilience and well-being. Council has examined the issue of clinician well-being and resilience in the past and developed proposed policy for ASHP policy 1825, Clinician Well-Being and Resilience. The Accreditation Council for Graduate Medical Education (ACGME) recently incorporated requirements for clinician well-being and resilience into residency program requirements. The requirements emphasize that “psychological, emotional, and physical well-being are critical in the development of the competent, caring, and resilient physician.” As the ASHP Commission on Credentialing (COC) revises the standards for pharmacy residency programs, the issue of incorporating well-being and resilience into the standards is under discussion. In addition to considering embedding well-being and resilience into the residency standards, the COC will be considering other platforms, such as initiatives, ideas, and routines, which can be implemented in pharmacy residency programs to promote clinician well-being and resilience.

The discussion on the proposed addition of clinician well-being and resilience requirements into pharmacy residency standards included the possibility of expanding the effort to include preceptors and residency program directors. Council members provided examples of how organizations and departments are addressing this issue. For example, one program spends the last 20 minutes of each day discussing what went well that day and
another program covers available services during the resident on-boarding process. The Council agreed on the importance of identifying and educating residents and preceptors on available resources and signs of burnout before a crisis occurs. ASHP was encouraged to continue to provide resources and best practices on well-being and resilience to members. The Council discussion on this topic will be shared with the COC as they continue this discussion.

Pharmacists Role in Mitigating the Primary Care Physician Shortage

The Council examined the role that pharmacists, as direct care providers, can assume to incorporate pharmacists into primary care models of care to help address the shortage of primary care physicians. The Association of American Medical Colleges (AAMC) published an updated report in April 2019, Complexity of Physician Supply and Demand: Projections from 2017-2032, that projected a shortage of up to 122,000 physicians by the year 2032, including a shortfall of up to 55,200 primary care physicians. Population growth and aging are the most important contributing factors for increased demand in healthcare services. The shift from fee-for-service to value-based care as part of the U.S. healthcare system transformation places an increased emphasis on population health initiatives that achieve the quadruple aim of including healthcare lowering costs, improving quality, and improving the patient and provider experience. Increases in chronic disease, mental health concerns, and the opioid epidemic have influenced the number of patients needing care, and improving access to care is a goal of the Affordable Care Act. Rural and underserved communities are particularly impacted by the primary care provider shortage, leading to health disparities and poorer outcomes.

Pharmacists are considered our nation’s medication experts, and multiple organizations, including the National Governors’ Association, the Patient Centered Primary Care Collaborative (PCPCC), and Get the Medications Right Institute, advocate for recognizing pharmacists as providers, embedding pharmacists into primary care practices, and creating financial sustainability for the provision of comprehensive medication management by pharmacists. ASHP has long championed the role of the pharmacist on interprofessional teams and the development of collaborative practice agreements, and served as a leader in developing best practices in ambulatory care. Pharmacists across the country provide a wide variety of services in interprofessional teams including but not limited to annual wellness visits, disease management, transitions of care, comprehensive medication management, immunizations, medication assistance, medication adherence programs, and many others.

In order to increase uptake of these models, ASHP developed the Ambulatory Care Self-Assessment as part of the Practice Advancement Initiative and support pharmacists and health systems with the development of innovative care models that increase access to care and improve patient care outcomes through the A3 Collaborative. Although pharmacists could improve patient care outcomes through the provision of direct patient care services, the AAMC report focuses primarily on the role that physician assistants and nurse practitioners play in mitigating the primary care physician shortage. As the nation grapples with how to care for an aging population and provide comprehensive, accessible, patient-centered care for a growing population, it is paramount that pharmacists are seen as a profession that can mitigate the primary care provider shortage. Continued collaboration with medical, physician assistant, and nurse practitioner professional organizations as well as groups such as Get the Medications Right Institute, the A3 Collaborative, PCPCC, the Centers for Medicare & Medicaid Services, and
others is warranted so that the profession of pharmacy is at the table when solutions to the primary care shortage are developed. Council discussed the fact that pharmacists working as primary care providers could be especially important in rural and underserved communities. As of today, individual states authorize pharmacists to offer certain healthcare services for patients, including immunizations, diabetes management, blood pressure screenings, and various routine checks. However, these services are not federally recognized, and there is no direct path for Medicare to reimburse for these services. This is a barrier to pharmacists providing primary care.

The Veterans Health Administration is a model of pharmacists providing primary care—practicing at the top of their licenses and scopes of practice, demonstrating impact for quality care and improving access to care for patients. Council members felt that it was imperative that the workforce, new graduates, and current practitioners, continue to prepare to provide primary care now. The need for continued provider status advocacy on the state and national level is imperative. The ASHP Statement on the Pharmacist’s Role in Primary Care will be updated and brought back to Council for approval.

**Updates on ASHP Residencies, Well-being and Resilience Initiative, and Preceptor Resources**

The Council was provided with updates on topics from previous Council discussions. During the update on residencies, it was announced that the number of residency program has exceeded 2500 programs. Although the number of programs continues to grow, PGY2 residency growth exceeds PGY1 growth. There has been progress in requiring accredited education for licensure of technicians with NABP, and New Hampshire is now looking at this issue. An update on ASHP’s Workforce Well-Being and Resilience initiative highlighted new milestones in the upcoming year, including a December 2019 Well-Being Collaborative, continued dedicated programming at ASHP national meetings, expanded Resource Center information for members, a membership-wide survey, and continued collaborations with the National Academy of Medicine. Finally, an update on the Section of Inpatient Care Practitioners Section Advisory Group on Pharmacy Practices Experiences Precepting’s initial work on IPPE Preceptor resources was presented.

**Credentialing, Privileging, and Competency Assessment**

At its Policy Week 2019 meeting, the Council on Public Policy reviewed ASHP Policy 1907 on the suggestion of the ASHP House of Delegates and voted to recommend amending that policy. After reviewing the proposed amendments (provided below), the Council on Public Policy noted that ASHP policy 1415, Credentialing, Privileging, and Competency Assessment, contained very similar language and asked the Council on Education and Workforce Development to review the two policies (policy 1415 and the proposed revisions to policy 1907) for potential consolidation. The Council on Public Policy recommended amending policy 1907 to read as follows:

To recommend the use of credentialing and clinical privileging in a manner consistent with other healthcare professionals to assess a pharmacist’s competence to engage in patient care services.
The Council on Education and Workforce Development reviewed the two policies and agreed that the two policies could be consolidated by revising policy 1415 as follows (underscore indicates new text; strikethrough indicates deleted text):

To support the use of post-licensure credentialing, privileging, and competency assessment to practice pharmacy as a direct patient-care practitioner; further,

To recommend the use of post-licensure credentialing, privileging, and competency assessment in a manner consistent with other healthcare professionals to assess a pharmacist’s competence to engage in patient care services; further,

To advocate that all post-licensure pharmacy credentialing programs meet the guiding principles established by the Council on Credentialing in Pharmacy; further,

To recognize that pharmacists are responsible for maintaining competency to practice in direct patient care.

The Council also noted that the Board of Directors and the House of Delegates had not yet had a chance to review and potentially amend the revised policy 1907, and agreed to defer action on consolidating the two policies until the Board and House of Delegates take action.

**Council Review of ASHP Policy 1715, Collaborative Practice**

On the suggestion of the Council on Public Policy, the Council reviewed ASHP policy 1715, Collaborative Practice, for potential consolidation with policy 1415. The Council concluded that the topics of the policies were substantially different and that consolidation would not be appropriate, so no action was taken.
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.

Kristina L. Butler, Board Liaison (Oregon)

Council Members
Victoria Serrano Adams, Chair (California)
Staci Hermann, Vice Chair (New Hampshire)
Ashley Bowden, New Practitioner (Utah)
Daniel Dong (California)
Lynn Eschenbacher (Missouri)
Amanda Hays (Missouri)
Jessica Hill (New Jersey)
Rondell Jaggers (Georgia)
Trinh Le (North Carolina)
Bonnie Levin (Maryland)
Arpit Mehta (Pennsylvania)
Lyndsay Ryan, Student (New Mexico)
Eric Maroyka, Secretary

1. Pharmacist’s Role in Health Insurance Benefit Design

To advocate that pharmacy practice leaders collaborate with internal and external partners who design, negotiate, and select their own organization’s health plans and pharmacy benefit management contracts to preserve the integrity of health-system pharmacy operations.

Rationale
Pharmacy leadership should be directly involved in the selection of the health system’s pharmacy benefit manager (PBM) servicing their employee’s health plan, and the terms of that contract with that PBM. Employers typically look to balance value for the employee while attempting to control costs. As health systems evaluate and select plans, there may not always be due consideration given to the potential impact to that health system’s pharmacy operations and financial solvency in servicing employees’ prescriptions through the selected PBM. Aside from the safety and continuity of care implications to the patient if the health system’s pharmacy is excluded from the employees’ network, organizations may unknowingly undermine utilization of their outpatient cancer and infusion programs. Three PBMs control the majority of the PBM market, exerting heavy influence in costs, pharmacy participation, formulary, and prior authorization criteria. By including pharmacy leadership to help make a well-informed decision about selecting a servicing PBM for a health system, and the contract terms associated with that PBM (i.e., clinical and financial aspects), some of these unintended consequences could be avoided.
Background
Given the significance of the topics in the proposed policy for the responsibility for the care of patients and the fiscal solvency of hospitals and health systems, the Council recommended ASHP support education for pharmacy practice leaders on the key elements of this proposed policy. Consideration should be given to executive leader skills to ensure presence and leadership to influence employee health and pharmacy benefit design; how to conduct a formulary review in the 21st century, keeping the care continuum in mind; a pharmacy benefit management “boot camp” (i.e., economics of the business of pharmacy); and partnership with other pharmacy and nonpharmacy associations (e.g., Academy of Managed Care Pharmacy, American College of Healthcare Executives, Society for Human Resource Management, National Community Pharmacists Association). Additionally, ASHP should support research and develop educational resources for hospital executives, providers, and patients to address concerns about biosimilar formulary changes (e.g., safety concerns, interchangeability, emotional impact).

2. Preserving Patient Access to Pharmacy Services in Medically Underserved Areas

To advocate for funding and innovative payment models to preserve patient access to acute and ambulatory care pharmacy services in rural and medically underserved areas; further,

To support the use of telepharmacy to maintain pharmacy operations and pharmacist-led comprehensive medication management that extend patient care services and enhance continuity of care in rural and medically underserved areas; further,

To advocate that the advanced communication technologies required for telepharmacy be available in rural and medically underserved areas; further,

To advocate for funding of loan forgiveness or incentive programs that recruit pharmacists and pharmacy technicians to practice in rural and medically underserved areas.

Rationale
Increasing hospital closures are not a recent phenomenon – rural areas have been closing hospitals for decades. For instance, 140 rural hospitals closed between 1985 and 1988 after the implementation of Medicare’s Inpatient Prospective Payment System. This payment model led to large Medicare losses and increased financial distress for many rural hospitals, ultimately resulting in numerous hospital closings.

Today, many rural hospitals are facing a similar fate. Nationally, 430 rural hospitals are at high financial risk due to low reimbursement rates and decreasing local populations. These factors make it difficult for hospitals to cover fixed costs, let alone remain up to date with
technological advances and emerging healthcare practices.

Since 2010, 99 hospitals in rural and medically underserved areas in the U.S. have closed. Between 2013 and 2017 alone, 64 rural hospitals closed, which is more than twice as many as the previous 5-year period. Hospital closures disproportionately affected rural hospitals in the South (64% of rural hospital closures) and are more prevalent in states that did not expand Medicaid coverage. It is estimated that hundreds more hospitals are at risk of closing; therefore, the impact of these closures on access to and continuity of care should be assessed.

Although hospital closures in rural areas have numerous consequences, reduced access to care for the populations served is the most obvious one. An analysis by the Medicare Payment Advisory Commission determined that one third of hospitals that have closed since 2013 are more than 20 miles from the next closest hospital. An issue brief published by The Kaiser Commission on Medicaid and the Uninsured found a major impact of hospital closure to be loss of access to emergency care in the community; more specifically, a lack of access for people with acute mental health or addiction treatment needs was found.

Other consequences of rural hospital closures are focused around accessibility of physicians and other healthcare providers. Regardless of hospital closures, rural communities commonly struggle to recruit and retain healthcare providers. Retention of these providers becomes increasingly difficult when a hospital closes due to providers relocating to an alternative hospital or clinic location. As a result, communities are often left without vital healthcare providers and exacerbate gaps in access to specialty care. For instance, specialists who visited the local hospital on a regular basis become unavailable to residents in the area after the hospital closes, or residents lose their access point for referrals to subspecialists. In addition, once hospitals close other resources dwindle, such as home health, pharmacy, hospice, and emergency medical services care, thus leading to hospital deserts and a dramatic decrease in access to and continuity of care for residents.

With the number of hospital deserts increasing, residents are forced to seek care elsewhere, if at all. In a 2018 Government Accountability Office report, elderly and low-income populations were more likely to be negatively impacted by rural hospital closures, and these populations were also found to be more likely to delay or forgo care after a hospital closure if the patient had to travel longer distances.

Finally, it is important to note that not all rural hospital closures lead to a complete depletion in access to care for residents. There has been some success with transitions to community-based primary care following a hospital closure. In this scenario local residents still have access to primary care services, but not necessarily critical services, such as those necessary for cardiac arrest or stroke. Currently there is no systematic approach to determine which services are critical to provide locally or virtually, and not every hospital closing can be smoothly transitioned into a primary care facility to address residents’ healthcare needs.

Background
The Council discussed the growing trend of hospital closures in rural and medically underserved areas on access to and continuity of care as it relates to safe and effective medication use, primary care, and population health. The Council recommended the Section of Inpatient Care Practitioners (SICP) Section Advisory Group on Small and Rural Hospitals review the proposed
policy draft clauses to help influence the content. As part of the ASHP grassroots advocacy agenda, the Council stressed the need for ASHP to work with its constituents to influence state legislators, payers, and boards of pharmacy for supporting safe, innovative, and scalable approaches to preserving care in rural and medically underserved areas. This includes adoption and use of telepharmacy, subsidizing infrastructure needs (e.g., for USP Chapter 797 compliance), and a sustainable payment model. The Council also discussed the need for effective recruitment and retention strategies to offset the paucity of pharmacist and pharmacy technician skill sets in underserved areas, even those areas with ready access to telehealth. This includes, but is not limited to, advocacy efforts in support of loan forgiveness and incentive programs for the pharmacy workforce to practice in underserved areas. Given the variety of topics in the proposed policy recommendation, the Council recommended that SICP, the Section of Pharmacy Practice Leaders, and/or the Section of Ambulatory Care Practitioners develop survival tools to help inform strategies to assist the underserved on the fringes of a large health system. Consideration should be given to how to build facility and digital infrastructure, identifying and supporting practice-based needs, fostering the recruitment and retention of pharmacy staff to bridge gaps in care, and staff development of a multifaceted pharmacist generalist to support these struggling practice settings. Finally, the Council also recommended SICP explore any publication, networking, and/or education needs to highlight best practices to preserve patient access to pharmacy services when a rural or medically underserved area grapples with closures.

3. Multistate Pharmacist Licensure

1. To advocate for multistate pharmacist licensure to expand the mobility of pharmacists and their ability to practice remotely.

**Rationale**

Rapid changes in technology have increasingly allowed healthcare to be delivered at a distance, and the growth of health systems and the consolidation and closing of hospitals in rural areas have created a demand for practitioner mobility across state lines. The century-old state-by-state licensure model of pharmacy has not kept pace with these changes, creating barriers to care. The nursing profession has addressed this challenge by creating the enhanced Nurse Licensure Compact (NLC). Under the NLC, registered nurses and licensed practical/vocational nurses who meet uniform standards are granted one multistate license that provides the privilege to practice in their home state and any other NLC state. This licensing model protects the interests of the state in ensuring the qualifications of its healthcare providers while fostering provider mobility and distance healthcare, increasing access to care. This licensing model has demonstrated its value by growing to include 25 states over 20 years. In addition, the NLC reduces the cost and administrative burden of licensure to both healthcare organizations and providers.
Background
As the Council discussed the growing trend of hospital closures in rural and medically underserved areas, it concluded that multistate licensure could help address this challenge by encouraging telepharmacy and pharmacists’ ability to practice in different states. The Board felt that the issue of multistate pharmacist licensure was sufficiently important and distinct that it merited a standalone policy.

4. Continuity of Care in Pharmacy Payer Networks

To oppose provider access criteria that impose requirements or qualifications on participation in pharmacy payer networks that interfere with patient continuity of care or patient site-of-care options.

Rationale
As hospitals and healthcare organizations have become more engaged in developing ambulatory care services, pharmacies (e.g., specialty, outpatient infusion) and pharmacists working in those settings increasingly find themselves excluded from healthcare payer networks. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to profitably operate), but when creating provider networks, payers should also consider the potential impacts on a patient’s care and choice. Patients generally choose pharmacies that are most convenient for them. When providers or pharmacies are locked out of a payer network, patients may face barriers (e.g., physical access) to therapy, which can delay or otherwise frustrate treatment. Pharmacies within health systems have an advantage when it comes to electronic health record (EHR) integration, proximity and relationship to providers, and in some cases onsite clinical pharmacy specialists. This clinically superior environment, coupled with health systems’ ability to measure and meet outcome-based metrics, allows them to easily show their performance against other pharmacies. Therefore, giving payer network access to integrated health-system pharmacies could improve care coordination and quality-based care, and reduce overall cost.

Background
The Council reviewed ASHP policy on pharmacist and pharmacy access to provider networks and recognized a need to address the potential impact of provider access criteria on patient continuity of care, and the Board agreed that a standalone policy was needed to address this gap. The Council also recommended an ASHP partnership with other nonpharmacy associations for leverage and a broader advocacy message related to integrated end-to-end, patient-centered care, not just for billing but also for managing the patient experience and outcomes, including deprescribing opportunities. This approach is centered on keeping care within a system, without financial penalty or denied reimbursement, if that health system is not the payer-preferred site of care. The Council also recommended that ASHP provide education for members on how to navigate and succeed in a payer-directed world and the impact of risk-
sharing arrangements on transparency. Finally, ASHP should consider a survey of ASHP members to determine the scope of impact related to exclusionary pharmacy payer network requirements to help further inform the advocacy message.

## 5. 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,

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

3. 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,

4. 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,

5. 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,

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

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

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

*Note: This policy would supersede ASHP policy 0507.*

**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.

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.

6. Medication Formulary System Management

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 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.
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 involvement of appropriate healthcare professionals, and are not based solely on economic factors.

Formulary management techniques may differ under an integrated or network system versus an individual healthcare entity. Standardized drug formularies within integrated health systems increase coordination complexity, but help drive standardized medication use processes across sites of care.

Additionally, insurance coverage of medications should not interfere with the safe and effective provision of care. For example, some hospitals are currently being forced to administer a specific payer-preferred biosimilar drug to a covered patient, which requires hospitals to stock a different product for each payer and then ensure the correct one is dispensed. This costly and resource-intensive practice also has medication safety implications and negatively affects supply chain efficiency. Biosimilar drugs are considered to be 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.

### 7. Health-System Use of Medications Supplied to Patients

1. To encourage hospitals and health systems not to permit administration of medications brought to the hospital or clinic by the patient, caregiver, or specialty pharmacy when storage conditions or the source cannot be verified, unless it is determined that the risk of not using such a medication exceeds the risk of using it; further,

2. To support care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further,

3. To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications.

*Note: This policy would supersede ASHP policy 0806.*
Rationale
Medications brought into a hospital or health system without an institution’s direct oversight raise questions about a product’s proper storage and pedigree. These include patient home medications, including specialty pharmaceuticals (i.e., brown-bagging) brought in by the patient or caregiver, and specialty pharmaceuticals shipped directly from a specialty pharmacy directly to the location where they are being administered (i.e., white-bagging). The hospital or health system should have policies and procedures in place and make a reasonable attempt to verify the medication pedigree and product integrity to ensure safe and appropriate administration of medications. Health and pharmacy benefit management models should ensure fair reimbursement and payment for medication preparation and administration and in the provision of direct patient care services for medications supplied to patients from a supplier outside of a hospital or health system.

Background
The Council reviewed ASHP policy 0806, Health-System Use of Medications and Administration Devices Supplied Directly to Patients, as part of sunset review and voted to recommend splitting it into two policies, one focused on medications brought into a hospital or health system without the institution’s direct oversight (this recommendation) and one focused on safe and appropriate use of administration devices brought into facilities by patients (see Voted to Recommend 10 below). The Council voted to recommend amending ASHP policy 0806 as follows (underscore indicates new text; strikethrough indicates deletions):

To encourage hospitals and health systems not to permit administration of medications brought to the hospital or clinic by the patient, or caregiver, or specialty pharmacy when storage conditions or the source cannot be verified, unless it is determined that the risk of not using such a medication exceeds the risk of using it; further,

To support care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further,

To encourage hospitals and health systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients) unless it is determined that the risk of not using such a device exceeds the risk of using it; further,

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices.
8. Health-System Use of Administration Devices Supplied Directly to Patients

To encourage hospitals and health systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients), unless it is determined that the risk of not using such a device exceeds the risk of using it; further,

To encourage hospitals and health systems to train staff on the handling and use of medication administration devices brought in by patients; further,

To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team.

Note: This policy would supersede ASHP policy 0806.

Rationale
The potential exists for serious patient safety and liability issues for healthcare staff when the use of patients’ own infusion devices is allowed. Devices unfamiliar to staff are particularly risky and may result in patient harm. There are, however, occasions when the benefits of using patients’ own devices may outweigh the risks. Organizational policies and procedures should exist for handling such situations, complemented by expedient methods to gain familiarity and competency demonstration with a device. A pharmacist should be available to verify the medication and the associated device and use a technique (e.g., SBAR, team huddle) for communicating critical information to the interprofessional care team.

Background
The Council reviewed ASHP policy 0806, Health-System Use of Medications and Administration Devices Supplied Directly to Patients, as part of sunset review and voted to recommend splitting it into two policies, one focused on medications brought into a hospital or health system without the institution’s direct oversight (see Voted to Recommend 9 above) and one focused on safe and appropriate use of administration devices brought into facilities by patients (this recommendation). The Council recommended amending two clauses from ASHP policy 0806 as follows (underscore indicates new text; first two clauses are from ASHP policy 0806):

To encourage hospitals and health systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients), unless it is determined that the risk of not using such a device exceeds the risk of using it; further,

To advocate adequate reimbursement for preparation, order review, and other costs.
associated with the safe provision and administration of medications and use of related devices; further,

To encourage hospitals and health systems to train staff on the handling and use of medication administration devices brought in by patients; further,

To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team.

9. Staffing for Safe and Effective Patient Care

To encourage pharmacy managers to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care; further,

To encourage pharmacy managers to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings; further,

To support the following principles:

- Sufficient qualified staff must exist to ensure safe and effective patient care;
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care;
- Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services; and
- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

Note: This policy would supersede ASHP policy 0201.
Rationale

The advancement of the pharmacy profession over the past decade has prepared and positioned pharmacists to care for complex patients and adapt to the dynamic and rapidly progressive field of medicine. Throughout the years, an increased involvement of pharmacists in specialty areas such as transplant, critical care, oncology, and pain and palliative care has been observed. Therefore, it is imperative that such advancement is considered when developing staffing models, in order to ensure the pharmacy workforce is appropriately allocated for the provision of consistent, safe, and high-quality patient care.

The complexity of patient care will continue to increase, and with that, so will the expected responsibilities, opportunities, and skills of the pharmacy workforce. Consequently, pharmacists engaged in direct patient care are encouraged to pursue and maintain their training and credentialing in order to continue to enhance their competency, skills, and participation in innovative practice. The expansion and dynamic nature of the pharmacy profession requires new approaches to explore flexible staffing models to avoid a stagnant practice, encourage continual advancement, and accommodate the evolving priorities of the pharmacy workforce.

The development and implementation of flexible staffing models can enable pharmacists to engage in further professional development and career advancement (e.g., training in areas of specialization, degree programs) and enjoy a more stable work-life integration experience. Recently, more attention has been drawn to burnout, resilience, and job satisfaction among the pharmacy workforce. Research has shown that pharmacists are reporting increased job stress over the previous years and that approximately 53% of pharmacists are reporting a high degree of burnout, which can consequently threaten patient safety. Therefore, there is an imperative to develop staffing models to meet staff members’ changing priorities and for additional flexibility in the workplace. Implementation of flexible staffing models could improve performance and joy in the workplace. Pharmacy leaders should be committed to maintaining high-quality and consistent patient care services and to also promote models that balance patient care with staff priorities.

Various options to consider when exploring flexible staffing models are remote order review and verification (i.e., telecommuting), and productivity measures to ensure patient census is well distributed among pharmacists in charge of providing clinical services. Another concept related to flexible staffing models is leveraging pharmacy technicians’ roles to support pharmacist engagement in direct patient care activities. Some institutions have explored data-driven, staffing-to-demand models based on real-time patient-volume metrics. The concept is to allocate staff to tasks based on the current workload, which is evaluated daily. Other institutions are also utilizing metrics such as number of doses dispensed at a certain point in time and volume of order verification throughout the day in order to divide patient care units evenly among pharmacists that perform order verification or provide clinical services. Similarly, other healthcare disciplines (e.g., nursing) have historically utilized flexible staffing models to optimize services, reduce the risk of adverse events, and improve patient outcomes. The different models explored by nursing include patient ratio, patient acuity, collaborative staffing, and supplemental staffing model. There is limited literature on the use of flexible staffing models, but the concept is being explored by various health-system pharmacy departments.
Background
The Council reviewed ASHP policy 0201, Staffing for Safe and Effective Patient Care, and voted to recommend amending it as follows (underscore indicates new text):

To encourage pharmacy managers to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care; further,

To encourage pharmacy managers to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings; further,

To support the following principles:

- Sufficient qualified staff must exist to ensure safe and effective patient care;
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care;
- Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services; and
- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

The Council recommended ASHP (possibly the New Practitioners Forum) survey members about the use of innovative staffing models to combat burnout and maintain well-being and resilience. Membership education on the survey results and identified best practice pearls should follow. The Council recommended ASHP update its Guidelines on the Recruitment, Selection, and Retention of Pharmacy Personnel. Finally, ASHP should further support the study, publication, and promotion of such staffing models that provide flexibility for practitioners in the continuously evolving profession of pharmacy, without sacrificing consistent, safe, and high-quality patient care.

Board Actions

Sunset Review of Professional Policies
As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed
to continue these policies.)

- Identification of Prescription Drug Coverage and Eligibility for Patient Assistance Programs (1521)
- Pharmacist’s Role in Population Health Management (1523)
- Pharmacy Staff Fatigue and Medication Errors (0504)
- Disposition of Illicit Substance (1522)

Other Council Activity

**Joint Meeting on Violence and Firearm-related Injury and Death**

On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described several public health initiatives and organizational efforts that have been launched to address the problem of violence, including the American Hospital Association Hospitals Against Violence Initiative, which focuses on the dissemination of knowledge and best practices in the prevention of youth violence, workplace violence, and human trafficking. Some attendees said their hospitals made physical or procedural changes after consulting with local law enforcement to identify security gaps and described workplace programs that help hospital staff prepare for violent events and recognize potential hazards. Examples included active shooter drills, training to identify victims of domestic violence or human trafficking, and the use of color-coded room tags or linens to alert staff to patients with the potential to become violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury from firearms, including Stop the Bleed, a national campaign that encourages the public to learn how to respond to a bleeding emergency before professional help arrives on the scene, as well as community programs such as Cure Violence and hospital-based violence intervention programs. Afterward, the Council on Pharmacy Practice developed proposed policy based on the discussion.

**ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive**

The Council discussed the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive as part of sunset review. The Council determined the statement is in need of a contemporary update to include, but not be limited to, entrepreneurial, data science, supply chain, health benefit design, and the system vs. matrixed organization aspects that face today’s pharmacy executive. The Council recommended the Section of Pharmacy Practice Leaders
identify volunteers to review and update the statement. Members of the Council volunteered to work with the Section members to finalize the statement.

**Application of USP Standards**

The Council discussed recent guidance from the American Urological Association (AUA) and the American Society of Clinical Oncologists (ASCO) that would likely conflict with most hospital and pharmacy department interpretations of United States Pharmacopeia (USP) standards and determine the need for ASHP policy or action. Bacillus Calmette-Guerin (BCG) preparation has become an interesting topic, with the American Urological Association (AUA) issuing guidance to their members that is likely in conflict with most hospital and pharmacy department interpretations of USP chapters 795, 797, and 800. ASCO is also issuing information to their members that does not reflect best practice consistent with USP chapters 795, 797, and 800.

Of note, there have been seven appeals filed from various groups that could result in further changes and/or postponement of the December 1, 2019, implementation date for all three USP chapters. Most appeals focused on beyond-use date provisions in both chapters 795 and 797. There was an appeal on the applicability of the chapters to veterinary practice, an appeal to the removal of language in current chapter 797 that allows the use of “new technologies and techniques,” and an appeal to the reference to Controlled Environment Testing Association certification of engineering controls in chapter 797. There were also appeals to postpone the implementation date. Consequently, there may or may not be changes to the chapter. Even if there are no changes, there is a chance that the appeal process will force a delay in the December 1, 2019, implementation date.

The Council recommended that ASHP create educational resources that provide guidance on the topics, including case studies to define successful application of USP standards, presentations at professional medical meetings to bring awareness and understanding of the USP standards, and practical tips in layman’s terms, specific to care setting, for other national medical associations regarding the proper handling and preparation of hazardous medications and compounded sterile and nonsterile products.

The Council agreed a more strongly worded policy to address the handling issues and patient safety concerns is needed. The Council suggested the Council on Pharmacy Practice (CPhP) consider more action based language for ASHP policies 0402 and 1711 to advocate for more ready-to-use formulations to minimize regulatory hurdles. Additionally, CPhP should explore any policy or guideline needs regarding the storage, handling, and transport considerations of USP chapter 800 for wholesalers and delivery drivers.

The Council mentioned ASHP should consider advocating for responsible oversight by an accrediting body to enforce USP standards in those practice settings outside accredited facilities (e.g., physician practice).

The Council also suggested ASHP support research on safe practice with or without application of USP standards to determine if there is a medication quality and safety difference.
Integration of Displaced Community Pharmacists into Hospitals and Health Systems

Dr. Hill introduced the topic. The Council discussed how the job outlook for community pharmacists and health-system pharmacists varies based on the recent U.S. Bureau of Labor Statistics pharmacist employment model for 2018 – 2028. Members noted the anticipated negative growth trend with community pharmacy settings through 2028.

The Council recognized that community pharmacists have extensive experience in providing patient care through medication education, medication preparation, and immunizations and can effectively bridge gaps in care through medication therapy management, troubleshooting insurance-related issues, and completing prior authorization processes. Members expressed these functions could translate to help to fill voids and allow displaced community pharmacists to serve as effective members of a hospital or health-system pharmacy team. The Council also stated opportunities to reposition community-based pharmacists within hospitals and health-systems in a declining community-pharmacy job market is a potential means to support expanding ambulatory care portfolios and to fill critical needs in medically underserved settings. The Council asked whether ASHP policies address the increasing challenge for the profession and how it could benefit hospitals and health systems.

With respect to postgraduate training, the Council pointed out community-based pharmacy residency programs exist to help ensure pharmacists receive training to serve as leaders in the community setting; however, completion of these programs is not widespread. Although organizations will determine minimum qualifications for employment, it was noted that the ASHP Pharmacy Advancement Initiative advocates that all entry-level pharmacists have completed an ASHP-accredited residency to work in a hospital or health system. These qualifications and/or the level of effort (e.g., time, investment cost) required to train this displaced population may limit the ability of community pharmacists to find meaningful employment in hospital settings.

Council members highlighted the success of the ASHP professional certificate programs to enhance the professional development of pharmacists and provide them with unique skills to advance patient care and practice. Members see these programs as a way to support pharmacist continuing professional development, particularly for displaced community pharmacists seeking employment in a hospital or health system.

The Council’s discussion resulted in the following recommendations:

- Consider possible Council on Public Policy amendment of ASHP policy position 0218, Pharmacist Recruitment and Retention, and/or the ASHP Guidelines on the Recruitment, Selection, and Retention of Pharmacy Personnel, to address support of community pharmacists who have been displaced due to loss of employment through opportunities for integration within hospitals and health systems.
- Investigate opportunities for ASHP to target certificate programs for community pharmacists, to assist hospitals and health systems with the on-boarding, competency development, and integration of this segment into acute care roles.
- Encourage tool creation in partnership with other community-based pharmacy organizations.
- Partner with colleges/schools of pharmacy and ASHP state affiliates to encourage them
to emphasize pursuit of other than community-pharmacy roles within the profession.

- Explore *AJHP* publication opportunities (e.g., an editorial) addressing this issue.
- Consider as a joint council topic during ASHP 2020 Policy Week.
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

Council Members
Jennifer Burnette, Chair (Texas)
Andrew Stivers, Vice Chair (Georgia)
Jason Bergsbaken (Wisconsin)
Michael Dickens (Idaho)
Karl Gumpper (Massachusetts)
Amanda Hansen (Ohio)
Barbara Hintzen (Minnesota)
Molly Leber (Connecticut)
Karen McConnell (Colorado)
Alex Mersch, New Practitioner (Iowa)
Brittany Riley (West Virginia)
Jamielynn Sebaaly (North Carolina)
Cassandra Schmitt, Student (Virginia)
Anna Legreid Dopp, Secretary

1. Role of the Pharmacy Workforce in Violence Prevention

1. To recognize that violence in the U.S. is a public health crisis; further,

2. To affirm that the pharmacy workforce has important roles in a comprehensive public health and medical approach to violence prevention, including leadership roles in their communities and workplaces; further,

3. To encourage members of the pharmacy workforce to seek out opportunities to engage in violence prevention efforts in their communities and workplaces; further,

4. To promote collaboration between the pharmacy workforce and community and healthcare organizations in violence prevention efforts; further,

5. To foster education, training, and the development of resources to prepare the pharmacy workforce for their roles in violence prevention; further,

6. To support research and dissemination of information on the effectiveness of pharmacy-focused violence-prevention strategies.
Rationale
The World Health Organization defines violence as “the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation.” The Centers for Disease Control and Prevention (CDC) reports that in the U.S. 7 people die a violent death each hour -- 47,000 from suicide and 19,500 from homicide annually -- and a 2015 report found more than 2.5 million violence-related injuries annually. The CDC estimates that violence costs the U.S. $9 billion annually in medical costs and lost work, and a separate estimate places the cost of violence as a whole to U.S. hospitals and health systems at $2.7 billion dollars in 2016. The staggering human loss and soaring costs have led numerous organizations of healthcare and public health professionals to label violence a public health crisis and take action to address violence as a public health problem. One prominent example is the American Hospital Association Hospitals Against Violence Initiative, which provides examples and best practices to address its three central topics: workforce and workplace violence, combating human trafficking, and preventing youth violence.

ASHP believes that members of the pharmacy workforce have “a responsibility to participate in global, national, state, regional, and institutional efforts to promote public health” and that the pharmacy workforce has important roles in primary, secondary, and tertiary interventions to prevent violence. The CDC National Center for Injury Prevention and Control, Division of Violence Prevention states that the different forms of violence they identify—child abuse and neglect, youth violence, intimate partner violence, sexual violence, elder abuse, and suicidal behavior—are strongly connected and share common risk and protective factors. Interventions the pharmacy workforce could be involved in include but are not limited to

- improving access to mental health services, including treatment for substance use disorder;
- screening to identify victims of or individuals at risk of violence;
- providing trauma informed care;
- providing lethal means counseling;
- supporting hotlines and community support systems for people in crisis;
- providing or promoting Stop-the-Bleed bystander training; and
- participating in or promoting community- or hospital-based violence prevention organizations.

To fill these important roles, members of the pharmacy workforce will need appropriate education, training, and resources. Although some education, training, and resources are appropriate for different healthcare providers, ASHP is committed to the development of resources to prepare the pharmacy workforce for pharmacy-specific roles in violence prevention and to supporting research and dissemination of information on the effectiveness pharmacy-focused violence-prevention strategies. In addition, institutional and community leaders need to be aware of the pharmacy workforce’s commitment to preventing violence. ASHP is committed to raising awareness with other stakeholders of the profession’s commitment to collaborate to end the cycle of violence in their institutions and communities.
Background
The Council considered the topic of violence after participating in the Joint Meeting on Violence and Firearm-related Injury and Death. The consensus of the Council is that ASHP policy related to the prevention of violence is needed to create member and stakeholder awareness and stimulate resource development. This policy is intended to be different from ASHP policies related to violence in healthcare settings, thereby emphasizing the intention of the policy to be focused on violence as a public health issue. The intent of the policy is to affirm the pharmacy profession’s role in addressing violence using public health and medical models. In doing so, pharmacy personnel can leverage the policy to seek inclusion in public health intervention programs in their communities and institutions.

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 a 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

2. 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.
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.

### 3. 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.

### Board Actions

**Sunset Review of Professional Policies**

As part of sunset review of existing ASHP policies, the following were reviewed by the Council and Board and found to be still appropriate. (No action by the House of Delegates is needed to continue these policies.)

- Support for Second Victims (1524)
- Role of Pharmacists in Safe Technology Implementation (1020)
- Pharmacist’s Role in Urgent and Emergency Situations (1527)
- Health Care Quality Standards and Pharmacy Services (0502)
- Standardization of Doses (1525)

### Other Council Activity

**Joint Meeting on Violence and Firearm-related Injury and Death**

On Thursday, September 12, members of all councils and the Commission on Affiliate Relations met to hear presentations from Anna Legreid Dopp, Director of Clinical Guidelines and Quality Improvement, on public health approaches to preventing violence and preventing injury and death from firearms, and from Douglas J. Scheckelhoff, Senior Vice President of the Office of Practice Advancement, on the policies of healthcare professional organizations on violence and firearms. Several attendees shared stories of violent events at their workplaces, including some involving pharmacy staff, such as the shooting death of pharmacy resident Dayna Less in November 2018 at Mercy Hospital and Medical Center in Chicago. Dr. Legreid Dopp described
several public health initiatives and organizational efforts that have been launched to address
the problem of violence, including the American Hospital Association Hospitals Against Violence
Initiative, which focuses on the dissemination of knowledge and best practices in the
prevention of youth violence, workplace violence, and human trafficking. Some attendees said
their hospitals made physical or procedural changes after consulting with local law
enforcement to identify security gaps and described workplace programs that help hospital
staff prepare for violent events and recognize potential hazards. Examples included active
shooter drills, training to identify victims of domestic violence or human trafficking, and the use
of color-coded room tags or linens to alert staff to patients with the potential to become
violent. Dr. Legreid Dopp also outlined public health approaches to preventing death and injury
from firearms, including Stop the Bleed, a national campaign that encourages the public to
learn how to respond to a bleeding emergency before professional help arrives on the scene, as
well as community programs such as Cure Violence and hospital-based violence intervention
programs. Afterward, the Council developed proposed policy based on the discussion.

Role of the Pharmacist in Ensuring Safe Use of Outsourced Products
The Council discussed whether ASHP policy adequately addresses the patient safety
considerations of outsourced medications obtained by pharmacy departments from facilities
registered as human drug compounding outsourcing facilities under section 503B of the
to request that the Council on Public Policy investigate potential ASHP policy advocating for
more publicly available information regarding the quality of compounded sterile preparations
produced by 503B compounding facilities.

Pharmacists have a role in ensuring patient safety and understanding regarding the use
of compounded sterile preparations (CSPs) that have been obtained from an outside entity. Examples of considerations for ensuring safe use of outsourced CSPs include but are not limited
to product labeling and packaging variability; pharmacy department handling of outsourced
products, especially those that are high-alert medications; nonpharmacy healthcare personnel
awareness of safety risks; error and safety concern reporting; and patient education.

Pharmacies are mandated by state boards of pharmacy and pharmaceutical
manufacturers are required by USP <7> to adhere to certain medication labeling expectations. However, 503B outsourcing facilities are immune from such requirements, creating
inconsistencies and variability in labeling and packaging (e.g., differences in how medication
strength is denoted, look-alike labeling and packaging, and barcode scanning incompatibility).

In addition, pharmacy departments face special handling considerations in the
procurement, storage, distribution, administration, and disposal of outsourced products that
extend throughout the hospital and health system. These considerations include informatics
decisions related to and actions required for the handling of outsourced medications in the
electronic health record and policies and procedures needed to reduce the risk of error or
minimize the harm from high-risk medications.

The Council noted the difficulty in prospectively evaluating the quality of CSPs produced
by 503B compounding facilities. Purchasers are responsible for the quality of CSPs they
purchase and assume liability for their use, but the information available from FDA inspections
(e.g., information provided in FDA Form 483) is woefully inadequate for this task. Important information is often redacted on the publicly available Form 483, and the FDA explicitly states that a Form 483 “is not an all-inclusive list of every possible deviation from law and regulation.” Even if it were, a list of violations from one inspection would be insufficient to evaluate a 503B compounding facility’s performance over time, given the small sample size and the age of the information. Although purchasers are often required by state law to inspect facilities from which CSPs are purchased or do so as a best practice, the differences between the sterile compounding processes they are most familiar with (i.e., those used in 503A compounding facilities) and those of 503B compounding facilities make such inspections difficult. These challenges are so daunting that many pharmacies do not contract with 503B compounding facilities except in the most exceptional of circumstances, preferring to perform their own compounding or outsourcing to 503A facilities when possible. The Council suggested that information from FDA inspections or a standard survey of 503B compounding facilities could be used to construct a quality rating system, such as that proposed in ASHP policy position 1818, Federal Quality Rating Program for Pharmaceutical Manufacturers, or that an independent third-party accreditor could ensure a standard level of quality through inspections and accreditation.

The Council also discussed potential roles for ASHP in helping members address these challenges. The Council suggested that the ASHP Guidelines on Outsourcing Sterile Compounding Services could be updated to provide more information on how to inspect 503B compounding facilities, how purchasers can evaluate the quality of 503B compounding facility products, how to evaluate contractor performance, and how different components of health systems can share information when they have separate contracting processes. The Council was encouraged to hear that the newly formed Section of Inpatient Care Providers Section Advisory Group on Compounding was investigating the possibility of revising the ASHP guidelines. The Council also suggested that the ASHP Foundation Contractor Assessment Tool could be updated and made available. The Council also wondered whether it would be possible to consolidate information from different sources on 503B compounding facilities into a shared resource.

**Drug Shortages**

The Council voted to request that the Council on Public Policy consider amending ASHP policy position 1905, Mitigating Drug Product Shortages, to include the concepts in ASHP policy position 0002, Drug Shortages.

The Council reviewed ASHP policy position 0002, Drug Shortages, as part of sunset review, and voted to request that the Council on Public Policy consider amending ASHP policy position 1905, Mitigating Drug Product Shortages, to advocate that pharmaceutical manufacturers, distributors, group purchasing organizations, and regulatory bodies, when making decisions that could create drug product shortages, strive to prevent those decisions from compromising the quality and safety of patient care. The Council concluded that the subject fit well within policy position 1905 and that ASHP and members would benefit from having one consolidated policy position on the topic of drug shortages. The Council tabled sunset review of policy position 0002 until the Council on Public Policy reviews the request.
FDA Labeling Requirement to Dispense in Original Packaging
The Council voted to request that the Council on Public Policy investigate potential ASHP policy advocating that the FDA require more information in prescribing information to explain why a drug product should be dispensed in its original packaging.

The Council discussed challenges with maintaining inventory of medications packaged in one-size-fits-all containers. The experience is that this practice increases medication waste when the opened package yields leftover product. The Council is requesting that the Council on Public Policy consider the need to advocate with the FDA to limit this practice by the manufacturers.

ASHP Statement on the Pharmacist’s Role in Substance Abuse Prevention, Education, and Assistance
The Council voted to revise the ASHP Statement on the Pharmacist’s Role in Substance Abuse Prevention, Education, and Assistance. The Council suggested that the statement be updated to use less stigmatizing language throughout and include the following topics in the revision: substance use in the elderly, medication-assisted treatment, prescription and nonprescription drugs of abuse, vaping, accessing prescription monitoring plans, and rehabilitation and recovery services (including for professionals). The Council also suggested incorporating and reinforcing all current ASHP policy positions related to substance use. Several volunteers from the Council were identified (Amanda Hansen, Jamielynn Sebaaly, Brittany Riley, and Cassie Schmidt).

ASHP Guidelines on the Pharmacist’s Role in Immunization
The Council voted to revise the ASHP Guidelines on the Pharmacist’s Role in Immunization. The Council noted the need to revise the Guidelines on the Pharmacist’s Role in Immunization. Topics suggested for inclusion in the revision include: pharmacy department’s role in improving patient access to vaccines in health-systems, contemporize reimbursement language, reference current increase in outbreaks, acknowledge the use of pharmacist extenders in administration of vaccines, addition of Vaccine for Children policy language, reference to state immunization registries and interoperability with health information systems, the use of standing protocols, and pharmacy personnel role in addressing vaccine hesitation counseling and vaccine misinformation. Several volunteers from the Council were identified (Jennifer Burnette, Karl Gumpper, Molly Leber, and Alex Mersch).

ASHP Policy Positions on Controlled Substances Diversion
The Council voted to request the Council on Pharmacy Management to consider consolidating ASHP policy positions 1614, Controlled Substance Diversion and Patient Access, and 1709, Controlled Substance Diversion Prevention, to provide easier access to ASHP policy on the topic.

In the course of reviewing ASHP policy position 0021, Medication Errors and Risk Management, the Council noted potential redundancy between ASHP policy positions 1614 and 1709.
The Section of Inpatient Care Practitioners supports the personal and professional development and broad interests of members to achieve optimal patient outcomes by promoting best practices, opportunities for networking, collaboration, and creating tools and resources for members across diverse inpatient practice settings.

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).
ASHP Statement on the Use of Artificial Intelligence in Pharmacy

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. 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.

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. Given the anticipated trend of increasing development and use of digital therapeutics and a blend between chemical, biological, and digital therapies, 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. 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
Education and engagement

Education about and exposure to AI is necessary throughout all domains of pharmacy practice. 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.

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.

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