First Board of Directors Report: 
Policy Recommendations for the 
June 2019 House of Delegates

First of Two Reports

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JOINT COUNCIL POLICY RECOMMENDATION


1. Suicide Awareness and Prevention

   1. To support the goal of zero patient or healthcare worker suicides; further,

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

   3. To acknowledge that optimal suicide awareness and prevention efforts focus both on preventing patient suicides and on maintaining the health and well-being of the healthcare workforce; further,

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

   5. To foster development of standardized tools to aid pharmacists in assessing the influence of medications and environmental and physiological factors on suicidality; further,

   6. To provide education that assists the pharmacy workforce in their continuing professional development efforts related to suicide awareness and prevention; further,

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

   8. To encourage state-based efforts that support universal education and training of healthcare providers in suicide awareness and prevention; further,

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

  10. To enhance awareness of the National Suicide Prevention Lifeline funded by the Substance Abuse and Mental Health Services Administration; further,

  11. To foster research on suicide awareness and prevention.
**Rationale**

The high and increasing number of suicides in the U.S. has created a call for national action. The U.S. Surgeon General and the National Action Alliance for Suicide Prevention, in the 2012 National Strategy for Suicide Prevention, provided general guidance for various societal approaches, including public awareness and development of effective clinical practices targeting suicide prevention. The National Strategy set an aspirational zero suicides goal for healthcare services, which will require a systemwide effort to improve healthcare’s approach to suicide prevention, including clinician training and implementation of better referral systems.

The responsibility for healthcare professionals to become involved in suicide prevention extends beyond those specializing in mental health services, as suicide may be viewed as a response to multiple biological, psychological, interpersonal, environmental, and societal influences that interact with one another and may change over time. Suicide prevention, when viewed as the collective efforts of government, public and private organizations, and care providers to reduce the incidence of suicide, requires a correspondingly broad response by healthcare professionals. In 2016, the Joint Commission published a Sentinel Event Alert urging healthcare organizations to develop policies, staff education, and comprehensive care plans to utilize suicide risk assessment tools and support patients with suicide risk factors. The Joint Commission urged all healthcare organizations to develop clinical environment readiness by identifying, developing, and integrating comprehensive behavioral health, primary care, and community resources to assure continuity of care for individuals at risk for suicide.

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

Given the leading role of pharmacists in overseeing safe medication use, the dangers of medications relating to suicide risk, and the high degree of pharmacist interaction with patients, pharmacists are well positioned to play a key role in suicide awareness and prevention efforts. The pharmacist’s role could include, for example, ensuring appropriate use of medications in management of mental health and other medical conditions; identifying patients at risk for suicide, and evaluating that suicide risk; and recommending care, making referrals, and following up on referrals with patients and providers. Strategies could range from evaluating patients’ prescribed medications and identifying those that increase risk for suicidality; to counseling patients, caregivers, and other healthcare providers about those risks; to educating the public about the dangers of unused medications and the need for proper disposal. Clinical pharmacy specialists trained in behavioral health could also be incorporated into behavioral health programs to serve as a resource to the healthcare team. Other pharmacy practitioners (student pharmacists and pharmacy technicians) could perform vital services in suicide awareness and prevention efforts as well, such as medication reviews. The goal of zero
patient or healthcare worker suicides will also require a combined effort from individual healthcare workers and the healthcare system as a whole to sustain clinician well-being and resilience, as further described in ASHP policy 1825, Clinician Well-Being and Resilience.

To ensure that pharmacy practitioners have the competence and confidence to properly fill these key roles, ASHP is committed to providing education and tools to assist pharmacy practitioners in suicide awareness and prevention efforts. Further, ASHP advocates inclusion of suicide awareness and prevention in college of pharmacy curricula and postgraduate educational and training programs, through a multimodal approach. ASHP also advocates universal, state-based suicide awareness and prevention training for healthcare providers, including pharmacists. Adequate government and private-sector funding of suicide awareness and prevention efforts will be required to promote the success of suicide awareness and prevention efforts. ASHP joins other organizations in supporting efforts to promote awareness of the National Suicide Prevention Lifeline (1-800-273-TALK [8255]), with the ultimate goal of making the Lifeline number as memorable as the 911 emergency hotline. The Lifeline, accessible via phone and chat (https://suicidepreventionlifeline.org/), is a national network of 150 local crisis centers that provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. Finally, ASHP urges research on suicide awareness and prevention, including research on patient assessment tools, the role of genomic testing in drug approval and patient care, and practice models and strategies to identify and manage patients at risk for suicide.

Background

In response to a recommendation from the House of Delegates regarding the pharmacist’s role in suicide awareness and prevention, ASHP convened a joint meeting of all councils and the Commission on Affiliate Relations during its 2018 Policy Week to consider the topic. On Tuesday, September 25, members of all councils and the Commission were asked to suggest elements of ASHP policy on suicide awareness and prevention as well as ASHP programmatic activities relating to the pharmacist’s role in suicide awareness and prevention. Those suggestions were collated for presentation on Thursday, September 27. On Thursday, members of all councils and the Commission met to hear a presentation from Dr. Daina L. Wells, Pharm.D., BCPS, BCPP, National Program Manager, Academic Detailing Service, VACO Pharmacy Benefits Management. Dr. Wells provided an overview of suicide awareness and prevention, the role of pharmacists in suicide awareness and prevention, and lessons learned from the Veterans Administration’s efforts on suicide prevention. Council and Commission members were then presented with the results of the card-storming exercise and engaged in a brief discussion. Council and Commission members then returned to committee deliberation to reflect on current scientific evidence, best practices, the presentation from Dr. Wells, background reading, the meeting discussion, and personal experience to consider the need for new or revised ASHP professional policy and related ASHP programmatic activities related to topics within its purview. The policy recommendations from all the councils were consolidated into the policy recommendation above, which was approved by all the councils as a joint recommendation.
# COUNCIL ON PHARMACY PRACTICE
## POLICY RECOMMENDATION

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.

Paul C. Walker, Board Liaison

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<tr>
<td>Joseph Slecht, Chair (Kansas)</td>
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<td>Rachel Cartus, Student (Pennsylvania)</td>
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<td>Jason Bergsaklie (Texas)</td>
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## 1. Safe Administration of Hazardous Drugs

1. To advocate that health systems proactively conduct an interprofessional assessment of risk for exposure to hazardous drugs (HDs) during administration when closed-system transfer devices (CSTDs) cannot be used; further,

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

3. To encourage device and pharmaceutical manufacturers and the Food and Drug Administration to foster development of CSTD-compatible, ready-to-administer HD products.

### Rationale

Hazardous drugs (HDs) present well-known risks to healthcare workers who handle them. Most HDs are administered orally or intravenously, however non-traditional routes of administration such as, but not inclusive to, intrathecal, intraventricular, intravesicular, and perfusion into a vessel or organ cavity. These procedures are becoming more common. It is mandated that healthcare providers use personal protective equipment (PPE) and other protective devices,
such as closed-system transfer devices (CSTDs) when the dosage form allows. The protective precautions required for administration through these routes is well described in United States Pharmacopeia (USP) General Chapter 800, the ASHP Guidelines on Handling Hazardous Drugs, the Oncology Nursing Society’s Safe Handling of Hazardous Drugs, and other sources.

HDs are sometimes administered through other routes (e.g., Ommaya reservoirs, intraperitoneal infusion) for which protective precautions are not as well described or CSTD use is not possible. ASHP encourages health systems to conduct an interprofessional, proactive assessment of risk of such procedures to assess the potential exposure risks for healthcare providers and identify mitigating measures. Given their depth of knowledge regarding the handling of hazardous drugs, pharmacists should be involved in the development of policies, procedures, and operational assessments regarding administration of HDs in such circumstances. To reduce the risks to healthcare providers, ASHP encourages device and pharmaceutical manufacturers and the Food and Drug Administration to foster the development of CSTD-compatible, ready-to-administer HD drug products. The goal would be that CSTD’s be utilized for all routes of administration of HD products as a best practice; however if this is not possible then an assessment of risk can identify gaps and assure there are pharmacy guided policies that can address the handling, compounding, and administration for all healthcare staff coming into contact with HDs during these non-traditional routes of administration. This would also include any specialized training for staff in procedural areas, or the availability of a HDs specialized trained staff member whom can assist in the administration of the drug (e.g., a “chemo nurse”).

**Background**

The 2018 the ASHP Guidelines on Handling Hazardous Drugs acknowledge that administration of hazardous drugs “in nontraditional locations, such as the operating room” presents “challenges in training of personnel and in proper containment of drugs and drug residue.” The Council noted that CSTDs are often used to protect healthcare providers administering HDs but recognized that CSTDs and other standard precautions may not be suitable for atypical or unusual administration procedures. The intent of this policy is to encourage health systems to consider such situations and develop policies and procedures to protect healthcare workers involved in them, as well as to encourage device and pharmaceutical manufacturers to develop CSTD-compatible, ready-to-administer HD drug products to help address this issue.
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.)

- Standardization of Oral Liquid Medication Concentrations (1401)
- Safe Use of Radiopharmaceuticals (1402)
- Pharmacist’s Role on Ethics Committees (1403)
- Pharmacist’s Role in Providing Care for an Aging Population (0902)
- Pharmaceutical Waste (0903)
- Use of Use of Color To Identify Drug Products (9608)

Other Council Activity

Joint Meeting: Pharmacist’s Role in Suicide Awareness and Prevention
On Tuesday, September 25 members of all councils and the Commission on Affiliate Relations were asked to suggest through a card-storming exercise potential elements of ASHP policy on as well as ASHP programmatic activities relating to the pharmacist’s role in suicide awareness and prevention. Those suggestions were collated for presentation on Thursday, September 27. On Thursday, members of all councils and the Commission on Affiliate Relations met to hear a presentation from Dr. Daina L. Wells, Pharm.D., BCPS, BCPP, National Program Manager, Academic Detailing Service, VACO Pharmacy Benefits Management. Dr. Wells provided an overview of suicide awareness and prevention, the role of pharmacists in suicide awareness and prevention, and lessons learned from the VA’s efforts on suicide prevention. Council and Commission members were then presented with the results of the card-storming exercise and engaged in a brief discussion. Council and Commission members then returned to committee deliberation to reflect on current scientific evidence, best practices, the presentation from the outside expert, background reading, the meeting discussion, and personal experience to consider the need for new or revised ASHP professional policy and related ASHP programmatic activities related to topics within its purview.

The Council considered the need for new or revised ASHP professional policy related to topics within its purview, including the responsibilities of pharmacy practitioners, practitioner care for individual patients, practitioner activities in public health, pharmacy practice standards and quality, professional ethics, and interprofessional and public relations. Topics identified for consideration in advance of the Joint Meeting included counseling of patients taking prescription and nonprescription drugs that present a risk of suicidality, practitioner interventions to identify and treat patients at risk of suicide, and the quality of pharmacy practice standards related to suicide awareness and prevention. The Council developed draft policy language that was incorporated into the joint council policy recommendation on suicide
awareness and prevention. The Council also to develop an ASHP statement on the pharmacist’s role in suicide awareness and prevention.

The Council concluded that the broad scope of topics within its purview (the responsibilities of pharmacy practitioners, practitioner care for individual patients, and practitioner activities in public health) were better suited to the longer format of an ASHP statement, similar to that of other ASHP statements on the pharmacist’s role in other activities. The tentative outline for the statement follows the four recommendations outlined by Dr. Wells:
- Ensure appropriate management of mental health and medical conditions
- Recognize and identify patients at risk for suicide
- Evaluate suicide risk
- Recommend care, make referrals, and follow-up

**Naloxone Distribution at Discharge**

The Council discussed the pharmacist’s responsibility to assess whether a patient who receives an opioid prescription or who has a history of opioid overdose requires naloxone upon discharge from the hospital or an ambulatory care setting. The Council noted that due to the severity of the opioid epidemic, several states have taken action during the recent years to provide naloxone to patients at risk of overdose. The Substance Abuse and Mental Health Services Administration (SAMSHA) describes three prescription models: 1) traditional doctor-to-patient prescription, 2) third-party, and 3) non-patient-specific. Currently there are four processes that states can utilize for non-patient-specific dispensing: 1) standing orders pre-approved by a provider, 2) protocol orders, 3) collaborative practice agreements, and 4) pharmacist prescriptive authority. As of 2018, 49 states and D.C. permit some model of non-patient-specific prescription process; the only state that doesn’t is Nebraska. A few states and the VA health system allow prescriptive authority to pharmacists, which would include naloxone. Recently, some states have passed laws that allow non-patient-specific prescriptions that authorize naloxone distribution to individuals or organizations that meet specific criteria (e.g., family members or community members).

The Council discussed the need for new or revised ASHP professional topic regarding naloxone distribution at discharge and concluded that the topic is adequately addressed by ASHP policy 1510, Naloxone Availability, which reads:

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

To support efforts to safely expand access to naloxone; further,

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

To foster education on the role of naloxone in opioid reversal and its proper administration, safe use, and appropriate follow-up care; further,
To support state efforts to authorize pharmacists’ prescribing authority for naloxone for opioid reversal.

Organizational Policy on Pharmacy Inventory
The Council discussed the challenge of pharmacy storage of nonpharmaceutical items (e.g., dietary formulas and supplements, IV solutions without additives, blood products, leeches, and biological hazardous substances such as fecal material for fecal transplants). The Council observed that many pharmacy departments are asked to purchase and store such products. These items can add significant costs to a pharmacy’s budget, reduce inventory space, and add special storage requirements. It was the Council’s opinion that hospitals should review items and have a policy that reflects current hospital practices of how to deal with such products, including physical location, departmental budget breakdown, and any training or additional education needed by staff that may come in contact and dispense the products. The Council noted that ASHP policy 0232, Pharmacist’s Role in Drug Procurement, Distribution, Surveillance, and Control, provides the policy needed to address this issue but suggested that an ASHP web resource center, FAQ sheet, or AJHP commentary would better fill the needs or members.

Ready-To-Use Packaging for All Settings
The Council discussed ASHP policy 0402, Ready-To-Use Packaging for All Settings, as part of sunset review but deferred action to further consider what approach ASHP should take regarding ready-to-use and ready-to-administer packaging.
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.

Todd A. Karpinski, Board Liaison

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Jeff Little, Vice Chair (Kansas)
Emily Dyer (Virginia)
Erin Fox (Utah)
Roy Guharoy (Alabama)
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Mike Powell (Iowa)
Steve Riddle (Washington)
Jillanne Schulte Wall, Secretary

1. Notification of Drug Product Price Increases

1. To advocate for manufacturers to provide advance notice and justification to the public and healthcare providers in advance of drug price increases; further,

2. To advocate for transparency in drug product pricing.

Rationale
Many factors contribute to high drug product costs, and addressing the problem is made difficult by lack of knowledge about the marketplace for those products. For example, rebates negotiated by pharmacy benefit managers (PBMs) and discounts to other buyers make it difficult to determine the actual price of a drug product. ASHP advocates for more publicly accessible information on drug product pricing, such as an annual report on increases in drug product prices. Such information would provide patients and their healthcare providers with the information needed to make drug product purchasing choices. The purpose of this policy is to advocate for laws and regulations that would require drug product manufacturers to publicly report price increases in advance and provide justification for those increases, as well as to advocate for transparency regarding drug product pricing decisions. The policy is intended to increase public knowledge concerning pricing decisions made by different parties in the drug product supply chain (e.g., manufacturers, distributors, PBMs, group purchasing organizations) who may influence drug product prices.
Background

In 2017, the ASHP Formulary Review Panel recommended that the Council revise ASHP policy 0814 to advocate that drug product manufacturers be required to provide public notification in advance of significant price increases. At the Regional Delegate Conferences and the 2018 House of Delegates meetings, delegates expressed concern that the addition did not align with the intent of policy 0814, which is to advocate for federal review of anticompetitive practices by drug product manufacturers. Although delegates agreed that the new language should be ASHP policy, the amendment to policy 0814 was not approved by the House. Delegates recommended that the Council develop new, stand-alone policy on the topic. The 2018 Council crafted the policy recommendation above, removing the word “significant” from the Formulary Review Panel’s proposed amendment to address the concern that the term was subject to interpretation and would need to be defined.

In addition, the Council discussed the role of pharmacists in educating the public about factors that drive up drug product costs. The sense of the Council is that the general public is not aware of the complexities of the drug product marketplace and how those complexities impact drug product prices. Pharmacists have an important role in educating consumers about the complex marketplace, as well as options consumers may have in their purchases. For example, the Council cited a recently passed law that bans so-called “gag clauses” that prevent a pharmacist from notifying patients when an out-of-pocket payment is lower than the cost when the same product is purchased through their insurance or PBM coverage. Pharmacists also have a role in identifying cheaper generic alternatives and assisting patients in enrolling in manufacturer-sponsored drug discount programs.

2. Preventing Drug Product Shortages

1. To advocate for ongoing federal evaluation of whether drug product shortages present risks to national security; further,

2. To advocate that drug product manufacturers be required to disclose manufacturing sites and sources of active pharmaceutical ingredients (APIs) to facilitate such a risk assessment; further,

3. To recommend that the Food and Drug Administration (FDA) require drug product manufacturers to have contingency plans for maintaining drug supplies; further,

4. To advocate that drug product manufacturers be required to provide a specific reason for a shortage and an estimated timeline for resolution in their Food and Drug Administration Safety and Innovation Act notifications to FDA; further,

5. To advocate that FDA be required to provide quality ratings for 503B outsourcing facilities preparing copies of drug products under the exemption for products on FDA’s shortage list; further,
Rationale
In November 2017, ASHP convened a meeting of healthcare professional organizations to review and identify new opportunities to address the ongoing supply chain and patient care challenges associated with drug product shortages. Participants at the meeting examined how the 2012 FDA Safety and Innovation Act (FDASIA) has impacted drug product shortages and made recommendations to prevent and mitigate future shortages. One of those recommendations was that the federal government undertake an evaluation of the risks drug product shortages could present to national security. Such an evaluation would need to consider the risks posed by sourcing of APIs and excipients, as well as by the location of manufacturing sites.

The FDA’s Strategic Plan for Preventing and Mitigating Drug Shortages recommends that drug product purchasers consider quality in making purchasing decisions. Information that purchasers would find helpful in prospectively assessing drug product quality includes the production and compliance history of a manufacturer, the specific name and location of the manufacturing plant, and the source of raw materials. Because approximately 80 percent of APIs used in U.S. drug product manufacturing comes from foreign sources, the FDA has limited ability to inspect and certify that those APIs are unadulterated. In addition, although FDA publishes some quality information about manufacturers, it is sometimes difficult to know who the actual manufacturer is and which specific plant location produced the product, because drug companies may rely on contract manufacturers to produce drug products through licensing agreements. Requiring manufacturers to disclose that information would allow for improved evaluation of a manufacturer’s integrity and alignment with current good manufacturing processes. Detailed knowledge of manufacturing sites would also allow the government and healthcare systems to plan for or avoid disruptions to the supply chain like those that followed Hurricanes Irma and Maria in 2017, when supplies of 40 critical pharmaceutical products went into shortage, in part because of disruption to the large number of pharmaceutical manufacturing facilities in Puerto Rico. Lack of information about such disruptions can also lead to hoarding, which exacerbates an existing shortage. To avoid similar disruptions, the FDA should require manufacturers to have contingency plans for maintaining drug product supplies during events that could disrupt production, such as natural and manmade disasters (e.g., hurricanes, cyber-attacks, electricity failures, shipping disruptions).

FDASIA requires that drug product manufacturers submit a notification of a production disruption to FDA. Manufacturers should also be required to provide in these notices a specific reason for the shortage and an estimated timeline for resolution. This information would be helpful not only to those affected but also in the federal evaluation of the risks posed by drug product shortages. Healthcare providers addressing drug product shortages also need information to evaluate the quality of copies of drug products produced by 503B outsourcing facilities under the exemption for products on FDA’s shortage list. Congress should require the FDA to provide quality ratings for those manufacturers.

Finally, to avoid future drug product shortages, the Federal Trade Commission should be
required to evaluate the potential for drug product supply chain interruptions when considering manufacturer consolidations.

**Background**
The purpose of this policy is to advocate for solutions to prevent drug product shortages. In November 2017, ASHP convened a meeting of healthcare professional organizations — the American Hospital Association (AHA), the FDA, and the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) — to review and identify new opportunities to address the ongoing supply chain and patient care challenges associated with drug product shortages. The meeting served as an opportunity to examine how the FDA Safety and Innovation Act (FDASIA), enacted in 2012, has impacted shortages, and to address whether there is a need to build on the law with new recommendations. Held at ASHP headquarters, the meeting featured attendees that represented not only a large part of the clinician community, but also the AHA, the Pew Charitable Trusts, and the University of Utah Drug Information Services. At the meeting, representatives from the American Society of Anesthesiologists, the American Society of Clinical Oncology, the American Medical Association, the American Society of Parenteral and Enteral Nutrition, the Institute for Safe Medication Practices, and the Society of Critical Care Medicine discussed the ongoing challenges of drug product shortages and their impact on patient care. In addition, the FDA and the ASPR’s Office of Emergency Management were in attendance. The meeting resulted in a number of new recommendations to prevent and mitigate drug shortages. Attendees of the roundtable discussed various policy options that build upon existing law, in terms of reporting, as well as new requirements. The Council developed this new policy recommendation based on the recommendations from that meeting.

### 3. Emergency Refills

1. To advocate for state laws to allow any pharmacist, during a declared emergency, to dispense without a prescription refills of a drug product in quantities that meet the needs of patients.

**Rationale**
Many states allow pharmacists to provide emergency supplies of prescription drug products during or in the immediate aftermath of a declared emergency. States such as Florida allow this practice for up to 72 hours after an emergency has been declared (i.e., a patient can obtain a 72-hour supply during an emergency or disaster). However, the long duration of events like hurricanes demonstrates the need to expand the 72-hour window. Hurricanes, for example, typically generate an emergency declaration prior to the storm, and the impact can last until days after the storm, when flood waters crest. Several states, including California and Texas, allow pharmacists to adequately provide prescription drug products, excluding controlled substances, during disasters, emergencies, or catastrophic events. In California, pharmacists are empowered to use their professional judgment when determining the appropriate quantity of a fill. In these situations, patients without a prescription may use an empty pill bottle or other
documentation to demonstrate their need for a drug product. In addition, states sometimes require appropriate follow-up by the pharmacist with the patient’s prescriber and supporting documentation of the provision of care under an emergency declaration. American Medical Association policy H-120.933, Emergency Prescription Drug Refills, calls for emergency refills beyond the 72-hour period and excludes controlled substances.

**Background**
The intent of this policy is to advocate for states to expand access to prescription drug products during declared emergencies. The Council reviewed several state laws and American Medical Association policy H-120.933 in drafting this policy recommendation. The Council concluded that ASHP policy should not specify whether controlled substances should be excluded, leaving that decision to the states. Similarly, the Council concluded that ASHP policy should not take a stance on expanding the emergency supply beyond 72 hours but rather leave the limit to the discretion of the states.

### 4. Credentialing and Privileging by Regulators, Payers, and Providers for Collaborative Practice

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

2. To acknowledge that as a step toward the goal of universal recognition of and payment for pharmacist medication management services, public or private third-party payers may require licensed pharmacists to demonstrate their competence to provide medication management services, before the payers authorize them to engage in or be paid for such clinical services; further,

3. 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,

4. To support the use of clinical privileging by hospitals and health systems to assess a licensed pharmacist’s competence to engage in medication management services within the hospital or health system; further,

5. To advocate that state boards of pharmacy apply the principles of continuous quality improvement in assessing the quality, safety, and outcomes of medication management services.

(Note: This policy would supersede ASHP policy 0905.)
**Rationale**
Nearly all states permit some form of collaborative practice. ASHP not only supports collaborative practice but advocates its expansion. To help achieve the goal of recognizing and paying pharmacists for medication management services (a step toward universal recognition of pharmacists as healthcare providers), ASHP recognizes that public and private payers may require pharmacists to demonstrate competence to provide medication management services and that state licensure may not be the only state-imposed legal requirement to provide those services.

ASHP supports a professional initiative to develop national standards for determining pharmacist competence and the appropriate use of these standards by clinical privileging systems, governments, and public or third-party payers. ASHP continues to support the application of the clinical privileging process to medication management services as practiced within hospitals and health systems and notes the need for state boards of pharmacy to establish quality improvement processes with respect to patient safety and outcomes of medication management services.

**Background**
The Council considered ASHP policy 0905, Credentialing and Privileging by Regulators, Payers, and Providers for Collaborative Drug Therapy Management, as part of sunset review, and voted to recommend amending policy 0905 as follows (underscore indicates new text; strikethrough indicates deletions):

To advocate expansion of collaborative practice agreements, collaborative drug therapy management (CDTM) practices in which the prescriber and the licensed pharmacist agree upon the conditions under which the pharmacist initiates, monitors, and adjusts a patient’s drug therapy; further,

To acknowledge that as a step toward the goal of universal recognition of and payment for pharmacist medication management services CDTM services, public or private third-party payers may require licensed pharmacists to demonstrate their competence to provide medication management services CDTM, before the payers authorize them to engage in or be paid for such clinical services; 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 CDTM and (2) the appropriate use of these standards by clinical privileging systems, government authorities, and public or third-party payers; further,

To support the use of clinical privileging by hospitals and health systems to assess a licensed pharmacist’s competence to engage in medication management services CDTM within the hospital or health system; further,

To advocate that state boards of pharmacy apply the principles of continuous quality improvement in assessing the quality, safety, and outcomes of medication management services CDTM.
The Council revised the policy to reflect changing terminology regarding collaborative practice as well as the Joint Commission of Pharmacy Practitioners definition of medication management services.

**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 Role in the Healthcare (Medical) Home (0908)
- Regulation of Interstate Pharmacy Practice (0909)
- Federal and State Regulation of Compounding (1406)
- State Prescription Drug Monitoring Programs (1408)
- Drug Nomenclature (9011)

**Other Council Activity**

**Joint Meeting: Pharmacists Role in Suicide Awareness and Prevention**
On Tuesday, September 25 members of all councils and the Commission on Affiliate Relations were asked to suggest through a card-storming exercise potential elements of ASHP policy on as well as ASHP programmatic activities relating to the pharmacist’s role in suicide awareness and prevention. Those suggestions were collated for presentation on Thursday, September 27. On Thursday, members of all councils and the Commission on Affiliate Relations met to hear a presentation from Dr. Daina L. Wells, Pharm.D., BCPS, BCPP, National Program Manager, Academic Detailing Service, VACO Pharmacy Benefits Management. Dr. Wells provided an overview of suicide awareness and prevention, the role of pharmacists in suicide awareness and prevention, and lessons learned from the Veterans Administration’s efforts on suicide prevention. Council and Commission members were then presented with the results of the card-storming exercise and engaged in a brief discussion. Council and Commission members then returned to committee deliberation to reflect on current scientific evidence, best practices, the presentation from the outside expert, background reading, the meeting discussion, and personal experience to consider the need for new or revised ASHP professional policy and related ASHP programmatic activities related to topics within its purview. Topics identified for consideration in advance of the Joint Meeting included state-mandated suicide awareness and prevention continuing education, FDA processes for assessing the suicidality risk of investigational drugs and informing the public of those risks, and the potential liability risk to pharmacists dispensing drugs that increase the risk of suicidal thoughts and behaviors. The Council developed draft policy language that was incorporated into the joint council policy recommendation on suicide awareness and prevention.
This issue was brought forth by a member of the Council who noted that federal law passed in June expands the right-to-try program that enables patients who are suffering from terminal illness to access investigational drugs that have not yet been approved by the FDA. In addition, in 2015, the Council on Public Policy developed a policy on compassionate use that recognizes that FDA is the proper authoritative body to grant access to drugs that are still in clinical trials.

**Right-to-Try Laws**
The Council member brought this policy back for discussion to compare with the recently enacted right-to-try law and potentially update ASHP policy to reflect the change.

The right-to-try law expands access to drugs in phase I clinical trials. Patients who are terminally ill can work with their physician to be granted access to these drugs. One of the concerns expressed by the Council is the potential for the right-to-try law to create a loophole in the drug approval process by allowing use of a product that has not been approved. The concern is that a manufacturer could use this program to give access to a phase I drug, and then apply for orphan drug status to get around the full FDA approval processes. The Council believes that the right-to-try regime should not serve as a new business model. Council members were also concerned over the authority of hospital internal review boards and their ability to determine whether patients get access to nonapproved drugs.

Ultimately, the Council decided that more information is needed on how the program will be implemented and what impact it could have on patients and hospitals. As a result, the Council voted to table any new policy until the FDA releases regulations or guidance that implements the right-to-try law.
COUNCIL ON THERAPEUTICS
POLICY RECOMMENDATION

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.

Linda S. Tyler, Board Liaison

Council Members
Kurt Mahan, Chair (New Mexico)
Snehal Bhatt, Vice Chair (Massachusetts)
Sarah Anderson (Colorado)
Amie Blaszczzyk (Texas)
Michael Cooley, Student (Georgia)
Megan Corrigan (Illinois)
Rena Gosser (Washington)
Cyrine Haider (Tennessee)
Christi Jen (Arizona)
Morgan King, New Practitioner (Ohio)
Nathan Pinner (Alabama)
Brian Potoski (Pennsylvania)
Vicki Basalyga, Secretary

1. Therapeutic Use of Cannabidiol

1. To support continued research on the therapeutic uses of cannabidiol (CBD); further,

2. To provide education on the therapeutic uses of CBD; further,

3. To oppose use of CBD-containing products not approved by the Food and Drug Administration; further,

4. To advocate for enhanced public education regarding safe use of CBD and unapproved CBD-containing products.

Rationale
In June 2018, the FDA approved Epidiolex, an oral solution containing cannabidiol (CBD), for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is the first prescription formulation of highly purified component of the Cannabis sativa plant. Because it does not contain a significant amount of tetrahydrocannabinol, the substance in Cannabis sativa that causes intoxication, in September 2018 the Drug Enforcement Administration placed Epidiolex in schedule V of the Controlled Substances Act (CSA), the least restrictive schedule of the Act.
Given the patchwork of state legislation regarding recreational and medical cannabis, there is a robust but largely unregulated industry in cannabis derivatives, including products promoted as containing CBD. These formulations range from lotions for topical application to oils for enteral consumption, and their components and CBD concentrations vary, leading to questions about their safety. The FDA has issued over 40 warning letters to firms marketing products that allegedly contain CBD. As part of these actions, the FDA has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed to contain. The FDA has concluded that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. Under that provision, if a substance has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was “marketed as” a dietary supplement or a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case with CBD.

With its easy availability came erroneous claims regarding the efficacy of CBD in treating a number of maladies. The lack of a standardized product has inhibited legitimate research on most of these claims, and ASHP encourages research on the potential therapeutic uses of the FDA-approved product. ASHP is also committed to providing education to pharmacists and other healthcare providers on those uses, and advocates that pharmacists take a leadership role in educating patients and the public about the risks of unapproved CBD-containing products. Given the availability of an FDA-approved CBD product, ASHP opposes use of CBD-containing products not approved by the Food and Drug Administration in research and patient care. Further, due to concerns that patients may substitute unapproved cannabis derivative products for the FDA-approved drug or confuse the two, ASHP advocates for enhanced public education regarding safe use of CBD and unapproved cannabis derivatives.

Background
The Council discussed the growing number of mostly consumer-driven claims of conditions that can be treated with CBD, particularly what is marketed as “CBD oil.” Despite the FDA approval of Epidiolex CBD oral solution for two very specific seizure disorders, the Council expressed concern about the growing popularity of CBD oil, including the practice of patients bringing CBD oil into the hospital to continue use as a “patient’s own medication.” Council members discussed their hospital policies on CBD oil as a patient’s own medication. Many ban or restrict its use, especially in states where CBD oil is illegal. The Council recognized the ethical dilemma of discontinuing CBD oil for patients who have maintained themselves seizure-free on a CBD oil regimen. The Council also discussed the stigma associated with using a marijuana derivative such as CBD oil, which may make patients reluctant to disclose use as a part of a medication history, which can lead to significant drug-drug and drug-disease interactions.
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.)

- Safe and Effective Use of Heparin in Neonatal Patients (0912)
- Automatic Stop Orders (1405)
- Therapeutic Interchange (8708)
- Access to Oral Contraceptives as an Intermediate Category of Drug Products (1410)

Other Council Activity

Joint Meeting: Pharmacists Role in Suicide Awareness and Prevention
On Tuesday, September 25, members of all councils and the Commission on Affiliate Relations were asked to suggest through a card-storming exercise potential elements of ASHP policy on suicide awareness and prevention as well as ASHP programmatic activities relating to the pharmacist’s role in suicide awareness and prevention. Those suggestions were collated for presentation on Thursday, September 27. On Thursday, members of all councils and the Commission on Affiliate Relations met to hear a presentation from Dr. Daina L. Wells, Pharm.D., BCPS, BCPP, National Program Manager, Academic Detailing Service, VACO Pharmacy Benefits Management. Dr. Wells provided an overview of suicide awareness and prevention, the role of pharmacists in suicide awareness and prevention, and lessons learned from the Veterans Administration’s efforts on suicide prevention. Council and Commission members were then presented with the results of the card-storming exercise and engaged in a brief discussion. Council and Commission members then returned to committee deliberation to reflect on current scientific evidence, best practices, the presentation from the outside expert, background reading, the meeting discussion, and personal experience to consider the need for new or revised ASHP professional policy and related ASHP programmatic activities related to topics within its purview. Topics identified for consideration in advance of the Joint Meeting included student and postgraduate education and training on suicide awareness and prevention; prevention of student and resident suicides; and specialty education, training, and credentialing on suicide prevention. The Council developed draft policy language that was incorporated into the joint council policy recommendation on suicide awareness and prevention.

Intravenous to Enteral Antimicrobial Interchange
The Council discussed the current Infectious Diseases Society of America (IDSA) guidelines on antimicrobial stewardship, including the provision that advocates for conversion of intravenous
(IV) to enteral (PO) medications. Members discussed how this provision of the guidelines is implemented across the country, with current practices varying widely based on location and type of facility. Shared practices include automatic conversions for patients who meet certain criteria, pharmacist-led identification for conversion when a patient has met discharge requirements, and no active strategies or policies to convert patients to enteral formulations while in the hospital. There were several reasons identified for this wide variability, including physician attitudes towards the use of IV medications (e.g., patients in a hospital should receive IV antibiotics), certain patient populations that would not qualify for conversion (e.g., febrile neutropenic patients), lack of knowledge for appropriate conversion, pharmacist comfort in recommending changes, and justification for hospitalization (i.e., patient is receiving IV antibiotics solely to remain in the hospital). The Council identified ways in which ASHP could assist pharmacists with these barriers: a review of the “basics” of antimicrobial stewardship approaches, including ways to identify patients for IV-to-PO conversion, working with providers to prioritize enteral administration when clinically appropriate, and developing protocols regarding selection of agents. This initiative could take the form of PowerPoint templates to assist those unfamiliar with this section of the IDSA guidelines; identification of “Centers of Excellence” that would share their successes and strategies; the formation of an antimicrobial stewardship advisory group; a survey on the barriers that pharmacists are encountering; and providing resources with key references for pharmacists and potential partnership with infectious disease organizations reinforcing antimicrobial stewardship strategies. The Council also reviewed the ASHP Statement on the Pharmacist’s Role in Antimicrobial Stewardship and Infection Prevention and Control and noted the section about the IDSA guidelines that includes strategies for IV-to-PO conversion could be expanded to address this issue. The Council will convey these recommendations to the Council on Pharmacy Practice as they will be reviewing the statement as a part of their sunset review later this year.

Safe and Effective Use of Ketamine
The Council reviewed the expanding used of ketamine across multiple areas of practice, including the emergency department, outpatient clinics, and units in the hospital outside anesthesia and the post-surgical care units. The Council reviewed the methods of administration utilized, including intranasal delivery as well as the different concentrations that are available for administration. This discussion also addressed safety issues, including the ability to rescue a patient in the field, as ketamine is being used to treat depressive episodes in psychiatry offices and is recommended as a treatment alternative to morphine for emergency medical services; the wide variety of dosing for these new indications; and the concern of diversion of this Schedule III medication. The effects of long-term use of ketamine are also unknown. Although there are some small-study data on the success of using ketamine to treat patients for post-traumatic stress disorder, there are no data to indicate that it would continue to be successful weighed against its adverse effects and potential for addiction. The Council recognized that there is increasing interest in using ketamine in new areas of practice but found many of the studies published were not strong enough to provide policy guidance or a therapeutics review publication in AJHP. However, the Council believed that publishing a scope in review on ketamine in AJHP would be an excellent way to highlight the new and emerging practices seen with this drug. Such a review would lay out what research questions need to be
answered, call for more research, share best practices, address the safety concerns of multiple concentrations of ketamine, highlight risks for overdose and diversion, considerations for boards of pharmacy and nursing, and dosing recommendations.

**Use of Antihyperglycemic Therapies to Meet Cardiovascular Risk Reduction Goals**

The Council reviewed the new American Diabetes Association (ADA) Standards of Care recommendation that for patients with Type 2 Diabetes Mellitus (T2DM) and established arteriosclerotic cardiovascular disease that antihyperglycemic therapy should start with lifestyle modifications and metformin, followed by an agent proven to reduce cardiovascular disease (CVD), such as glucagon-like peptide-1 receptor agonists (GLP-1) and sodium-glucose cotransporter-2 inhibitors (SGLT2). The Council discussed the risks and benefits for this recommendation, including that some of the trials that the recommendations are based on are safety studies rather than studies that prove cardiovascular protection. Members also shared their experiences when patients started these classes of medications and had significant metabolic benefits (mostly significant weight loss) but had recurrent urinary tract infections, fungal infections, and an increased potential for falls. These sequelae prompt the concerns that while these medications are helping with one disease, are they causing harm in other ways. The cost and availability of these classes was also discussed. Of the members of the Council, only one member had these agents on formulary, and they were often discontinued when a patient was admitted to the hospital. The Council also expressed concern that the Standards of Care do not address evaluation of adherence to medications and shared anecdotes of patients who thought they were adherent but in reality were not taking their medications properly. The Council does not discount the recommendations from the ADA, but rather recommends that a careful evaluation of a patient’s individual disease and medication regimen should be undertaken before starting one of these agents. The Council believed the best way to teach pharmacists to weigh the use of these medications as a way to meet cardiovascular risk reduction goals would be education from ASHP in the form of a presentation at the Midyear Clinical Meeting, a therapeutics debate webinar, or as a part of the programming offered through ASHP’s Board of Pharmacy Specialties recertification programs.

**Therapeutic Use of Essential Oils**

The Council discussed the increase in encounters with patients who use essential oils as a part of their wellness and treatment regimens. There was discussion regarding the risks and benefits of using essentials oils as a part of complementary and alternative medicine, with concerns about safety and efficacy in patients who may be at high risk for adverse effects, particularly the pediatric, elderly, and pregnant patient populations. Many institutions do not permit the use of essential oils in patients on research protocols or in the patient rooms, and Council members shared anecdotes about the content of diffusers being dispersed in the air and on clothing, triggering allergic or asthmatic attacks for other patients and caregivers. The Council also discussed topical application as a part of therapeutic touch and palliative care, which members noted is considered exempt in some institutions. The Council discussed the lack of in-depth research on essential oils and the role of the pharmacists in ensuring that therapies are
safe and effective, something that is hard to do when there is widespread use in aerosolizers, lotions, and drops, and the products can be used in a variety of ways, including topical application and enteral consumption. There have been case reports with Poison Control Centers that have demonstrated the adverse effects of essential oils, but these compete with the myriad of official-looking resources that tout the benefits of using essential oils as well. The Council also discussed the reality that many patients will continue to use essential oils because they are seen as natural complement to wellness and that the need is therefore how to help pharmacists evaluate the risks and benefits associated with their use. The Council believes this would best be served by creating an AJHP publication that encompasses items such as evaluation of the evidence currently available; resources for pharmacists; medication-use policies; health-system and safety approaches; strategies for approaching patient conversations, especially for patients who have a strong belief in using essential oils; and the approach for palliative care patients. The Council believed that a separate policy that addresses the use of essential oils is not necessary but that the rationale that supports ASHP policy 1511, Complementary and Alternative Medicine (CAM) in Patient Care, should be updated to include essential oils in the list of types of CAM along with other minor updates to the rationale.
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.

Stephen F. Eckel, Board Liaison

Council Members
Whitney White, Chair (Alabama)
Seena Haines, Vice Chair (Mississippi)
David Gregory (Tennessee)
Fischer Herald, Student (Iowa)
Tadd Hellwig (South Dakota)
Carol Heunisch (Illinois)
Jesse Hogue (Michigan)
Denise Kelley (Florida)
Krystal Moorman (Utah)
Garrett Schramm (Minnesota)
Rebecca Taylor (Ohio)
Molly Wascher, New Practitioner (Maryland)
Erika Thomas, Secretary

1. Pharmacy Expertise in Sterile Compounding

1. To support colleges of pharmacy in providing sterile compounding and aseptic technique instruction in didactic and experiential curricula that reflect the needs of the workforce; further,

4. To promote the use of sterile compounding training programs to foster an increase in the number of pharmacists and pharmacy technicians with sterile compounding expertise; further,

7. To advocate that pharmacists and pharmacy technicians who work in sterile compounding attain compounded sterile preparations advanced certifications.

(Note: This policy would supersede ASHP policy 0915.)

Rationale
ASHP distinguishes between two needs related to pharmacy expertise in sterile compounding: a need for new pharmacy graduates to possess baseline training and knowledge of sterile
compounding, and the need for pharmacists with an advanced body of knowledge on sterile compounding, especially in pharmacy departments where complex compounded sterile preparations (CSPs) are compounded.

Although there is a clear need for students to have a basic understanding of sterile compounding upon graduation, education in colleges of pharmacy on sterile compounding varies. Sterile compounding and aseptic technique instruction are important areas of pharmacy practice to incorporate in the didactic curriculum and during experiential education.

The complexity of intravenous therapy, the risk of errors or patient harm, and new biologic therapies all demand a higher level of expertise in sterile compounding in the pharmacy, however. United States Pharmacopeia Chapter 797 and other efforts have increased the focus on the quality of CSP compounding and have prompted organizations to improve staff training, facilities, and procedures. In such an environment, there is a clear need for pharmacists whose education, training, and experience in sterile compounding provide expertise rather than baseline knowledge. To demonstrate competency, pharmacy technicians should attain PTCB’s advanced Compounded Sterile Preparation Technician (CSPT) certification, and pharmacists, the Board of Pharmacy Specialties (BPS) Compounded Sterile Preparations Pharmacy (BCSCP) certification.

**Background**
The Council reviewed ASHP policy 0915, Pharmacy Expertise in the Preparation and Handling of Injectable Medications, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To support encourage colleges of pharmacy in providing sterile compounding and aseptic technique instruction in the didactic curriculum and during experiential education curricula that reflect the needs of the workforce; further,

To support promote the use of postgraduate, curriculum-based sterile compounding training programs to foster an increase in the number of pharmacists and pharmacy technicians with sterile compounding expertise; further,

To advocate that pharmacists and pharmacy technicians who work in sterile compounding attain compounded sterile preparations advanced certifications.
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.)

- Pharmacy Residency Training (0917)
- Continuing Professional Development (0916)
- Credentialing, Privileging, and Competency Assessment (1415)
- Pharmacy Student Experiences in Medically Underserved Areas (0913)

Other Council Activity

Joint Meeting: Pharmacists Role in Suicide Awareness and Prevention
On Tuesday, September 25, members of all councils and the Commission on Affiliate Relations were asked to suggest through a card-storming exercise potential elements of ASHP policy on suicide awareness and prevention as well as ASHP programmatic activities relating to the pharmacist’s role in suicide awareness and prevention. Those suggestions were collated for presentation on Thursday, September 27. On Thursday, members of all councils and the Commission on Affiliate Relations met to hear a presentation from Dr. Daina L. Wells, Pharm.D., BCPS, BCPP, National Program Manager, Academic Detailing Service, VACO Pharmacy Benefits Management. Dr. Wells provided an overview of suicide awareness and prevention, the role of pharmacists in suicide awareness and prevention, and lessons learned from the Veterans Administration’s efforts on suicide prevention. Council and Commission members were then presented with the results of the card-storming exercise and engaged in a brief discussion. Council and Commission members then returned to committee deliberation to reflect on current scientific evidence, best practices, the presentation from the outside expert, background reading, the meeting discussion, and personal experience to consider the need for new or revised ASHP professional policy and related ASHP programmatic activities related to topics within its purview. Topics identified for consideration in advance of the Joint Meeting included student and postgraduate education and training on suicide awareness and prevention; prevention of student and resident suicides; and specialty education, training, and credentialing on suicide prevention. The Council developed draft policy language that was incorporated into the joint council policy recommendation on suicide awareness and prevention.

Recent Pharmacy Workforce-related Survey Results
The Council participated in a discussion of several recent pharmacy workforce-related survey results, including the 2018 Graduating Student Survey, Independent Analysis of Bureau of Labor Statistics Projections Report, Pharmacy Demand Index (Second Quarter 2018), and selected
2018 ASHP National Survey results to determine whether there are implications for ASHP policy. Of note, Council members discussed possible reasons for the slightly lower quality rating for Introductory Pharmacy Practice Experiences (IPPEs) when compared to Advanced Pharmacy Practice Experiences (APPEs). Council members recognized that ASHP has a variety of useful tools for APPE preceptors available on the Preceptors Toolkit, but nothing specific to IPPE preceptors. The Council felt that, since many ASHP members serve as IPPE and APPE preceptors, additional tools directed to the IPPE preceptor would be useful, such as IPPE best practices case studies including examples of successful innovative and contemporary learning models, and suggestions for incorporating interprofessional education (IPE) exercises.

Pharmacy Technician Workforce
Council members discussed PTCB’s launch of a new Compounded Sterile Preparation Technician (CSPT) certification. PTCB’s first advanced certification program, the CSPT Program certifies pharmacy technicians in compounded sterile preparation. Becoming certified as a CSPT is a way for PTCB-certified pharmacy technicians to further demonstrate their commitment to medication safety and could allow for advancement opportunities in a pharmacy technician career ladder. Council members learned that PTCB is considering a new advanced certification program in informatics as well.

Council members were pleased to learn of the increasing number of online accredited training programs and that more remote programs are under review for accreditation. The need for state board of pharmacy regulations to require that pharmacy technicians be certified was discussed, and action on this goal is currently in progress. Council members also discussed how to implement this requirement within their own health systems, including the need to set this as a system goal and meeting with hospital administrators to discuss implementation, citing important issues such as cost avoidance and pharmacy technician turnover rates. Finally, Council members suggested working with state affiliates on strategies to require PTCB certification of technicians.

Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems
The Council participated in a review of the draft ASHP Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems to assess completeness and identify areas for improvement. Published last in 2007, the ASHP Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems establishes an intention to engage, prepare, and leverage the pharmacy workforce in an evolving healthcare environment to ensure that medication use is optimal, safe, and effective for all people all of the time. ASHP seeks to identify an aspirational and achievable vision for the pharmacy workforce providing medication management services in hospitals and health systems. Considering anticipated changes to the healthcare landscape, the vision will enable a targeted investment and collective call to action to advance pharmacy practice by ensuring an engaged, prepared, and thriving pharmacy workforce. These are the areas in which ASHP will focus future resources, initiatives, and advocacy efforts.
To update ASHP Long-Range Vision for the Pharmacy Workforce in Hospitals and Health Systems, an extensive review process is being conducted, including Council member review and reaction. Numerous suggestions for inclusion in the document were presented, including the following: impact of mergers and acquisitions, greater emphasis on regulatory complexity and social determinants of health considerations, impact of the physician shortage, accountability for outcomes, broadening student experiences, vision for expanding pharmacy services, emerging role of biologics, pharmacy department research, supply chain optimization, clinician well-being and resilience, telehealth, and expanding the section on support staff, referred to as ancillary staff in the document. Recommendations from the Council will be addressed in the upcoming draft version.

**Professional Engagement as a Professional Obligation**

The Council participated in a discussion of professional engagement as a professional obligation. The purpose of this discussion was to address a recommendation from the ASHP House of Delegates on “Professional Organization Involvement/Engagement as a Professional Obligation.” Engagement is defined as a positive, fulfilling, work-related state of mind that is characterized by vigor, dedication, and absorption in work. Engaged employees have a sense of energetic and effective connection with their work activities. In nursing, the literature demonstrates that nurse engagement in a professional nursing organization leads to professional growth and increased knowledge, and engagement ultimately leads to improved health outcomes of populations. Professional membership associations offer members value through collective interests and the acquisition of selective benefits. Research also suggests that young professionals join organizations and are motivated by a variety of factors, including career development, altruism, and social obligations. Peer support, also a benefit of engagement and membership in a professional association, has always been critical to helping pharmacists navigate professional challenges. Additionally, support by employers is important, and there are many employer benefits, including innovations, practice advancement, and engaged and contemporary employees. Further, professional engagement is important to student pharmacists. Student pharmacists should be exposed to the concept of professional socialization by professors, preceptors, and mentors. The professionally engaged students learn the benefits and satisfaction of being involved in the profession and are more likely to become professionally engaged pharmacists.

Council members agreed that professional engagement has many benefits for an individual and improves satisfaction with a job and the college of pharmacy experience. The Council discussed the fact that students are often overwhelmed with the number of professional organizations in colleges of pharmacy and that many choose not to join an association at all. Council members believed that a policy was not needed at this time but suggested that ASHP members and members of ASHP state affiliates should continue to promote awareness and the benefits of involvement with ASHP and ASHP state affiliates, especially in colleges of pharmacy. The Council also discussed the importance of promoting the value of ASHP membership to important and influential groups, including college of pharmacy faculty, residency preceptors, and technician educators.
Social Determinants of Health
Council members participated in a discussion of social determinants of health. The purpose of the discussion was to address a recommendation from the ASHP House of Delegates to encourage the development of policy related to training pharmacists and student pharmacists to understand, identify, and address social determinants of health in collaboration with other healthcare team members. Healthy People 2020 defines social determinants of health as conditions in the environments in which people live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Examples of social determinants include access to health care services, transportation options, availability of resources to meet daily needs (e.g., safe housing and local food markets), socioeconomic conditions (e.g., concentrated poverty and the stressful conditions that accompany it), and language/literacy. Conditions (e.g., social, economic, and physical) in these various environments and settings (e.g., school, church, workplace, and neighborhood) have been referred to as “place.” In addition to the more material attributes of “place,” the patterns of social engagement and sense of security and well-being are also affected by where people live. Resources that enhance quality of life can have a significant influence on population health outcomes. Examples of these resources include safe and affordable housing, availability of healthy foods, and local emergency/health services. Healthy People 2020 highlights the importance of addressing social determinants of health by including “create social and physical environments that promote good health for all” as one of the four overarching goals for the decade.

The Council discussed two Accreditation Council for Pharmacy Education (ACPE) standards. Standard 3, Approach to Practice and Care, reads “The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to solve problems; educate, advocate, and collaborate, working with a broad range of people; recognize social determinants of health; and effectively communicate verbally and nonverbally.” Standard 3.5, Cultural Sensitivity, reads “The graduate is able to recognize social determinants of health to diminish disparities and inequities in access to quality care.” Council members felt that the topic is adequately addressed in college of pharmacy curricula but that there may be an educational gap with practitioners, although it was noted that pharmacists have already taken active roles in other public health initiatives, such as immunizations. The Council felt that a policy was not warranted but that social determinants of health would most appropriately be incorporated in the ASHP Statement on the Role of Health-System Pharmacists in Public Health that is currently under revision and practitioner education.
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.

Jennifer M. Schultz, Board Liaison

Council Members
Katherine Miller, Chair (Missouri)
Victoria Serrano Adams, Vice Chair (California)
Nitish Bangalore (Wisconsin)
Patrice Dupart (New York)
Monica Dziuba (Louisiana)
Lynn Eschenbacher (Missouri)
Staci Hermann (New Hampshire)
Rondell Jaggers (Georgia)
Trinh Le (North Carolina)
Bonnie Levin (Maryland)
Stuart Pope, Student (Kentucky)
Anthony Trovato, New Practitioner (Utah)
Eric Maroyka, Secretary

1. Pharmaceutical Distribution Systems

To support drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,

To oppose manufacturers, distributors, and wholesalers making availability of drug products contingent on how those products are used; further,

To encourage selection of a wholesale distributor that (1) purchases products only from a manufacturer before distribution to the purchasing end user; (2) is licensed in the state where it is conducting business; (3) complies with the requirements of the Drug Supply Chain Security Act; and (4) is accredited under the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors program.

(Note: This policy would supersede ASHP policy 1707.)
Rationale
Wholesalers and distributors have traditionally contracted with hospitals and health systems for basic drug product distribution and other services. Many wholesalers have made a large portion of their revenue through speculative buying and other business practices that are no longer desirable because of requirements for pedigrees, the risk of buying counterfeit or adulterated products, demands by manufacturers to limit product transactions, and the need to manage drug recalls. These changes, plus the vast diversification of many wholesaler distributors, have resulted in new business models that will affect how hospitals acquire and manage pharmaceuticals. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient.

Additionally, some wholesalers have required that pharmacies ensure certain drugs are not used or sold for use for particular purposes, and there are concerns that this practice could grow. ASHP supports wholesaler and distribution business models that meet the requirements of hospitals and health systems, which includes the ability for pharmacies to obtain drug products for established patient care uses without restriction.

ASHP supports using strict vendor vetting policies to prevent sales from nonreputable or gray market vendors. Vendors should purchase products only from a manufacturer, not a secondary source; should be licensed in the state in which it operates; comply with the requirements of the Drug Supply Chain Security Act; and be accredited under the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors (VAWD) program. VAWD accreditation requires a rigorous criteria compliance review to ensure that a wholesale distribution facility operates legitimately, is licensed in good standing, and employs security and best practices for safe prescription drug distribution from manufacturers to pharmacies. As of 2018, 23 states had recognized VAWD accreditation.

Background
The Council reviewed ASHP policy 1707, Pharmaceutical Distribution Systems, and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To support drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,

To oppose manufacturers, distributors, and wholesalers making availability of drug products contingent on how those products are used; further,

To encourage selection of a wholesale distributor that (1) purchases products only from a manufacturer before distribution to the purchasing end user; (2) is licensed in the state where it is conducting business; (3) complies with the requirements of the Drug
Supply Chain Security Act; and (4) is accredited under the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors program.

2. Safe Medication Preparation in All Sites of Care

To advocate that all sites of care be required to meet the same regulatory standards for medication preparation and compounding.

Rationale
As pharmacy costs become increasingly relevant in managing the overall cost of healthcare, third-party payers have increased their attention to sites of care, increasing the pressure to manage this trend. Integrated pharmacy benefit models are working to funnel patients to lower-cost settings and deliver more comprehensive care by leveraging big data.

Consolidation in the pharmacy benefit management sector has resulted in just three major companies. To protect and further grow their margins and fend off disruptive entrants, the big three are reinventing themselves within vertically integrated conglomerates, allowing them to tap into other parts of the healthcare value chain. Patients are increasingly receiving care at nonhospital sites of care, where they can receive the care they need at a lower cost, rather than through traditional venues, such as hospital outpatient infusion centers. In addition to these alternative sites being less expensive for payers and purchasers, patients who seek care from alternative sites often have lower out-of-pocket costs and may perceive these sites as more convenient than traditional sites of care (e.g., emergency departments, hospital-based clinics). This trend has led to lower hospital outpatient revenues. Vertical integration of the healthcare value chain has given payers more control over healthcare costs and has better positioned them to link directly with providers and negotiate value-based contracts. Vertically integrated systems may allow payers to steer patients toward lower cost-of-care options (e.g., providers, pharmacies). In the ASHP Foundation Pharmacy Forecast 2018, 44% of panelists predicted at least 25% of health systems will discontinue or abandon plans to begin drug dispensing services (e.g., distribution of specialty or infusion products) because of insufficient financial margins.

One of the challenges that confronts health systems is the level of infrastructure investment required to adequately address regulatory and accreditation requirements focused on quality and safety (e.g., United States Pharmacopeia Chapters 797 and 800, state boards of pharmacy regulations, and the standards of accreditors such as The Joint Commission and Det Norske Veritas Healthcare). Physician offices, dialysis centers, stand-alone cancer care centers, freestanding neighborhood hospitals, and other nonhospital sites of care are commonly devoid of this same level of regulatory and accreditation scrutiny.

Background
The Council discussed the growing trend of payer-directed sites of care and the challenges and opportunities of vertical integration. The margin compression many hospitals are experiencing
because of rising drug costs is likely to continue due to site-of-care reimbursement changes and modifications to the 340B program. The Council stressed the need for ASHP to advocate for uniform application of medication-use standards where medications are prepared, dispensed, and administered, regardless of site. The Council also discussed whether ASHP should consider partnering with the American College of Healthcare Executives and representatives from managed care (e.g., pharmacy benefit managers, self-insured populations) to help pharmacy leaders better understand emerging business models and their influence on safe medication use, continuity of care, patient experience, and competitive positioning. Pharmacy leadership should seek to be part of business discussions regarding nontraditional partnerships to help with continuity of care, promote safe medication use, and bring awareness to health-system leadership regarding potential changes in revenue with nonhospital-based sites of care. Additionally, the Council discussed the idea of an innovation think tank and whether ASHP should explore the creation of a task force or guiding coalition to inform ASHP on how to assist members get ahead of or be part of forward-thinking and disruptive innovation. Such an effort could include networking sessions about innovating and strategic incubation at ASHP meetings.

### 3. Pharmacy Department Business Partnerships

1. To recognize that a key objective of pharmacy departments is to provide medication management services across the continuum of patient care, and that pharmacy leaders should proactively evaluate potential business partnerships against this objective; further,

2. To recognize that hospitals and health-system pharmacy leaders must ensure that business partners meet all applicable patient safety and accountability standards; further,

3. To provide education and tools for pharmacy leaders to aid in the evaluation of and development of business partnerships; further,

4. To educate health-system administrators on the importance of pharmacy leadership in evaluating and developing pharmacy-related business partnerships; further,

5. To encourage health-system pharmacy leaders to consider evolving healthcare financing systems when evaluating and developing business partnerships.

(Note: This policy would supersede ASHP policy 1416.)

**Rationale**

Hospitals and health-system pharmacy leaders have to increasingly assess and engage with external business partners in order to facilitate continuity of care for their patients and
optimize outcomes. Hospitals and health-system leaders must be positioned to provide the most comprehensive care for their patient populations. As these external entities expand their market share and become more engaged across the healthcare continuum, a significant number of hospitals and health systems are dealing with how to best evaluate potential business partnerships. In some cases hospital or health-system pharmacy leaders are seeking to create a network of pharmacy locations and services for their patients that the health system cannot build itself. In other cases hospital and health-system pharmacy leaders need to engage with external business partners to provide services they cannot provide or to improve the efficiency of services provided by the hospital or health system. Additionally, a number of business entities see changes in value-based purchasing and readmission payment as an opportunity to contract with health systems. Finally, there are also business partners (e.g., data management, automation, compounding, and consulting organizations) that pharmacy leaders need to engage with in order to manage their pharmacy enterprise. These changes have posed a political, logistical, and professional challenge for pharmacy leaders.

**Background**

The Council discussed ASHP policy 1416, Pharmacy Department Business Partnerships, as part of sunset review. The Council determined the policy to still be appropriate but voted to recommend making a minor amendment to the policy as follows (underscore indicates new text; strikethrough indicates deletions):

To recognize that a key objective of pharmacy departments is to provide comprehensive medication management services across the continuum of patient care, and that pharmacy leaders should proactively evaluate potential business partnerships against this objective; further,

To recognize that hospitals and health-system pharmacy leaders must ensure that business partners meet all applicable patient safety and accountability standards; further,

To provide education and tools for pharmacy leaders to aid in the evaluation of and development of business partnerships; further,

To educate health-system administrators on the importance of pharmacy leadership in evaluating and developing pharmacy-related business partnerships; further,

To encourage health-system pharmacy leaders to consider evolving healthcare financing systems when evaluating and developing business partnerships.

This policy was amended with the addition of “medication management services” to reflect the definition of medication management services approved by the Joint Commission of Pharmacy Practitioners Board of Governors in February 2018. The definition of medication management services encompasses a variety of services, including comprehensive medication management.
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 Leadership of the Pharmacy Department (1302)
- Integration of Pharmacy Services in Multifacility Health Systems (1417)
- Risk Assessment of Health Information Technology (1418)
- Documentation of Patient Care Services in the Permanent Health Record (1419)
- Workload Monitoring and Reporting (0901)
- Intimidating or Disruptive Behaviors (0919)
- Pharmacy Drug Theft (0303)
- Optimizing the Medication-Use Process (9903)

Other Council Activity

Joint Meeting: Pharmacist’s Role in Suicide Awareness and Prevention
On Tuesday, September 25, members of all councils and the Commission on Affiliate Relations were asked to suggest through a card-storming exercise potential elements of ASHP policy as well as ASHP programmatic activities relating to the pharmacist’s role in suicide awareness and prevention. Those suggestions were collated for presentation on Thursday, September 27. On Thursday, members of all councils and the Commission on Affiliate Relations met to hear a presentation from Dr. Daina L. Wells, Pharm.D., BCPS, BCPP, National Program Manager, Academic Detailing Service, VACO Pharmacy Benefits Management. Dr. Wells provided an overview of suicide awareness and prevention, the role of pharmacists in suicide awareness and prevention, and lessons learned from the Veterans Administration’s efforts on suicide prevention. Council and Commission members were then presented with the results of the card-storming exercise and engaged in a brief discussion. Council and Commission members then returned to committee deliberation to reflect on current scientific evidence, best practices, the presentation from the outside expert, background reading, the meeting discussion, and personal experience to consider the need for new or revised ASHP professional policy and related ASHP programmatic activities related to topics within its purview. Topics identified for consideration in advance of the Joint Meeting included deployment of resources for suicide awareness and prevention, reimbursement for suicide awareness and prevention efforts, promotion of suicide awareness and prevention efforts at transitions of care, and the role of technology in suicide awareness and prevention efforts. The Council developed draft policy language that was incorporated into the joint council policy recommendation on suicide awareness and prevention.
Predictive Analytics and Artificial Intelligence in Healthcare

The Council voted to develop an ASHP statement on predictive analytics and artificial intelligence in healthcare in cooperation with the Section of Pharmacy Informatics and Technology.

The Council discussed agenda topics related to artificial intelligence/machine learning (AI/ML), predictive analytics, and big data. The Council, in drafting a policy recommendation, decided to combine the topics into one proposed policy. The considerations given were that advanced analytics capabilities (e.g., predictive analytics, AI/ML) develop in stages, each one building on the other to handle more complex data and to provide more meaningful outputs. Advanced analytics refers to a broad range of analytics that are intended to give users greater insight into their data. Some of these techniques include AI/ML, data mining, predictive analytics, location analytics, big data analytics, and location intelligence.

Advanced healthcare analytics is an emerging area and pharmacists should take a leadership role in how it will support and enhance the pharmacist and pharmacy process (e.g., operations, clinical efficiencies, re-purposing of staff). The Council cited some areas of concern, including the lack of transparency of methods used by proprietary predictive modeling tools, absence of vendor standards, lack of structured data across systems, and information security through downstream control of data. The Council also discussed uncertainties in how to use big data effectively to impact patient care. Specifically, membership education is needed on its use to enforce practice standards, enhance clinical decision support, guide treatment decisions, use for information only, and to assist with population health management. The Council indicated a desire to ensure elements of meaningful use are incorporated with advanced analytics to ensure outputs are actionable. Advanced analytics technologies hold great promise leveraging pharmacy services in rural practice settings to augment risk-stratification and clinical decision making capabilities. Given the length and variety of topics in the proposed policy recommendation, the Council recommended that the Section of Pharmacy Informatics and Technology (SOPIT) develop a statement on the future role of the pharmacist in the advanced analytics in healthcare. Consideration should be given to how the pharmacist should be involved on the front end for analysis and implementation, ways to re-purpose pharmacy staff to perform other value-added activities, and opportunities for amplifying clinical pharmacy roles by leveraging these technologies. The Council also recommended SOPIT explore any additional policy, AJHP publication, and/or education needs regarding these technologies.

Role of Autoverification in Pharmacy Practice

The Council discussed the role of autoverification of medication orders in pharmacy practice. Autoverification can be seen as a way to decrease pharmacist time dedicated to medication order review in order to redirect pharmacist focus on performing medication management services, improving patient access, and ensuring safe and effective medication use during care transitions.

Autoverification occurs when a medication order becomes active on the basis of previously approved criteria without review by a pharmacist. According to the 2016 ASHP National Survey of Pharmacy Practice in Hospital Settings, 51.6% of hospitals make use of autoverification within a computerized provider order entry (CPOE) system.
Over the past few decades, advancements in technology have improved many healthcare processes. Specifically, technology has enhanced pharmacy efficiency in verifying medication orders. With advanced technology, most medication orders are now processed electronically through a CPOE system. These medication orders are routed to the pharmacist for review before being administered to a patient. However, advancements in technology have also allowed some medication orders to skip pharmacist review and be automatically verified. With autoverification, there is uncertainty if a medication order can be safely dispensed and administered without pharmacist review.

Clinical decision support (CDS), within electronic ordering systems, may act as a pharmacist surrogate by checking each medication order for drug-allergy interactions, dose limits, duplication of therapy, drug-drug interactions, or drug-disease interactions, along with many other programmable checks. During a medication order review, a pharmacist is alerted by CDS if there are any interactions. With the use of CDS, many medication orders could be on autoverification, especially if these medication orders have little associated risk or harm. By using a risk stratification method with CDS technology, pharmacist verification queues could decrease. This stratification method could allow autoverification on less risky medication orders and mandate pharmacist verification for more risky, high-alert orders. Pharmacy leaders should determine whether CDS can automate verification of medication orders without pharmacist review and ensure safe outcomes. If so, a determination must be made, with organization and medical staff approval, about which medication orders are deemed “safe enough” to allow bypass of pharmacist verification.

Currently, there is a paucity of literature and standards related to autoverification. The Joint Commission (TJC) considers pharmacists as integral to the medication management process. TJC expects that when onsite pharmacy services are available, pharmacists must review “all prescription or medication orders unless a licensed independent practitioner controls the ordering, preparation, and administration of the medication; or in urgent situations when the resulting delay would harm the patient, including situations in which the patient experiences a sudden change in clinical status.” Pharmacy leaders should consider pursuing opportunities for additional research on safety and workflow efficiencies to validate the use of autoverification.

The Council discussed the willingness of technology vendors to build and support architecture for risk-stratified assisted verification. Beyond the quality assurance aspects of autoverification, a concern of the Council was the potential impact autoverification models may have on pharmacy resource allocation based on workload tied to the requirement for prospective order review by a pharmacist.

The Council recommended ASHP support research on the safety of order verification models (e.g., risk-stratified assisted verification, protocol-based algorithms, centralized order verification) for select eligible orders before widespread adoption is supported. The Council also selected optimal order verification models as a topic for further discussion with the Section of Pharmacy Informatics and Technology to explore any policy, guideline, and/or education needs in this area.
Standardized Clinical Drug Nomenclature
The Council discussed ASHP policy 0920, Standardized Clinical Drug Nomenclature, as part of sunset review. The Council acknowledged an opportunity to possibly merge this policy with ASHP policy 9011, Drug Nomenclature. However, after conferring, the Council on Public Policy was not in favor of merging the policies as they felt the intent of each policy was different. The Council decided review of and further discussion related to ASHP policy 0920 should be tabled until the winter conference call.
PHARMACY TECHNICIAN FORUM

POLICY RECOMMENDATION

The Pharmacy Technician Forum serves as the collective voice for pharmacy technicians by supporting their advancement, professionalism, and engagement within ASHP.

Kathleen S. Pawlicki, Board Liaison

Executive Committee

Barbara Hintzen, Chair (Minnesota)
Margarita Fedorova (California)
Glen Gard (Illinois)
Tiffany Kofroth (Texas)
Tara McNulty (Florida)
Tyffani Wingfield, Secretary

1. Pharmacy Technician Student Drug Testing

To advocate for the use of pre-enrollment, random, and for-cause drug testing as a mandatory component throughout any accredited or unaccredited pharmacy technician training program and practice experience, based on defined criteria with appropriate testing validation procedures; further,

To encourage pharmacy technician training programs to develop policies and processes to identify impaired individuals; further,

To encourage pharmacy technician training programs to facilitate access to and promote programs for treatment and to support recovery; further,

To encourage pharmacy technician training programs to use validated testing panels that have demonstrated effectiveness detecting commonly misused, abused, or illegally used substances.

Rationale
Pharmacy technicians are essential members of the healthcare team and help ensure the health, safety, and welfare of patients. They have access to controlled substances and confidential information, and operate in settings that require the exercise of good judgment and ethical behavior. In addition, some state boards of pharmacy have reported that drug-abusing and -diverting persons are enrolling in pharmacy technician training programs to access drugs during experiential training and employment. Thus, an assessment of a pharmacy technician student’s possible impairment, which could diminish his or her capacity to function in such a setting, is imperative to promote the highest level of integrity in healthcare services.
ASHP recognizes that drug testing pharmacy technician students, whose responsibilities may bring them into contact with controlled substances, is an essential element of diversion prevention programs. Pre-enrollment, random, and for-cause drug testing should be performed based on defined criteria, with appropriate testing validation procedures, and have demonstrated effectiveness detecting commonly abused or illegally used substances.

**Background**
The Executive Committee of the Pharmacy Technician Forum met at the ASHP Midyear Meeting in December 2018 and considered the topic of drug testing for students in pharmacy technician training programs. They reviewed existing ASHP policy on drug testing for employees (ASHP policy 1717, *Drug Testing*) and students (ASHP policy 1826, *Student Pharmacist Drug Testing*) and concluded that a separate policy on drug testing for students in pharmacy technician training programs is needed.
SECTION OF INPATIENT CARE PRACTITIONERS
POLICY RECOMMENDATION

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.

Paul C. Walker, Board Liaison

Executive Committee
Todd Lemke, Chair (Minnesota)
Paul Milligan (Missouri)
Linda Spooner (Washington)
Susan Skledar (Pennsylvania)
Erika Thomas, Director

1. ASHP Statement on the Role of the Medication Safety Leader

To approve the ASHP Statement on the Role of the Medication Safety Leader (Appendix).
ASHP Statement on the Role of the Medication Safety Leader

Position
The American Society of Health-System Pharmacists (ASHP) believes that medication safety is a fundamental responsibility of all members of the profession of pharmacy. For a medication safety program to succeed, however, it is essential that there be an innovative leader to set a vision and direction, identify opportunities to improve the medication-use system, and lead implementation of error-prevention strategies. The medication safety leader’s role includes responsibility for leadership, medication safety expertise, influencing practice change, research, and education. ASHP believes that because of their training, knowledge of the medication-use process, skills, and abilities, pharmacists are uniquely qualified to fill the roles and meet the responsibilities of the medication safety leader in hospitals and health systems.

Background
Hospital and health-system pharmacists have improved pharmacy systems over the past 60 years to reduce the risk that medications could harm patients. Medication safety was at the heart of such historic innovations in pharmacy services as unit-dose systems, decentralized clinical pharmacy services, and intravenous admixture services. The crucial leadership role of pharmacists in medication safety has been summarized as follows:

Pharmacy leadership is the core of a successful medication safety program. Pharmacy leaders can play an enormously important role in performance improvement. They can be part of the senior leadership team’s DNA because their impact and view go far beyond the walls of the pharmacy . . . . Pharmacists can play an important role as leaders to reduce patient safety risks, optimize the safe function of medication
management systems, and align pharmacy services with national initiatives that measure and reward quality performance.¹

The landmark Institute of Medicine (IOM) report To Err Is Human: Building a Safer Health System² generated major patient safety initiatives by government agencies, regulatory and accrediting bodies, professional and organizational associations, and health care organizations. The Joint Commission National Patient Safety Goals (NPSGs)³ are an example of a response to the original IOM report. The Practice Advancement Initiative (PAI)⁴ and the National Quality Forum (NQF) Safe Practice 18: Pharmacist Leadership Structures and Systems⁵ incorporate medication safety principles to ensure optimal patient safety and outcomes.

The medication safety leader (also referred to as a medication safety officer, medication safety manager, or medication safety coordinator, among other titles) is a clinical practitioner designated by an organization to serve as the authoritative expert in safe medication use. Traditionally, the medication safety leader has been a clinical pharmacist or manager within the department of pharmacy, although the position is sometimes filled by a nurse or physician. The medication safety leader may report to the organization’s risk-management department, its office of quality, or a senior administrator (e.g., hospital vice president, chief medical officer, chief executive officer). Reporting outside the pharmacy department may foster interdisciplinary approaches to medication safety. Medication safety leadership may encompass a single hospital or a group of organizations (e.g., spanning a health system or at a corporate level of a larger organization). Regardless of organization size, it is critical that the fundamentals of medication safety are the central component of the medication safety leader’s job function. Although medication safety leaders may have other responsibilities in smaller institutions, medication safety should remain their core responsibility, and they must be strategically positioned and empowered to lead efforts to reduce the risks of medication use.

The characteristics of a medication safety leader include

1. A strong understanding of the facility’s internal systems and processes developed through firsthand experience, observations, medication-use evaluations, interviews, and data analysis for the spectrum of patient populations treated in their organization.
ASHP Statement: Role of the Medication Safety Leader

2. Clinical expertise and a broad understanding of health care systems and processes to facilitate accurate interpretation of clinical events.

3. Knowledge of and experience with all aspects of the medication-use system, including procurement, prescribing, transcribing, preparation, distribution, administration, documentation, and monitoring.

4. Strong analytical skills and an understanding of statistics, population data, and the concepts of risk and prioritization.

5. Knowledge of performance-improvement methodology and tools, including root cause analysis (RCA), failure mode and effects analysis (FMEA), cause-and-effect diagramming, process-flow mapping, and methods for monitoring projects and measuring the progress of performance-improvement initiatives.

6. Post-graduate specialized training (e.g., medication safety residency or fellowship) or three or more years of health-system practice experience.

7. Demonstrated leadership skills.

8. Excellent small- and large-group presentation skills.

9. Excellent oral communication skills, especially the ability to communicate to all types of health care providers as individuals as well as in small and large groups.

10. Excellent writing and editing skills.

11. Strong personal belief that resolving the problem of medication errors is a systems issue and not an individual health care provider issue.

12. Ability to function proactively rather than reactively.

13. Strong personal belief in the concept of a “just culture” that enhances transparency, opens participation to all health care professionals, and fosters a “lessons learned” environment in an organization’s medication error reporting system.

14. Understanding of concepts and application of safety principles, continuous quality improvement, and human factors engineering.

15. Appropriate assertiveness.

17. Proven success in working with interdisciplinary teams and engaging diverse groups.
18. Strong personal belief in engaging patients as part of the health care team.
19. Eagerness to learn from events outside one’s own facility (e.g., through external sources of information) to apply learning about what went wrong in order to identify and remedy possible system weaknesses to prevent patient harm.

The scope of a medication safety leader’s responsibilities reaches into every corner of the health care system and encompasses many roles, such as educator, preceptor, mentor, detective, compliance officer, risk manager, engineer, accountant, statistician, computer analyst, and counselor. A typical day may include attending safety rounds, precepting pharmacy students and residents, writing policies, reviewing adverse drug events and medication error reports, developing error-prevention strategies, leading process-improvement teams, implementing action items, reviewing smart pump libraries, ensuring safe use of automated medication dispensing systems, assessing the safety of replacement drug products during drug shortages, orienting new professional staff, designing and optimizing the medication reconciliation process, conducting tracers to ensure compliance with accreditation standards (e.g., Joint Commission medication management standards and NPSGs), working with practitioners to resolve acute events, attending medical staff meetings, and educating staff and leaders across the system on the culture of safety. Most medication safety leaders quickly find themselves involved in many projects and committees as well as serving as the contact person when nursing, pharmacy, or medical staff have questions or problems. The medication safety leader needs a solid understanding of patient safety principles and must have the ability to prioritize work activities to have a positive impact on the safety of patient care. The medication safety leader should strive to acquire additional skills crucial to success, such as presentation and communication skills, as well as expertise in process-improvement methodologies such as Six Sigma and Lean. Formalized training in medication safety can be achieved through residency, fellowship, and certificate programs and other methods of continuing education. ASHP supports the expansion of pharmacy education and postgraduate residency training to include an emphasis on medication safety. 8
Responsibilities of Medication Safety Leaders

Medication safety leaders must collaborate with all types of health care professionals, support staff, and management and consider all components of the medication-use process in all settings of healthcare (e.g., inpatient, clinic, community pharmacies, drug distribution centers) in order to improve medication safety. The medication safety leader’s role includes responsibility for leadership, medication safety expertise, influencing practice change, research, and education.

**Leadership.** To provide leadership, the medication safety leader will

1. Develop a vision of an ideal safe medication-use system for the organization.
2. Oversee the planning, creation, review, and refinement of a medication safety plan.
3. Proactively develop and lead implementation of error-prevention strategies based on practice standards, best practice guidelines (or recommendations), literature review, external error reports, medication safety tools, and analysis of the organization’s medication safety data.
4. Participate in the planning, design, and implementation of the organization’s medication-use technology and automation systems.
5. Build a culture of safety through “lesson learned” education and communication across the entire organization.
6. Oversee processes to collect information on the organization’s medication errors and system failures to ensure that they are captured and barriers to reporting are addressed.
7. Ensure compliance with state and federal regulatory and legal requirements relating to medication safety and assist in the accreditation process by ensuring that the organization’s medication-use processes meet applicable medication management standards and NPSGs.

**Medication Safety Expertise.** In the role of medication safety expert, the medication safety leader will
1. Serve as an authoritative resource on medication safety for the organization.

2. Contribute the medication safety perspective for technology initiatives.

3. Contribute the medication safety perspective to internal and external emergency-preparedness planning.

4. Serve as an internal consultant to investigate medication safety events or issues and develop recommendations for action.

5. Serve as the chair of the medication safety committee, whose duties may include setting the agenda, reviewing general and specific error reports, and examining the progress of projects and initiatives assigned to the medication safety team.

6. Be knowledgeable in the application and use of a variety of quality-improvement methodologies and tools (e.g., FOCUS-PDCA or Lean methodologies, RCA, FMEA).

7. Collect, review, and analyze the organization’s medication-use process, medication errors, adverse drug reactions, and continuous quality-improvement data (e.g., markers of adverse drug events, smart pump event data, triggers and surveillance information, automated dispensing system and bedside bar-code scanning reports) and use appropriate data analysis techniques to identify needed improvements and develop high-leverage error-reduction strategies.

8. Predict and prepare to manage medication safety issues caused by potential or actual drug product shortages and the use of replacement drug products.

9. Maintain knowledge of trends and developments in the patient safety field through continuous professional development: reading articles, journals, and related material; attending appropriate seminars, conferences, or educational programs; and using information from the Institute of Safe Medication Practices (ISMP) National Medication Error Reporting Program, the Food and Drug Administration (FDA) MedWatch program, and similar programs.

10. Participate at local and national levels in patient safety and medication safety organizations and initiatives. Medication safety leaders are also encouraged to seek and share best practices with other regional safety leaders and practice sites.
**Influencing Practice Change.** To influence practice change, the medication safety leader will

1. Collaborate with other departments (e.g., pharmacy, risk management, patient safety), hospital or health-system senior leadership, frontline staff, and nursing and medical staff leadership to identify and prioritize safety issues and develop risk-reduction strategies using the methods listed above to identify opportunities to improve medication safety.

2. Manage changes in the medication-use system to enhance medication safety, ensure that appropriate measures are taken to address and resolve medication safety issues, and see that hospital staff and faculty are supported in providing safe care for patients.

3. Work closely with others (e.g., the patient safety officer) to integrate medication safety into the overall strategic plan for patient safety and coordinate medication safety initiatives with organizational patient safety initiatives.

4. Participate in or lead multidisciplinary hospital and health-system committees concerned with medication errors, adverse drug events and reactions, near misses, policy review, safe medication use, new product review, and patient safety to identify risk points and prioritize system improvements to reduce the potential for medication error and patient harm.

5. Consult with and advise specific clinical teams and the hospital and health system generally on opportunities and strategies to improve patient care.

6. Encourage organization wide medication error reporting through an established and accepted error reporting system that utilizes appropriate error detection methods (e.g., trigger tools) and through other appropriate avenues such as the pharmacy and therapeutics committee, medication safety committee, and patient safety committee.

7. Develop effective methods for spreading best medication-use practices throughout the organization.

8. Use continuous quality-improvement principles to assess and report on the status of efforts to improve medication safety.

9. Periodically review and update clinical decision-support tools to alert staff to high-risk situations and educate staff as needed.
Research and Education. To further research and education regarding medication safety, the medication safety leader will

1. Design and assist in the implementation of education and orientation programs in safe medication use, including

2. Development of competency assessment for
   - staff tasks related to medication safety (e.g., use of smart pumps and automated medication dispensing systems);
   - Education of health care providers, other pertinent staff, and (as possible) patients to ensure they are competent in safe medication-use practices; and
   - Provision of effective ongoing programs and presentations related to safe medication use to diverse audiences (e.g., nursing, pharmacy, respiratory care, and medical staff).

3. Share information about actual or potential medication errors or harm with safety organizations such as ISMP, FDA, drug or product manufacturers, and state error reporting programs.

4. Conduct medication-use safety research through well-designed, externally validated studies and implement evidence-based practices for medication safety.

5. Contribute to the literature on medication safety.

6. Provide medication safety education to pharmacy colleagues, students, and residents, as well as other health care professionals.

7. Integrate medication safety into orientation and training for all health care providers who participate in the medication-use process.

Conclusion

ASHP believes that pharmacists, as experts on medication use, are uniquely qualified to serve as medication safety leaders. Medication safety leaders articulate the vision and direction for improving the safety of the medication-use system to prevent patient harm. The medication safety leader’s role includes responsibility for leadership through direction and prioritization,
medication safety expertise, influencing practice change, research, and education. Through analysis of the organization’s medication safety data and literature review, the medication safety leader will lead development and implementation of proactive error-prevention strategies and build a culture of safety across the organization.

References
8. American Society of Health-System Pharmacists. Required educational outcomes, goals, and objectives for postgraduate year two (PGY2) pharmacy residencies in medication-use safety. [https://www.ashp.org/-/media/assets/professional-development/residencies/docs/pgy2-medication-use-](https://www.ashp.org/-/media/assets/professional-development/residencies/docs/pgy2-medication-use-).
Suggested Readings


https://www.jointcommission.org/assets/1/6/Chassin_and_Lobe_0913_final.pdf


Web Resources

www.ashp.org  
www.ismp.org  
www.safemedication.com  
www.medsafetyofficer.org  
www.asmso.org  
www.ahrq.gov  
www.fda.gov/cder/drugSafety.htm  
www.ihi.org  
www.jointcommission.org/standards_information/npsgs.aspx  
www.leapfroggroup.org  
www.qualityforum.org  
www.nccmerp.org
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