

# House of Delegates

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## Board of Directors Report: Policy Recommendations for the June 2021 House of Delegates

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# COUNCIL ON THERAPEUTICS

## POLICY RECOMMENDATIONS

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*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.*

Paul C. Walker, *Board Liaison*

### **Council Members**

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Amy Boblitt (Illinois)  
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Carolyn Oxencis (Wisconsin)  
Erin Warren, *Student* (South Carolina)  
Vicki Basalyga, *Secretary*

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### **1. Universal Influenza Vaccination**

- 1 To advocate for universal annual administration of influenza vaccinations to the United
- 2 States population; further,
  
- 3 To advocate that annual influenza vaccination be a national public health priority;
- 4 further,
  
- 5 To support the development of safe, effective, and affordable universal influenza
- 6 vaccination, with the goal of long-term immunity.

*Note: This policy would supersede ASHP policy 0601.*

### **Rationale**

Influenza places a significant health burden on the United States, with estimates of 9–35 million illnesses, 4–16 million outpatient medical visits, and 139,000–708,000 hospitalizations each season. The influenza virus evolves and changes each year, with changes in its genome that require adjustments to vaccine viruses each season. Furthermore, the timing of the onset, peak, and end of each flu season varies annually, typically falling in the fall and winter. Evidence from several observational studies demonstrate that higher influenza vaccination is associated with a lower risk of influenza outbreaks, but Healthy People 2030 estimates that only 49.2% of

persons 6 months or older were vaccinated for the 2017-18 season. Influenza vaccination in low-risk individuals has also shown to be effective and can prevent many illnesses, deaths, and losses in productivity.

The *Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza* emphasize that annual vaccination is the best method for preventing or mitigating the impact of influenza, and the 2030 Infectious Disease Goals for Healthy People 2030 have a goal of minimum vaccination rates of 70%. In 2019, an Executive Order created the National Influenza Vaccine Task Force, which identified that collaborative efforts across the federal government, academia, the private sector, and international stakeholders over the past decade have advanced influenza vaccine technologies. The Task Force also noted that influenza is a public health and national security challenge, with significant gaps remaining in vaccine effectiveness, pace of vaccine production, sustainable manufacturing, and vaccine access and coverage across all populations.

### **Background**

The Council reviewed ASHP policy 0601, Universal Influenza Vaccination, as part of sunset review and voted to recommend amending it as follows below along with recommending a name change to the policy to reflect the intent of universal administration (underscore indicates new text):

To advocate for universal annual administration of influenza vaccinations to the United States population; further,

To advocate that annual influenza vaccination be a national public health priority;  
further,

To support the development of safe, effective, and affordable universal influenza vaccination, with the goal of long-term immunity.

## **2. Vaccine Hesitancy**

- 1 To recognize the significant negative impact vaccine hesitancy has on public health in
- 2 the United States; further,
- 3 To affirm that pharmacists are integral members of the interprofessional team to
- 4 address vaccine hesitancy and promote disease prevention efforts; further,
- 5 To foster education, training, and the development of resources to assist healthcare
- 6 professionals in identifying factors that lead to vaccine hesitancy and addressing vaccine
- 7 hesitancy; further,

- 8 To promote pharmacist engagement with vaccine-hesitant patients, healthcare
- 9 providers, and caregivers, and to educate those populations on the risks
- 10 of vaccine hesitancy and the importance of timely vaccination.

### **Rationale**

Immunizations have led to a significant decrease in rates of vaccine-preventable diseases and have had a significant impact on the health of adults and children. In recent years, however, vaccine hesitancy, which is a delay in acceptance or refusal of vaccination despite availability of vaccination services, has increased. Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines, and is influenced by factors such as complacency, convenience, and confidence. The impact of vaccine hesitancy is significant: lower immunization rates observed in various European countries and the U.S. are likely to have contributed to the outbreaks of vaccine-preventable diseases that have been observed over recent years.

Vaccine-hesitant patients, healthcare providers, and caregivers have been found to be responsive to vaccine information, consider vaccination, and are not opposed to all vaccines, and therefore would benefit from counseling. Studies have shown that "presumptive recommendation" (informing patients and caregivers that vaccines are due) is more effective than "participatory recommendation" (asking what patients and caregivers thought about vaccines) in convincing patients and caregiver to accept vaccines. Healthcare providers, including pharmacists across healthcare settings, are trusted advisors and influencers of vaccination decisions, and they must be supported to provide trusted, credible information on vaccines.

### **Background**

The Council discussed vaccine hesitancy as a part of the sunset review of ASHP policy 0601, Universal Influenza Vaccination. During the course of that discussion, vaccine hesitancy was recognized as a significant barrier to universal administration of the influenza vaccine but not specific to flu vaccination administration, as the measles outbreaks of 2019 were due to vaccine hesitancy regarding childhood immunizations.

### **3. Therapeutic Indication in Clinical Decision Support**

- 1 To encourage healthcare organizations to optimize use of clinical decision support
- 2 systems with indications-based prescribing; further,
- 3 To advocate for federal and state laws and regulations to include diagnosis-based
- 4 indication(s) on medication order(s) or prescription(s), with the exception of protected
- 5 classes of drugs.

*Note: This policy would supersede ASHP policy 1608.*

**Rationale**

Several well-known studies have demonstrated reductions in wrong-patient errors and adverse events with the inclusion of indication on the prescription order. In 2010, Equale (*Drug Saf.* 2010; 33: 559-67) described the accuracy of indication information in electronic health records (EHRs). Galanter (*J Am Med Inform Assoc.* 2013;20:477–81) focused on preventing wrong-patient medication errors with the use of indication-based prescribing. Indication-based alerts resulted in an interception rate of 0.25 interceptions per 1000 alerts. One team of investigators conducted a trial of inpatient indication-based prescribing using computerized provider order entry (CPOE) with drugs commonly used off-label (*Appl Clin Inf.* 2011;2:94–103). Off-label prescription drug use without strong scientific evidence has also been associated with increased rates of adverse drug events (*JAMA Internal Medicine* 2016; 176:55-63). The authors suggested that use of and proper documentation of therapeutic indication can help improve surveillance and safety and decrease risk. This additional safety check is critical in limiting errors due to wrong and/or look-alike/sound-alike medications. In addition to error prevention, indication-based prescribing can improve patient engagement, patient education, and provide pharmacists with information that may be necessary for prior authorizations or claim processing. To foster successful implementation of indication-based prescribing in EHRs, several authors have documented the success of starting electronic prescriptions with a problem or indication list first before medications can be selected to reduce time and medication errors while maintaining clinician satisfaction.

In several countries, including Canada and Spain, the EHR includes indication as part of comprehensive documentation. ASHP first developed official policy on the importance of pharmacists' access to indications in 1993. In 1996, the National Coordinating Council for Medication Error Reporting and Prevention recommended including the purpose of medication orders because of concerns about safety, unless considered inappropriate by the prescribers. In 1999, the Institute for Safe Medication Practices recommended including the purpose of prescribing on all written orders. In 2004, the National Association of Boards of Pharmacy (NABP) approved a resolution encouraging national and state medical associations to support legislative and regulatory efforts to require prescribers to include indications for all oral, written, and electronically transmitted prescriptions. In 2012, the United States Pharmacopeia made amendments to the standards for prescription container labeling to include "purpose-for-use" language. In 2015, the National Council of Prescription Drug Plans drafted language to recommend diagnosis and SNOMED indication be sent with any prescription. Despite these recommendations, few states have adopted any laws requiring inclusion of indication on all medication orders or prescriptions.

More recently, the Institute for Safe Medication Practices recommended updating the five "rights" of patient, drug, dose, time, and route to include a sixth "right": the right indication. They cite benefits of indication-based prescribing as (1) helping to prevent errors by narrowing medication choices; (2) empowering and educating patients, which helps increase patient adherence; (3) improving communications among the healthcare team, patients, and families; (4) facilitating medication reconciliation; (5) helping prescribers select the best medications for their patients; and (6) aiding in measuring drug effectiveness and learning from off-label use.

ASHP also has policy on off-label use that encourages the use of the three authoritative

drug compendia, peer-reviewed literature, and consultation with experts in research and clinical practice to make specific coverage decisions. ASHP supports informed decision-making that promotes third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses. Furthermore, ASHP believes that diagnosis should not be required for all medication orders, particularly the six protected categories of drugs: 1) antidepressants; 2) antipsychotics; 3) anticonvulsants; 4) immunosuppressants for treatment of transplant rejection; 5) antiretrovirals; and 6) antineoplastics, as these may inadvertently cause result in breaches in patient privacy.

### **Background**

The Council reviewed ASHP policy 1608, Therapeutic Indication in Clinical Decision Support, as part of sunset review and voted to recommend amending it as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To ~~advocate that~~ encourage healthcare organizations to optimize use of clinical decision support systems with indications-based prescribing ~~by including the appropriate indication for medications;~~ further,

To advocate for federal and state laws and regulations to include diagnosis-based indications on medication orders or prescriptions, with the exception of protected classes of drugs.

#### **4. Preventing Exposure to Allergens**

1 To advocate for pharmacist participation in the collection, assessment, documentation  
2 and reconciliation of a complete list of allergens pertinent to medication therapy,  
3 including food, excipients, medications, devices, and supplies; further,

4 To encourage vendors of electronic health records to create readily available and  
5 distinct data fields with consistent designations for medication allergies and  
6 intolerances; further,

7 To advocate that vendors of medication-related databases incorporate and maintain  
8 information about medication-related allergens and cross reactivity; further,

9 To encourage the accurate and complete documentation of allergens within the  
10 electronic medical record, including detailed descriptions of the reactions occurring  
11 upon exposure, for the purpose of clinical decision-making; further,

12 To advocate that pharmacists actively review allergens pertinent to medication therapy  
13 and minimize patient and healthcare worker exposure to known allergens, as feasible;  
14 further,

15

- 16 To promote the education of the healthcare team and patients on the differences between medication-related allergic reactions and medication intolerances.

*Note: This policy would supersede ASHP policy 1619.*

### **Rationale**

The common theme of several ASHP policies is that patients may be exposed to potentially life-threatening allergens in items encountered in the medication-use process (e.g., natural rubber latex, drugs, drug product excipients, devices, and supplies). Pharmacy involvement in collection, assessment, and documentation of a complete list of allergens pertinent to the medication-use process, including food, excipients, medications, devices, and supplies, would assist in clinical decision-making. Pharmacists should also minimize patient and healthcare worker exposure to known allergens, for example by limiting or banning the use of latex gloves in pharmacies and striving for latex-safe medication formularies. Although allergy information is becoming more readily accessible through the electronic health record (EHR) and clinical decision support systems, some well-known cross-sensitivities are good candidates to be included in medication-related databases.

Only about 5-10% of all medication-related adverse events are allergic in nature. Patients are often labeled with an allergy to many drugs on the basis of a side effect or intolerances such as headache or GI disturbance. Allergen misidentification and documentation can be detrimental to patient care by preventing the use of optimal drug agents or by causing re-exposure to a true allergen. Pharmacists can help clarify and provide detailed documentation in the EHR regarding patient allergens. Furthermore, there is inconsistent standards on how and where allergies are located in the EHR and as such, there should be a consistent and standardized approach to documentation.

### **Background**

The Council reviewed ASHP policy 1619, Preventing Exposure to Allergens, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To advocate for ~~pharmacy~~ pharmacist participation in the collection, assessment, ~~and~~ documentation, and reconciliation of a complete list of allergens pertinent to medication therapy, including food, excipients, medications, devices, and supplies, ~~for the purpose of clinical decision-making~~; further,

To encourage vendors of electronic health records to create readily available and distinct data fields with consistent designations for medication allergies and intolerances; further,

To advocate that vendors of medication-related databases incorporate and maintain information about medication-related allergens and cross-sensitivities reactivity; further,

To encourage the accurate and complete documentation of allergens within the



electronic medical record, including detailed descriptions of the reactions occurring upon exposure, for the purpose of clinical decision-making; further,

To advocate that pharmacists actively review allergens pertinent to medication therapy and minimize patient and healthcare worker exposure to known allergens, as feasible; further,

To ~~encourage~~ promote the education of the healthcare team and patients of pharmacy personnel on the differences between medication-related allergens allergic reactions and medication intolerances.

### 5. Tobacco, Tobacco Products, and Electronic Nicotine Delivery Systems

- 1 To discourage the use, distribution, and sale of tobacco, tobacco products, and  
2 electronic nicotine delivery systems (e.g., vaporizers, vape pens, hookah pens, and  
3 electronic cigarettes and pipes) in and by pharmacies; further,
- 4 To advocate for tobacco-free environments in hospitals and health systems; further,
- 5 To promote the role of pharmacists in tobacco-cessation counseling and comprehensive  
6 medication management; further,
- 7 To join with other interested organizations in statements and expressions of opposition  
8 to the use of tobacco, tobacco products, and electronic nicotine delivery systems;  
9 further,
- 10 To educate the public and patients on the risks of nicotine consumption through  
11 traditional and electronic delivery systems.

*Note: This policy would supersede ASHP policy 1625.*

#### **Rationale**

Pharmacists, as healthcare providers, have long discouraged the use of tobacco and tobacco products as a threat to public health. Electronic nicotine delivery systems (e.g., vaporizers, vape pens, hookah pens, and electronic cigarettes and pipes) are new and unregulated delivery systems for nicotine. The contents of these systems include flavorings, propylene glycol, glycerin, and other unknown ingredients, and the long-term effects of their use have not been studied. Given these uncertainties, pharmacists should discourage their use as well.

Furthermore, pharmacists have a role in recommending and managing drug therapy to support cessation of nicotine-containing products, including tobacco and electronic nicotine delivery systems, as described in the [ASHP Therapeutic Position Statement on Cessation of Tobacco Use](#). Newer therapies, including varenicline, are associated with more and evolving safety risks when compared to nicotine replacement therapies. Given the complexity of drug

therapy, pharmacists should play a central role in ensuring the safe and appropriate use of these therapies.

### **Background**

The Council reviewed ASHP policy 1625, Tobacco, Tobacco Products, and Electronic Nicotine Delivery Systems, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To discourage the use, distribution, and sale of tobacco, tobacco products, and electronic nicotine delivery systems (e.g., vaporizers, vape pens, hookah pens, and electronic cigarettes and pipes) in and by pharmacies; further,

To advocate for tobacco-free environments in hospitals and health systems; further,

~~To seek, within the bounds of public law and policy, to eliminate the use and distribution of tobacco, tobacco products, and electronic nicotine delivery systems in meeting rooms and corridors at ASHP-sponsored events; further,~~

To promote the role of pharmacists in tobacco-cessation counseling and comprehensive medication ~~therapy~~ management; further,

To join with other interested organizations in statements and expressions of opposition to the use of tobacco, tobacco products, and electronic nicotine delivery systems; further,

To educate the public and patients on the risks of nicotine consumption through traditional and electronic delivery systems.

## **6. Use of Race Correction in Clinical Algorithms**

1 To recognize that clinical algorithms that only use race or ethnicity as a variable can  
2 attribute to inequities and adverse outcomes; further,

3 To oppose the use of race or ethnicity correction in clinical algorithms unless there is  
4 strong evidence to support its use and, when clinically relevant, to support uniform  
5 documentation in the electronic health record of a patient-identified designation of  
6 race or ethnicity; further,

7 To advocate that health systems remove algorithms based on race or ethnicity from all  
8 sources of therapy decisions, medication information, and the electronic health record,  
9 where strong evidence does not support its use; further,

- 10 To support further research on the impact of race or ethnicity on drug therapy and  
11 outcomes; further,
- 12 To advocate that if research includes considerations based on race or ethnicity, the  
13 reason for its use as a variable be specified; further,
- 14 To provide education on the limitations and appropriate use of race- or ethnicity-  
15 corrected clinical algorithms.

### **Rationale**

As outlined in the ASHP Statement on Racial and Ethnic Disparities in Health Care, race and ethnicity are social constructs with a cultural rather than a scientific basis. Although patient care can and should be informed by a patient's racial or ethnic identity, healthcare providers need to recognize the limited utility of that information

There are currently numerous clinical algorithms and practice guidelines that use a patient's race or ethnicity to determine outcomes. The clinical algorithms are then used by providers to help guide individualized risk assessments and clinical decisions. In return, these algorithms may direct attention and resources away from racial and ethnic minorities. However, the majority of these clinical algorithms do not have data to support a patient's race or ethnicity as a clinical factor. When a rationale is given and traced to its origins, the answer leads to outdated, suspect racial science, or biased data. Additionally, these algorithms do not take into account socioeconomic factors and other social determinants of health that may have a large influence on health outcomes.

Currently, a patient's race or ethnicity plays a role in a clinical algorithms or practice guidelines in almost every therapeutic class, including cardiology, surgery, nephrology, obstetrics, urology, and oncology. For example, the American Heart Association Get with the Guidelines - Heart Failure adds 3 points to the risk score of a patient that is non-Black. The higher scores in this tool predict higher in-hospital mortality. Ultimately, this tool is used to help guide clinical decisions for allocations of healthcare resources and referral to cardiology. The consequences of adding race to this algorithm would mean less direct patient care due to the patient being deemed as lower risk. There are many other clinical algorithms that adds points to their risk score for a patient that is non-Black, such as the STONE Score, Urinary Tract Infection Calculator, and Osteoporosis Risk SCORE. Another example is the estimated glomerular filtration rate (eGFR) MDRD and CKD-EPI equations. Both these equations report higher eGFR for Black patients than for other patients with the same serum creatinine levels. Originally, this disparity was thought to be due to patients that identify as Black having a higher average serum creatinine. However, there have been some concerns that this is not always true, especially when looking at the complexity of patient's racial backgrounds. Overestimating a patient's renal function can delay the time to referral to a kidney specialist or transplantation. In short, the addition of race to the clinical algorithms leads to less patient-specific interventions and ultimately worse patient outcomes.

Healthcare providers using the clinical algorithms and practice guidelines should be educated on how to critically evaluate the addition of race and ethnicity, along with the

consequences of adding race when not clinically appropriate. Many providers do not assess the algorithm prior to implementing the results, which can lead to improper treatment of a patient.

Education on the limitations of the clinical algorithms can help providers and patients overcome the barriers that the addition of race and ethnicity has created. Additionally, the medical community needs to advocate to re-evaluate our current clinical algorithms and evaluate future algorithms to determine if there is an evidence-based reason that race should be included. It is imperative that the medical community, primarily researchers, understand how race and ethnicity affects the outcome before adding it into a clinical algorithm.

Researchers have developed guidelines to follow when trying to rationalize when race and ethnicity should be included or excluded in a study, such as explaining how the category was determined, considering all confounders, and determining whether there is uncertainty in the algorithm. Researchers should then favor the practices that will help close health inequities over practices that might amplify them. Appropriately determining if race should be included in the algorithm will then help decrease the inappropriate clinical implementation of these tools.

Future research is needed to determine the relationship between pharmacogenomics, race, and ethnicity. Most providers and researchers use the standard five races and two ethnicities categories determined by the Office of Management and Budget to categorize people according to race and ethnicity. However, many individuals do not fit into these categories due to their complex racial and ethnic backgrounds, which may ultimately fail to account for genetic differences.

Drug therapy stems from these clinical algorithms and practice guidelines, and pharmacists need to work with other providers to critically evaluate the current tools. Additionally, pharmacists could collaborate with other providers to perform research to help better understand the differences between genomics and race. Therefore, providers could assess when race and ethnicity should be added to future clinical algorithms and practice guidelines.

### ***Background***

The Council discussed the need for an ASHP policy on the use of race in clinical algorithms as more data has been published demonstrating that many of the studies that used race as a variable within the algorithms did not correctly consider the impact of factors outside of race, such as social determinants of health, when created. The Council also discussed the impact that social determinants of health, genomics, and socioeconomic status have on health. Council members shared their experiences with students, residents, and members of the healthcare team who were not aware of the role that these factors play in creating clinical algorithms and agreed that more education is needed. Council members also recognized that many of these algorithms are a part of a health system's medical record system and can also be found in order sets, laboratory results, and other areas, and there should be a concerted effort to remove algorithms based on race from these areas.

## 7. Testing and Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship

- 1 To advocate that state board of pharmacy regulations include penicillin allergy skin  
2 testing under pharmacists' scope of practice; further,
- 3 To advocate involvement of pharmacists in the clarification and assessment of penicillin  
4 allergy, intolerance, and adverse drug events; further,
- 5 To advocate for documentation and de-labeling of penicillin allergies, intolerances,  
6 reactions, and severities in the medical record when appropriate to facilitate optimal  
7 antimicrobial selection; further,
- 8 To recommend the use of penicillin skin testing, graded antibiotic challenges, and oral  
9 direct challenges in appropriate candidates when clinically indicated to optimize  
10 antimicrobial selection; further,
- 11 To support the education and training of pharmacists in the assessment, management,  
12 and documentation of penicillin allergies, intolerances, and adverse events; further,
- 13 To advocate for reimbursement for pharmacists' patient care services involved in  
14 penicillin allergy skin testing; further,
- 15 To educate patients, healthcare providers, and the public about the risks of inaccurate  
16 penicillin allergy labeling and the role of pharmacists in health-record reconciliation and  
17 the value of pharmacist-driven health-record reconciliation, including penicillin skin  
18 testing.

*Note: This policy would supersede ASHP policy 1921.*

### **Rationale**

Approximately 10% of all patients in the United States report having a penicillin allergy; however, only 1 in 10 patients with a labeled penicillin allergy are truly allergic. Furthermore, approximately 80% of patients with an IgE-mediated penicillin allergy lose their sensitivity after 10 years. Specific rates of cross-reactivity between penicillins and cephalosporins vary depending on specific resources, although the likelihood of cross-reactivity is lower than previously described. Historically, it has been estimated that 10% of patients with a true penicillin allergy will experience an allergic reaction if administered a cephalosporin, but this data is from early cross-reactivity studies with potential contamination of early cephalosporin products with penicillin G. More recent data suggest cross-reactivity rates of less than 1%. Cross-reactivity is more closely associated with structurally similar R-1 side chains than with the beta-lactam ring itself.

Penicillin allergies have led to considerable public health risks and unintended consequences, including receipt of more broad-spectrum antibiotics, suboptimal therapy for infectious disease management, more antibiotic-related costs, increased risk of adverse effects, and increased risk of methicillin-resistant *Staphylococcus aureus* and *Clostridioides difficile*. As such, structured and thorough interview assessments with appropriate documentation and de-labeling of penicillin allergies are necessary to combat these potential negative consequences of labeled penicillin allergies. Penicillin skin testing and graded or oral challenges are excellent opportunities to assist in the assessment and de-labeling of penicillin allergies. Although pharmacists are well positioned to be involved in these processes, state boards of pharmacy have different regulations regarding whether penicillin skin testing is within pharmacists' scope of practice. Penicillin allergy assessment, management, and documentation are excellent opportunities to improve pharmacist involvement in patient care and to improve antimicrobial stewardship initiatives for health systems, and offer a potential opportunity for pharmacists to bill for their services.

The American Academy of Allergy, Asthma, and Immunology, as part of the [Choosing Wisely](#) campaign, recommends against the overuse of non-beta-lactam antibiotics in patients with a history of penicillin allergy, without appropriate evaluation. In a research abstract from the Canadian Society of Allergy and Clinical Immunology meeting in 2014, researchers found that only 15% of hospital-discharged patients notified a family physician of a negative penicillin allergy evaluation; at the same time, 30% were still listed as penicillin allergic upon readmission to the hospital. Additionally, the existence of a pharmacist-provided allergy skin test has proven to positively impact patient care by optimizing antibiotic regimens and accelerate discharges for patients while reducing healthcare costs.

### **Background**

The Council reviewed ASHP policy 1921, Testing and Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship, as part of the discussion on the Pharmacist Role in Penicillin Testing and voted to recommend amending it as follows (underscore indicates new text):

To advocate that state board of pharmacy regulations include penicillin allergy skin testing under pharmacists' scope of practice; further, [clause moved from below]

To advocate involvement of pharmacists in the clarification and assessment of penicillin allergy, intolerance, and adverse drug events; further,

To advocate for documentation and de-labeling of penicillin allergies, intolerances, reactions, and severities in the medical record when appropriate to facilitate optimal antimicrobial selection; further,

To recommend the use of penicillin skin testing, graded antibiotic challenges, and oral direct challenges in appropriate candidates when clinically indicated to optimize antimicrobial selection; further,

To support the education and training of pharmacists in the assessment, management, and documentation of penicillin allergies, intolerances, and adverse events; further,

~~To advocate that state board of pharmacy regulations include penicillin allergy skin testing under pharmacists' scope of practice. [clause moved above]~~

To advocate for reimbursement for pharmacists' patient care services involved in penicillin allergy skin testing; further,

To educate patients, healthcare providers, and the public about the risks of inaccurate penicillin allergy labeling and the role of pharmacists in health-record reconciliation and the value of pharmacist-driven health-record reconciliation, including penicillin skin testing.

## 8. Use of Unapproved Gene Therapy Products, Drugs, Biologics, and Medical Devices (Biohacking)

- 1 To advocate for enhanced government oversight and regulation of use of gene therapy,  
2 drugs, biologic products, and medical devices created outside of the Food and Drug  
3 Administration approval process (i.e., "biohacking"), and aggressive enforcement of  
4 those regulations; further,
- 5 To oppose use biohacking on vulnerable and at-risk populations and those unable to  
6 provide consent; further,
- 7 To promote education of healthcare professionals regarding use of biohacking and its  
8 implications in the medical setting; further,
- 9 To encourage the pharmacy workforce to include questions about use of biohacking  
10 when obtaining medication histories; further,
- 11 To encourage the pharmacy workforce to ensure that patients using biohacking are  
12 educated about the risks and benefits of these treatments, including lack of regulatory  
13 oversight; further,
- 14 To recommend that health systems use a consistent method for documenting use of  
15 biohacking in the electronic health record.

### **Rationale**

Biohacking has been defined as "do-it-yourself biology or "do-it-yourself citizen science merging body modification with technology" (Yetisen AK. Trends Biotechnol. 2018; 36:744-7).

Biohacking is performed by biology enthusiasts, citizen scientists, and other like-minded individuals and includes neurohacking (focuses on brain stimulation for change); manufacturing of pharmaceutical products; implantation of modified technology; and the genetic modification of bacteria, yeast, plants, and humans (as a form of self-experimentation) to improve oneself or treat a disease.

Genetic biohacking in particular has proven to be easy and affordable, with individuals using inexpensive, semi-professional and portable labs to carry out their experiments, including Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology, which permits the user to edit the genome by removing, adding, or altering sections of DNA. It is estimated that more than 30,000 people are involved in do-it-yourself biology in the United States alone. Furthermore, many see themselves as serving the greater health interests of the patient community at large with the right to experiment and create treatments such as gene therapy as a form of social justice. However, many of these biohackers have little to no formal training in safety and do not obtain ethical reviews of their work as one would in an institution with an internal review board. Although most biohackers currently experiment only on themselves, concern about the practice may grow as the cost of traditional therapies, particularly biologics, increases, luring sick and desperate patients to biohackers in hopes of cheaper or more accessible treatments.

The other concern about the biohacking movement is bioterrorism. The Federal Bureau of Investigation continues to form relationships with labs where genetic experimentation occurs to police this threat, but the concern remains.

Currently in the United States, there is no ban on genome editing outside of licensed laboratories. Although the Food and Drug Administration (FDA) does have jurisdiction over regular raw biological products, traditional drug products, and do-it-yourself CRISPR kits, they have not taken public enforcement action against those conducting genome editing. This may be due to practicality, however, as many biohackers are individuals or work within a small community and are hard to track. Additionally, many current laws are outdated and apply only to agricultural genetic modification. The FDA has issued draft guidance for the regulation of intentionally altered genomic DNA in animals and stated that “any use of CRISPR/Cas9 gene editing in humans [is] gene therapy” and therefore subject to regulation.

Another facet of biohacking that must be addressed is its potential impact on manufacturing. For example, due to the high cost of biosimilar insulins, a community of biohackers has created the Open Insulin Project to develop an insulin production method for personal use. This and similar projects may lead to intellectual property, regulatory, patent, and legal issues that could impact manufacturing.

Another aspect of do-it-yourself biology is implantation of devices into one’s body for medical purposes. Many of these devices are used to monitor a medical condition or to optimize drug delivery to manage disease, such as implantation of veterinary chips for monitoring vital signs, use of a wearable artificial kidney that performs dialysis via a coated skin port, and homemade insulin pumps. Pharmacists need to be aware of these devices, as they impact how patients receive medications and how they are treated. At some point in their health journey, patients using these devices are likely to be admitted to a hospital, a mechanism for documentation of this information in the electronic health record is necessary. Furthermore, pharmacists will need to understand the impact these devices have on the



pharmacokinetics, pharmacodynamics, and other aspects of drug therapy.

An overall approach that should be considered is that of education of those engaged in the biohacking movement regarding the role of the federal agencies in consumer protection, risks and benefits and establish practice standards and norms that minimize harm.

### **Background**

The Council discussed biohacking as a topic of interest from the ASHP membership at large. The Council discussed this emerging area, noting that there are gaps in regulatory oversight as well as the need for education for pharmacists. The Council believed that a policy in this area is necessary given the safety, ethical, and regulatory hurdles this movement will encounter, as well as the risk to patients.

## **Board Actions**

### **Sunset Review of Professional Policies**

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

- Patient-Reported Outcome Tools (1107)
- Appropriate Use of Antipsychotic Drug Therapies (1604)
- Safety of Epidural Steroid Injections (1605)

## **Other Council Activity**

### **Joint Meeting on Pandemic Preparedness**

On Tuesday, September 22, members of all councils and the Commission on Affiliate Relations met to hear presentations from Don R. Boyce and Joe Pinto of the Mount Sinai Health System on the lessons learned from Mount Sinai's experience with the COVID-19 pandemic. Council and Commission members were asked to reflect on current evidence, the presentations, background reading, meeting discussion, best practices, and personal experience to advise ASHP on pandemic-related policy issues relevant to the Council's purview. Council members considered existing and potential pharmacist roles in both operational and patient care aspects of the pandemic, and how the lessons learned from the pandemic could be applied to future crises that present similar circumstances. Key objectives of the discussion included considering the need for new or revised ASHP professional policy regarding pandemic preparedness and response, and suggesting elements of that policy, as well as reviewing current pharmacy practice related to pandemic preparedness and response and providing advice on ways ASHP can help advance pharmacy practice through the development of member tools and resources, best practices, education, and other programmatic approaches.

### **Adoption of Drug Therapies with Limited Data or Efficacy**

The Council discussed the issues that the current pandemic has brought to light, particularly surrounding the amount of information that has been published in the wake of the COVID-19

pandemic. The Council observed that there has been an incredible number of articles, case reports, and other publications in a short period of time about the care for these patients. These resources are often lacking in sample size, fail to demonstrate statistical or clinical significance, lack peer review, or have variable outcomes. The Council discussed how pharmacists and other medical professionals should balance the risks and benefits of relying on such studies in a time of urgent need, such as a pandemic, when safe and effective therapies are needed more urgently, considering the following:

- how to approach outcomes data where the effect of therapy on morbidity and mortality aren't clear;
- how to change disease management as therapies change as more information becomes available;
- how to assess free, open-access articles and press releases;
- the role of the pharmacist in therapy decision-making; and
- how ASHP and pharmacists at large should collaborate with other professional organizations to promote quality patient care.

Because the other councils were also looking at this topic as a larger discussion regarding pandemic preparedness, and the Council on Pharmacy Practice was creating policy on this issue, the Council on Therapeutics shared recommended clauses on the above-discussed areas with the Council on Pharmacy Practice.

### **Continuous Infusion Vancomycin Monitoring in the Outpatient Setting**

The Council reviewed the newly revised guideline: Therapeutic monitoring of vancomycin for serious methicillin-resistant *Staphylococcus aureus* infections and discussed the logistical and therapeutic considerations for continuous vancomycin monitoring, the patient populations would benefit most from outpatient continuous monitoring, barriers to this approach antimicrobial therapy, considerations for Bayesian monitoring, and education strategies providers to monitor this patient population. Ultimately, the Council believed that ASHP should provide more education on these published guidelines in the form of webinars, podcasts, and other media to aid pharmacists in evaluating and implementing these guidelines into their practice.

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# COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATIONS

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*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.*

Julie A. Groppi, *Board Liaison*

## **Council Members**

Garrett Schramm, *Chair* (Minnesota)  
Christopher Edwards, *Vice Chair* (Arizona)  
Joseph Barone (New Jersey)  
Angela Bingham (Pennsylvania)  
Lauren Busch, *Student* (Missouri)  
Carol Heunisch (Illinois)  
Jesse Hogue (Michigan)  
Amy Holmes (North Carolina)  
Norman Hooten (Florida)  
Denise Kelley (Texas)  
Ann Lloyd (Oklahoma)  
Tiffani Neubel-Johnson (Texas)  
Jennifer Sternbach (New Jersey)  
Erika Thomas, *Secretary*

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## **1. Professional Identity Formation**

- 1 To encourage the pharmacy workforce and pharmacy education and training programs
- 2 to foster professional identity formation.

*Note: This policy would supersede ASHP policy 1113.*

### **Rationale**

The terms “professionalism” and “professional identity” are sometimes mistakenly used interchangeably. Professionalism is defined by behaviors that are often outwardly visible (e.g., credentialing, continuing education, efforts to advance the profession). In contrast, professional identity formation (PIF) is defined as the process of internalizing a profession’s core values and beliefs. PIF incorporates the three domains of thinking, feeling, and acting. PIF in pharmacy may be described as the process of developing a commitment to: (1) high professional standards of pharmacy practice, (2) high personal standards of integrity and competence, (3) serving humanity, (4) creating a just and inclusive healthcare system and society, (5) analytical thinking and ethical reasoning, (6) continuing professional development, (7) acquiring personal leadership skills, (8) developing effective interpersonal skills, (9) maintaining personal well-being and resiliency, and (10) membership and participation in professional organizations.



Pharmacy professionals and educators have a direct or indirect responsibility to support the growth and success of others in the pharmacy workforce through mentorship and modelling. As pharmacy professionals interact with learners, new practitioners, and even seasoned colleagues, they have the ability to model professional behavior, integrity, ethical standards, and service to the community. Pharmacy professionals who serve in formal or informal leadership roles are in a unique position to mentor others in leadership skills. Pharmacy professionals should mentor others in the various career paths they may pursue as well as encourage them to elevate their practice level and education.

Some of the barriers to PIF include mentors and preceptors being pressured into a role rather than being allowed to decide whether they choose to do so voluntarily, increased pharmacy workload, and staff burnout. Developing student professionalism (sometimes referred to as “professional socialization”) has been part of pharmacy education for decades, but a broader focus on PIF more generally will better serve the profession of pharmacy during a time of practice transformation than the current approach to teaching professionalism. Colleges of pharmacy, other providers of education and training programs, and employers could promote PIF by providing mentorship programs and other resources.

### **Background**

The Council reviewed ASHP policy 1113, Professional Socialization, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To encourage ~~pharmacists~~ the pharmacy workforce and pharmacy education and training programs ~~to serve as mentors to students, residents, and colleagues in a manner that fosters~~ professional identity formation. the adoption of: (1) high- ~~professional standards of pharmacy practice, (2) high personal standards of integrity and competence, (3) a commitment to serve humanity, (4) analytical thinking and ethical reasoning, (5) a commitment to continuing professional development, and (6) personal leadership skills.~~

## **2. Career Opportunities for Pharmacy Technicians**

- 1 To promote pharmacy technicians as valuable contributors to healthcare delivery;
- 2 further,
- 3 To advocate that pharmacy technicians complete an education and training program
- 4 accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE), and
- 5 maintain Pharmacy Technician Certification Board certification; further,
- 6 To advocate that pharmacy technicians complete ACPE-approved certificate programs
- 7 that provide training for their current or anticipated roles; further,

- 8 To develop and disseminate information about career and training opportunities that  
9 enhance the recruitment and retention of qualified pharmacy technicians; further,
- 10 To encourage employers to offer career advancement opportunities (e.g., career  
11 ladders) for pharmacy technicians; further,
- 12 To urge compensation for pharmacy technicians commensurate with advanced roles  
13 and responsibilities.

*Note: This policy would supersede ASHP policy 1610.*

### **Rationale**

As the responsibilities of pharmacy technicians expand and their role as a vital member of the healthcare team is recognized, it is imperative that pharmacy technicians be well trained and competent to perform those responsibilities. Pharmacists cannot provide quality patient care without the support of competent pharmacy technicians. To support pharmacists and promote retention, it is important that pharmacy technician positions be viewed as a career and not just a job. Pharmacy technicians should be provided opportunities for life-long advancement and compensated appropriately for advanced roles that they assume. There is current ASHP policy 1912 that addresses the *Pharmacy Technician Training and Certification*, which advocates for the education, training, and certification for new pharmacy technicians. This covers a need for the on-going professional development and career advancement for pharmacy technicians.

### **Background**

The Council reviewed ASHP policy 1610, Career Opportunities for Pharmacy Technicians, as part of sunset review and voted to recommend amending it as follows (underline indicates new text; ~~strike through~~ indicates deletions):

To promote pharmacy technicians as valuable contributors to healthcare delivery; further,

To advocate that pharmacy technicians complete an education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE), and maintain Pharmacy Technician Certification Board certification; further,

To advocate that pharmacy technicians complete ACPE-approved certificate programs that provide training for their current or anticipated roles; further,

To develop and disseminate information about career and training opportunities that enhances the recruitment and retention of qualified pharmacy technicians; further,

To ~~support~~ encourage employers to offer pharmacy technician career advancement opportunities (e.g., career ladders) for pharmacy technicians, commensurate with training and education; further,

To ~~encourage~~ urge compensation models for pharmacy technicians ~~that provide a living wage~~ commensurate with advanced roles and responsibilities.

### 3. Zero Tolerance of Harassment and Discrimination

- 1 To assert that the pharmacy workforce has a right to expect and responsibility to ensure
- 2 a profession in which all individuals are treated with respect and civility, free of all
- 3 harassment and discrimination, including but not limited to sexual harassment and
- 4 malicious behaviors; further,
- 5 To commit to a culture of responsibility and accountability within the profession with
- 6 zero tolerance of harassment and discrimination; further,
- 7 To foster the development of tools, education, and other resources to promote such a
- 8 culture.

#### **Rationale**

The [Code of Ethics for Pharmacists](#) states that “A pharmacist acts with honesty and integrity in professional relationships.” The [ASHP Statement on Professionalism](#) includes among the elements of professionalism pride in and service to the profession, conscience and trustworthiness, and ethically sound decision-making. All forms of discrimination (e.g., race, color, sex, national origin, religious, sexual orientation/identity, age, disability), harassment (including sexual harassment), and malicious behaviors such as bullying, intimidation, or exploitation go against the core beliefs of the profession. All members of the pharmacy workforce have a professional responsibility to create and sustain a culture of responsibility and accountability within the profession in which all individuals are treated with respect and civility, with zero tolerance of harassment and discrimination.

A culture of responsibility and accountability requires that employers and organizations establish mechanisms for retaliation-free reporting of harassment and discrimination. For such a culture to thrive, the pharmacy workforce must recognize its professional obligation to not only follow institutional policies regarding prevention, reporting, and consequences for such behaviors but to seek out ways to improve the effectiveness of those policies and procedures. This culture of responsibility and accountability includes the workplace and learning environments but extends even to such personal but quasi-public conduct as interactions on social media. As stated in the [ASHP Statement on the Use of Social Media by Pharmacy Professionals](#), the “higher standards of conduct expected of professionals, even in personal behavior” imply that “[p]ostings on social media should be subject to the same professional standards and ethical considerations as other personal or public interactions.”

As stated in the [ASHP Statement on Professionalism](#), “[o]ne of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession’s ideals and mission.” Formal and informal mentorship relationships are fundamental to the

growth and health of any profession, and abuses of those positions of trust are especially injurious to victims and the profession. These relationships should be subjected to the strictest scrutiny and oversight to ensure they are held to the highest standards of conduct.

To further the goal of creating and sustaining a culture of responsibility and accountability regarding harassment and discrimination, ASHP commits to fostering the development of tools, education, and other resources to help members, employers, and other organizations address these important issues.

### **Background**

Recent events in society and the pharmacy profession have drawn attention to sexual harassment, discrimination, and malicious behaviors. The Council reviewed ASHP policy position 1916, Intimidating and Disruptive Behaviors, and the [ASHP Statement on Professionalism](#) to determine whether ASHP policy fully addresses these issues. Although these policies include relevant elements, the Council concluded that ASHP and its members would benefit from policy that more directly and clearly expresses ASHP's stance on sexual harassment, discrimination, and malicious behaviors. The Council recognized the ASHP's webinar series "Creating Respectful Organizations: Your Rights and Responsibilities" served as an example of how ASHP is already providing resources to help members, employers, and other organizations address these important issues.

## 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.)

- Quality of Pharmacy Education and Expansion on Colleges of Pharmacy (1108)
- Residency Equivalency (1109)
- Innovative Residency Models (1112)
- Cultural Competency (1613)

## Other Council Activity

### **Joint Meeting on Pandemic Preparedness**

On Tuesday, September 22, members of all councils and the Commission on Affiliate Relations met to hear presentations from Don R. Boyce and Joe Pinto of the Mount Sinai Health System on the lessons learned from Mount Sinai's experience with the COVID-19 pandemic. Council and Commission members were asked to reflect on current evidence, the presentations, background reading, meeting discussion, best practices, and personal experience to advise ASHP on pandemic-related policy issues relevant to the Council's purview. Council members considered existing and potential pharmacist roles in both operational and patient care aspects

of the pandemic, and how the lessons learned from the pandemic could be applied to future crises that present similar circumstances. Key objectives of the discussion included considering the need for new or revised ASHP professional policy regarding pandemic preparedness and response, and suggesting elements of that policy, as well as reviewing current pharmacy practice related to pandemic preparedness and response and providing advice on ways ASHP can help advance pharmacy practice through the development of member tools and resources, best practices, education, and other programmatic approaches.

## Endorsement of Camden Coalition Core Competencies

The Council voted to recommend endorsing the Camden Coalition Core Competencies for Front-Line Complex Care Providers.

## Recent Pharmacy Workforce-Related Survey Results and Updates

The Council discussed several recent pharmacy workforce-related survey results, including the AACP New Graduate Surveys, the 2019 National Pharmacist Workforce Survey (NPWS) and the recently launched Pharmacy Demand Report developed by the Pharmacy Workforce Center (PWC), to determine whether there are implications for ASHP policy.

The Council received an update on the Pharmacy Career Information Center (PCIC) and efforts underway to improve the pharmacy school applicant pipeline were highlighted. The Council discussed the importance of communicating to ASHP members that the profession is changing and the pharmacy workforce needs to be proactive about its future. The Council discussed how the profession should take this opportunity to highlight what pharmacists are trained to do and how we can continue to expand the scope of currently provided services.

## Pharmacy Residency Trends

The Council was provided pharmacy residency-related surveys, including Pharmacy Match 2020 statistics and high-level findings from the inaugural ASHP Resident Survey, to determine whether there are implications for ASHP policy. During the update on residencies, it was announced that the number of residency programs has exceeded 2600, although early estimates show a slowing of recruitment growth for the 2021-2020 pharmacy residency year, which could be related to workforce recruitment/retention impacted by the COVID-19 global pandemic. There has been a 39% growth in the number of residency programs in the past five years and continued growth in the early commitment process for PGY2 residency positions. Demographic data for residents and residency programs were previously removed due to the risk of discrimination; however, ASHP Accreditation Services has requested the addition of demographic data from Liaison International to connect the trends in pharmacy applicant, student, and resident diversity to evaluate the profession's journey on diversity, equity, and inclusion. Council members inquired about individual program level data from the resident and preceptor surveys, and ASHP will evaluate how to aggregate to minimize potential retaliation against residency program participants.

## ASHP Residency-Trained Credential

The Council discussed the topic of an ASHP residency credential in response to a



recommendation from the ASHP House of Delegates. Currently, there is no credential awarding pharmacists a letter designation (e.g., "RTP" for "residency trained pharmacist") for completion of an accredited residency training program. In the 2019 ASHP *Long-range Vision for the Pharmacy Workforce in Hospitals and Health Systems*, credentials are addressed, with no recommendation for a residency-trained letter designation. Specialty Board Certifications through the Board of Pharmacy Specialties (BPS) were emphasized instead. Council members noted the September 2020 ASHP letter to the sponsoring organizations of a recently released Emergency Medicine Residents Association (EMRA) Joint Statement on Post-Graduate Training of Nurse Practitioners and Physician Assistants, expressing ASHP's grave concern over the statement's call to limit use of the terms "resident," "residency," "fellow," and "fellowship" in a medical setting to postgraduate clinical training of medical school physician graduates within GME training programs.

The Council addressed this topic to explore the policy implications of creating a residency-trained credential to be used by pharmacists who have successfully completed an ASHP-accredited residency training program. Members agreed that this issue is most appropriately addressed through educational efforts to bridge divisions between pharmacy workforce practitioners rather than through creation of a separate credential for this segment of the pharmacy workforce.

## Workforce Support During Unprecedented Times

During this extraordinary time, hospitals and health systems were required to make decisions affecting their employees and took many approaches to stabilize their workforce. Now, as society continues through a global health threat, the Council was asked to reconsider workforce support and whether the pharmacy workforce is essential. As part of the conversation, Council members considered the definition of essential workers. According to the U.S. Department of Homeland Security, essential workers are those who conduct a range of operations and services that are typically essential to continue critical infrastructure operations. An essential employee is a designated employee who is required to work during a business closure in order to meet operational requirements. Council members reflected on the local impact of the ASHP Statement on Pharmacy Residency Furloughs from the COVID-19 pandemic, although the statement did not address the entire pharmacy workforce. Council members noted that the visibility of the role of pharmacists had in responding to the COVID-19 pandemic may assist with the Pharmacy is Right for Me campaign, a national online pharmacy student recruitment campaign that ASHP supports.

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# COUNCIL ON PHARMACY MANAGEMENT

## POLICY RECOMMENDATIONS

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*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.*

Jamie S. Sinclair, *Board Liaison*

### **Council Members**

Staci Hermann, *Chair* (New Hampshire)  
Arpit Mehta, *Vice Chair* (Pennsylvania)  
Jennifer Belavic (Pennsylvania)  
Daniel Dong (California)  
Monica Dziuba (Louisiana)  
Kaitlyn Grieves, *Student* (Kentucky)  
Amanda Hays (Missouri)  
Jessica Hill (New Jersey)  
Rondell Jagers (Georgia)  
Trinh Le (North Carolina)  
Bonnie Levin (Maryland)  
Christopher Scott (Indiana)  
Eric Maroyka, *Secretary*

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### **1. Minimizing the Use of Abbreviations**

- 1 To support efforts to minimize the use of abbreviations in healthcare; further,
- 2 To encourage education of healthcare professionals and learners (e.g., residents,
- 3 students) on minimizing the use of abbreviations across all patient care settings.

*Note: This policy would supersede ASHP policy 0604.*

### **Rationale**

Although there are anecdotal examples of medical abbreviations causing harm to patients, there is little good clinical evidence to demonstrate that medical abbreviation use is dangerous or is causing problems in the delivery of care. Nevertheless, minimizing or even eliminating the use of medical abbreviations in healthcare has been encouraged for decades. The Institute of Safe Medication Practices regularly receives reports of errors, some of which have resulted in adverse events, due to misinterpretation of medical abbreviations. The Joint Commission has regularly issued updates and guidance on the safe use of medical abbreviations and has also published a short list of dangerous medical abbreviations and dose expressions that should never be used. However, despite many key organizations discouraging the use of medical abbreviations, they continue to be used at an alarming rate. Such use can place new practitioners at great risk when they have to interpret the abbreviations, as the new practitioner may have limited knowledge about what the abbreviations mean.



**Background**

The Council reviewed ASHP policy 0604, Minimizing the Use of Abbreviations, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To support efforts to minimize the use of abbreviations in health care; further,

~~To collaborate with others in the development of a lexicon of a limited number of standard drug name abbreviations that can be safely used in patient care.~~

To encourage education of healthcare professionals and learners (e.g., residents, students) on minimizing the use of abbreviations across all patient care settings.

The Council suggested ASHP provide education and resources for healthcare professionals, students, and residents to help ensure they are equipped to identify and minimize or even eliminate the use of medical abbreviations in practice. The Council reviewed ASHP policy 0720, Standardizing Prefixes and Suffixes in Drug Product Names, as part of the background for this topic discussion and proposed that ASHP heighten its advocacy regarding its collaborative efforts to standardize drug prefixes and suffixes.

**2. Optimal Pharmacy Staffing**

- 1 To encourage pharmacy leaders to work in collaboration with physicians, nurses, health-  
2 system administrators, and others to outline key pharmacist services that are essential  
3 to safe and effective patient care and employee engagement; further,
- 4 To encourage pharmacy leaders to be innovative in their approach and to factor into  
5 their thinking the potential benefits and risks of flexible staffing models, telehealth  
6 practices, legal requirements, accreditation standards, professional standards of  
7 practice, and the resources and technology available in individual settings; further,
- 8 To encourage pharmacy leaders to develop contingency plans for changes in staffing  
9 models to accommodate rapid changes in the healthcare environment and the needs of  
10 patients and staff; further,
- 11 To encourage pharmacy leaders to develop key performance indicators to support safe  
12 staffing models.

*Note: This policy would supersede ASHP policy 2034.*

**Rationale**

The advancement of the pharmacy profession over the past decade has prepared and

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

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

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

Various options to consider when exploring flexible staffing models include telehealth practices, remote order review and verification (i.e., telecommuting), and productivity measures to ensure patient census is well distributed among pharmacists in charge of providing clinical services. Another concept related to flexible staffing models is leveraging pharmacy technicians' roles to support pharmacist engagement in direct patient care activities. Some institutions have explored data-driven, staffing-to-demand models based on real-time patient-volume metrics. The concept is to allocate staff to tasks based on the current workload, which is evaluated daily. Other institutions are also utilizing metrics such as number of doses dispensed at a certain point in time and volume of order verification throughout the day in order to divide patient care units evenly among pharmacists that perform order verification or provide clinical services. Flexible staffing models should support the following principles:

- Sufficient qualified staff must exist to ensure safe and effective patient care.
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care.
- Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that

are the most essential to safe and effective patient care and will, as necessary, curtail other services.

- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

The COVID-19 pandemic and the ensuing reduction in elective procedures, routine visits, and admissions amplified the emphasis on flexing staff to volume. To support fiscal solvency during and in the aftermath of the pandemic, organizations had to quickly pivot and align staff to accommodate shifts in volume, resulting in redesigned staffing models to optimize scheduling. These models have included a mix of onsite and remote offering of services to perform synchronous and asynchronous work in a more efficient manner, as well as staff furloughs. Flexing pharmacy staffing models have been previously described, such as pharmacy staffing-to-demand models; alternative work schedules; and productivity monitoring to guide hiring and staffing decisions.

Other healthcare disciplines (e.g., nursing) have historically utilized flexible staffing models to optimize services, reduce the risk of adverse events, and improve patient outcomes. The different models explored by nursing include patient ratio, key performance indicators, patient acuity, collaborative staffing, and supplemental staffing models. There is limited literature on the use of flexible staffing models, but the concept is being explored by various health-system pharmacy departments.

### **Background**

The Council reviewed ASHP policy 2034, Staffing for Safe and Effective Care, and voted to recommend amending it as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

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

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

To encourage pharmacy leaders to develop contingency plans for changes in staffing models to accommodate rapid changes in the healthcare environment and the needs of patients and staff; further,

To encourage pharmacy leaders to develop key performance indicators to support safe staffing models.

Recognizing that organizations are increasingly facing the prospect of staff expense reduction, the Council recommended ASHP explore the development of a statement or a set of guidelines related to best practice staffing model considerations for hospitals and health systems. The Council acknowledged that productivity metrics in and of themselves cannot be relied upon to support a particular practice model and that a combination of factors most effectively expresses the work and efforts of a pharmacy service. Different assumptions about staffing discussed by the Council, which could serve as a list of concepts for a best practice document, include: integration of onsite and remote staffing; extending reach with telehealth pharmacy practice (e.g., extension of baseline acute and ambulatory care clinical service capability to rural sites); and use of key performance indicators, taking into account census and non-census-based characteristics.

A concern voiced with an increased shift to remote work is potential degradation in relationship and trust building with onsite staff. The Council suggested ASHP review the ASHP Guidelines on Remote Order Entry Processing to determine whether revision of the document is required to reflect contemporary approaches. ASHP should further consider advocacy or partnership with organizations and state affiliates regarding options and education on changing expectations for remote work.

Finally, the Council recognized that there is now an opportunity for ASHP to take advantage of the lessons of COVID-19 to advocate for interstate pharmacist licensure (ASHP policy 2030) or a licensure compact to expand the mobility of pharmacists, particularly as it relates to remote work.

### 3. Patient Access to Pharmacist Care Within Provider Networks

- 1 To advocate for laws and regulations that require healthcare payer provider networks
- 2 to include pharmacists and pharmacies providing patient care services within their
- 3 scope of practice when such services are covered benefits; further,
  
- 4 To advocate for laws and regulations that require healthcare payer provider networks
- 5 to include all qualified pharmacists and pharmacies who apply to participate as a
- 6 provider in the network and to reimburse all participating providers fairly and equitably
- 7 for services that are a covered benefit; further,
  
- 8 To acknowledge that healthcare payers may develop and use criteria to determine
- 9 provider access to its networks to ensure the quality and viability of healthcare services
- 10 provided; further,
  
- 11 To advocate for laws and regulations that would help ensure the same level of patient
- 12 care within a payer network by requiring healthcare payers to (1) disclose to
- 13 participating providers and those applying to participate the criteria used to include,
- 14 retain, or exclude providers; (2) ensure that those criteria are standardized across all

- 15 network providers; and (3) collect data on how well providers meet those criteria and  
16 report that data to providers; further,
- 17 To advocate for comparative, transparent sharing of performance and quality measure  
18 data based on those criteria.

*Note: This policy would supersede ASHP policy 1808.*

### **Rationale**

As hospitals and healthcare organizations have become more engaged in developing ambulatory care and specialty pharmacy services, pharmacies and pharmacists providing patient care services within those settings increasingly find themselves excluded from healthcare payer networks and non-integrated delivery networks with specialty pharmacies. Insurers continue to carve out care from hospitals and health systems by providing patient care offerings that include but are not limited to infusion services. 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 allow payers to steer patients towards lower-cost-of-care options and block health-system pharmacies and pharmacists providing patient care services from joining their networks. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to profitably operate), but when creating provider networks, payers should include pharmacies and pharmacists providing patient care services, within their scope of practice, when such services are covered benefits. To ensure equal treatment for healthcare providers, payers should be required to disclose to participating providers and those applying to participate in a provider network the criteria used to include, retain, or exclude providers. When pharmacists obtain provider status, the infrastructure required to implement direct, independent patient care and billing for provider-based services needs to be in place and accessible. Although a possible risk of payer transparency is a reduction in market competition, comparative, transparent sharing of performance and quality measure data, based on standardized criteria, reveals the level of patient care provided and demonstrates to payers and providers where their performance and quality fall in comparison to others. Ensuring pharmacists and pharmacies have the opportunity to engage and have access to payers and payer networks improves coordination of care and patient access to pharmacists' care; reduces the burden on patients (e.g., access to limited distribution drugs, eliminating additional copays); and ensures laws, rules, regulations, standards, and best practices for medication management are implemented and enforced.

### **Background**

The Council reviewed ASHP policy 1808, Patient Access to Pharmacist Care Within Provider Networks, in response to a recommendation from the ASHP House of Delegates, and voted to recommend amending it as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To advocate for laws and regulations that require healthcare payer provider networks to include pharmacists and pharmacies providing patient care services within their scope of practice when such services are covered benefits; further,

To advocate for laws and regulations that ~~allow~~ require healthcare payer provider networks to include all qualified pharmacists and pharmacies who apply to participate as a provider within a healthcare payer's in the network and to reimburse all participating providers fairly and equitably for services that are a covered benefit if the pharmacist or pharmacy meets the payer's criteria for providing those healthcare services; further,

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

~~To advocate that healthcare payers be required to disclose to pharmacists and pharmacies applying to participate in a provider network the criteria used to include, retain, or exclude pharmacists or pharmacies.~~

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

To advocate for comparative, transparent sharing of performance and quality measure data based on those criteria.

Due to the far-reaching and complex implications of the policy, the Council sought review of proposed amendments and suggestions on wording from the executive committees of the Section of Specialty Pharmacy Practitioners (SSPP) and the Section of Pharmacy Practice Leaders (SPPL). The SSPP and SPPL executive committees reviewed the draft policy position and provided constructive edits, consistent with the intent of the policy rationale, to ensure the policy recommendation is relevant and assertive.

#### **4. ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive**

To approve the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive (Appendix A).



## 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.)

- Computerized Provider Order Entry (0105)
- Surface Contamination on Packages and Vials of Hazardous Drugs (1615)

## Other Council Activity

### Joint Meeting on Pandemic Preparedness

On Tuesday, September 22, members of all councils and the Commission on Affiliate Relations met to hear presentations from Don R. Boyce and Joe Pinto of the Mount Sinai Health System on the lessons learned from Mount Sinai's experience with the COVID-19 pandemic. Council and Commission members were asked to reflect on current evidence, the presentations, background reading, meeting discussion, best practices, and personal experience to advise ASHP on pandemic-related policy issues relevant to the Council's purview. Council members considered existing and potential pharmacist roles in both operational and patient care aspects of the pandemic, and how the lessons learned from the pandemic could be applied to future crises that present similar circumstances. Key objectives of the discussion included considering the need for new or revised ASHP professional policy regarding pandemic preparedness and response, and suggesting elements of that policy, as well as reviewing current pharmacy practice related to pandemic preparedness and response and providing advice on ways ASHP can help advance pharmacy practice through the development of member tools and resources, best practices, education, and other programmatic approaches.

### ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness

The Council recommended that the Council on Pharmacy Practice consider revision of the ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness. As preliminary guidance for a drafting team, the Council drafted suggestions on how the guidelines could be improved.

The Council also discussed the idea of an emergency preparedness self-assessment survey, similar to the web-based Practice Advancement Initiative gap assessment tools, as a tangible member tool for ASHP to explore. The intent of the tool would be to inform emergency preparedness readiness posture with a possibility to consider a mentor/match process to help struggling hospitals close significant emergency preparedness gaps. The Council proposed ASHP develop and promote education and training opportunities (e.g., a professional certificate program, journal theme collection) to ensure appropriate attention is placed on leadership and engagement with emergency preparedness and response and its impact on current and future

pharmacy operations. Continued efforts to amplify ASHP resources on well-being and resilience was also recommend by the Council.

## Ensuring the Security of Medications Stored in Perioperative Areas

During its June 2020 summer call, the Council discussed the practice implications of a position statement of the American Society of Anesthesiologists (ASA) that supports leaving noncontrolled medications in or on top of unlocked anesthesia carts in an operating room suite for brief periods. Subsequent to the summer call, a few Council members participated on a separate call to explore ASHP policy needs related to this topic and evaluate the different options in advance of 2020 Policy Week.

## ASHP Statement on Telepharmacy

The Council discussed the ASHP Statement on Telepharmacy as part of sunset review. The Council decided that the statement needs revision to take into account the near-term and emerging future roles of telehealth pharmacy practice. The term “telehealth pharmacy practice” was the terminology the Council agreed upon as a suggested replacement for “telepharmacy.” The Council developed a bullet-point list of topics that serves as preliminary policy guidance to address in the revised statement and suggested a joint drafting team, consisting of volunteers from the Council and section(s) (e.g., SOPIT, SPPL, SACP), be charged with revising the ASHP Statement on Telepharmacy.

There was brief discussion of telehealth pharmacy practice that suggested the Council would favor the development of guidelines or a more easily adaptable toolkit. Additionally, this may present an opportunity to align with or consolidate with other existing ASHP guidelines.

As stated elsewhere, the Council proposed ASHP investigate advocacy options regarding the pursuit and realization of an interstate pharmacist licensure (related ASHP policies 2030, 2024, and 1310) to enable leveraging use of tele-technologies across state lines.

The Council also suggested ASHP pursue survey and publication opportunities (e.g., case studies, journal theme collection) to capture how telehealth pharmacy practice is being effectively utilized to demonstrate gains in efficiency and improved patient access and medication safety. Finally, the Council encouraged strategic communications to improve awareness of the ASHP Telehealth Resource Center on [ashp.org](http://ashp.org).

## ASHP Guidelines on the Recruitment, Selection, and Retention of Pharmacy Personnel

The Council reviewed the ASHP Guidelines on the Recruitment, Selection, and Retention of Pharmacy Personnel and recommended that they be updated. The Council focused on creating a list of higher-level concepts that should be addressed in the guidelines and which would be addressed more in depth by the actual drafting team. Some concepts for the drafting team to consider when amending the guidelines include labor contracts; virtual and alternate work schedules; job sharing; generational differences; contemporary interview questions; career ladder opportunities; diversity, equity, and inclusion; and pharmacy technician recruitment.

## **ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems**

The Council reviewed ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems and recommended that they be revised to account for the current approaches to cost-saving initiatives and issues related to patient-centered care and fiscal stewardship. The Council suggested how the guidelines could be improved by offering higher-level concepts that should be addressed in the guidelines and which would be addressed more in depth by the actual drafting team.

The Council believed that physician leadership and front-line pharmacy staff do not always have an understanding of revenue cycle, proper chargemaster management, and medication cost-containment strategies. The Council suggested ASHP provide education on cost-containment strategies geared toward enhancing pharmacy staff understanding and physician leader buy-in that aligns with these strategies.

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

The Council reviewed the draft statement with amendments prepared by members of the Section of Pharmacy Practice Leaders (SPPL) Executive Committee. The Council felt key components were addressed to update the statement, taking into account contemporary and emerging roles of the pharmacy executive, but offered a few suggestions on how the document could be strengthened.

## **ASHP Statement on Leadership as a Professional Obligation**

The Council reviewed the ASHP Statement on Leadership as a Professional Obligation and recommended that it be updated.

## **ASHP Guidelines on Preventing Diversion of Controlled Substances**

The Council reviewed the ASHP Guidelines on Preventing Diversion of Controlled Substances and recommended that they be updated.

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# COUNCIL ON PHARMACY PRACTICE

## POLICY RECOMMENDATIONS

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*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.*

Kristina L. Butler, *Board Liaison*

### **Council Members**

Andrew Stivers, *Chair* (Georgia)  
Amanda Hansen, *Vice Chair* (Ohio)  
Michael Dickens (Idaho)  
Karl Gumper (Massachusetts)  
Barbara Hintzen (Minnesota)  
Molly Leber (Connecticut)  
Karen McConnell (Colorado)  
Alex Mersch (Iowa)  
Christopher Pack (Oklahoma)  
Kuldip Patel (North Carolina)  
Brittany Riley (West Virginia)  
Jamielynn Sebaaly (North Carolina)  
Kenny (Jon) Wilson, *Student* (Alabama)  
Anna Legreid Dopp, *Secretary*

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### **1. Role of the Pharmacist and Pharmacy Technician in Pandemic Preparedness and Response**

- 1 To advocate that all healthcare organizations include pandemic preparedness in
- 2 emergency preparedness planning; further,
  
- 3 To promote collaboration and communication among healthcare workers, healthcare
- 4 organizations, government agencies, industry, and other stakeholders in pandemic
- 5 preparedness and response; further,
  
- 6 To advocate that pharmacy personnel be included as leaders on teams responsible for
- 7 pandemic preparedness planning and response at the federal, state, local, and
- 8 institutional levels, and that they integrate such planning into emergency preparedness
- 9 planning for their workplaces; further,
  
- 10 To encourage all healthcare organizations to establish criteria for evidence-based
- 11 medication-use decisions, even when such evidence is scarce, incomplete, or conflicting,
- 12 and recognize the unique role that pharmacy personnel have in ensuring the safe and
- 13 effective use of medications based on best available evidence and resources; further,

- 14 To advocate that healthcare organizations recognize the unique and collective stress a  
15 pandemic places on healthcare workers and provide suitable resources to maintain  
16 workers' well-being and resilience; further,
- 17 To support research on and provide resources and education to aid the pharmacy  
18 workforce in preparing for and responding to pandemics.

### **Rationale**

ASHP has long advocated “that hospital and health-system pharmacists must assertively exercise their responsibilities in preparing for and responding to disasters, and the leaders of emergency planning at the federal, regional, state, and local levels must call on pharmacists to participate in the full range of issues related to pharmaceuticals.” (ASHP Statement on Emergency Preparedness)

The Coronavirus Disease 2019 (COVID-19) global pandemic differs from other types of disasters in significant respects, testing the resiliency of the healthcare system and workforce. Treating patients with a novel viral pathogen has driven rapid evolution in therapies, forcing healthcare providers to make patient care decisions based on scarce, incomplete, or conflicting information. These decisions have sometimes been complicated by shortages of crucial drugs, equipment, or staff, creating a crisis standard of care in which difficult patient care decisions must be made. The patient surges that healthcare organizations have had to manage have lasted significantly longer than those of other disasters. Healthcare workers have faced stressful patient care situations and extended shifts for a longer period of time than in other disasters. In addition, the fear of infection and of spreading that infection to family members and others has added additional stress. Infection control procedures have shut down some areas of healthcare operations, forcing healthcare workers into unfamiliar roles and care settings.

ASHP advocates that the lessons learned from the COVID-19 pandemic be shared broadly and incorporated into emergency planning at the federal, state, local, institutional, and pharmacy department levels. Pharmacy leaders, with their unique understanding of medication-use processes, should be relied upon to provide strategic direction on the full range of issues related to medication use, especially when evidence is scarce, incomplete, or conflicting, and drugs or other critical resources are in shortage. The pharmacy workforce should incorporate the lessons learned in its emergency planning efforts, integrating those efforts into the efforts of their institutions and communities. ASHP pledges to promote collaboration and communication among the various stakeholders in pandemic preparedness and response, and to provide resources and education to aid the pharmacy workforce and others in preparing for and responding to pandemics, including resources regarding novel therapies, shortages of drugs and other critical supplies, and healthcare worker well-being and resilience.

### **Background**

The Council considered the topic at the suggestion of ASHP members and staff and after participating in the Joint Council and Commission Meeting on Pandemic Preparedness and Response. The Council recognized that the topic has far-ranging implications for ASHP policy

and that other councils and the Commission on Affiliate Relations were also examining ASHP policy on the topic. The Council agreed that their proposed policy may need to be consolidated or harmonized with the recommendations of those other committees, and that that the topic would need to be addressed in a variety of ways, through revision of ASHP statements and guidelines, and through the development of other resources (see Other Council Activity for other Council actions).

## 2. Role of the Pharmacist and Pharmacy Technician in Supporting Patient Access to Medical Supplies

- 1 To support patient access to medical supplies as part of a comprehensive treatment
- 2 plan; further,
- 3 To advocate for policies that empower pharmacy personnel to facilitate patient access
- 4 to and effective use of medical supplies, including reimbursement policies; further,
- 5 To educate pharmacists, other healthcare professionals, payers, and policymakers
- 6 about the role of pharmacy personnel in helping patients obtain and use medical
- 7 supplies; further,
- 8 To collaborate with other healthcare professional and patient advocacy organizations to
- 9 advocate for expanded patient access to medical supplies.

*Note:* For purposes of this policy, “medical supplies” includes durable medical equipment, Food and Drug Administration-approved medical devices, and other nondurable disposable healthcare materials.

### **Rationale**

Pharmacists and pharmacy technicians have the knowledge and skills to support patient access to medical supplies and equipment, durable medical equipment (DME), and medical devices. These tools, like medications, are essential components to a patient’s personalized care plan. Although many providers combine medical supplies and equipment, DME, and medical devices under the umbrella term “medical supplies,” as is done here for purposes of this policy, there are critical differences between them that determine how these items are accessed and reimbursed. Under Centers for Medicare & Medicaid Services (CMS) rules, “medical supplies and equipment” (e.g., bandages and gauzes) are nondurable disposable healthcare materials used to serve a medical purpose that cannot be used in the absence of illness or injury or repeatedly by different individuals. CMS typically does not consider medical supplies and equipment as a covered benefit. DME (e.g., blood sugar monitors, blood sugar test strips, continuous glucose monitors, and infusion pumps and supplies) are durable healthcare materials used at home that can withstand repeated use, provide a medical purpose, and are not used in the absence of an illness or injury. In contrast to medical supplies and equipment, DME is covered under Medicare Part B. Finally, the Food and Drug Administration (FDA) defines

a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory (FDA. Medical Devices. Available at: <https://www.fda.gov/medical-devices>. Accessed August 20, 2020).

Pharmacists are experts in initiating and managing a patient's comprehensive medication management (CMM) plan. A CMM is an individualized care plan that helps patients achieve specific goals of therapy. The patient-centered medical home: integrating comprehensive medication management to optimize patient outcomes resource guide, 2nd ed. ([www.pcpsc.org/sites/default/files/media/medmanagement.pdf](http://www.pcpsc.org/sites/default/files/media/medmanagement.pdf)). Any intervention that supplements medication goals and improves a patient's quality of life and patient outcomes should be considered in the CMM process and plan, including use of medical supplies and equipment, DME, and medical devices, and provide an opportunity for a pharmacist or pharmacy technician to improve patient care.

ASHP has long advocated for the role pharmacists have in helping patients obtain and properly use drug delivery systems and devices. The ASHP Statement on the Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices states:

Pharmacists bear a substantial responsibility for ensuring optimal clinical outcomes from drug therapy and are suited by education, training, clinical expertise, and practice activities to assume responsibility for the professional supervision of drug delivery systems and administration devices. As a natural extension of efforts to optimize drug use, pharmacists should participate in organizational and clinical decisions with regard to these systems and devices.

Extension of those responsibilities to medication-related medical supplies and equipment, DME, and medical devices is a natural progression in pharmacist patient care. There are many actions that pharmacists can implement to help improve patient outcomes in regards to medical supplies and equipment, DME, and medical devices. To increase patient access, pharmacists can collaborate with patients and physicians to determine which device to use based on patient indication, preferences, and product specifications. Pharmacists could also collaborate with CMS and other insurance plans to ensure that patients have adequate coverage of DME along with advocating to allow pharmacists to submit claims for reimbursement. Furthermore, ASHP could collaborate with patient advocacy organizations and disease specific organizations (e.g., American Diabetes Association) to advocate for increased patient access to specific medical supplies and equipment.

Additionally, pharmacists can advocate for broader pharmacy management of medical supplies and equipment, DME, and medical devices along with medications as a part of the patient's CMM plan. Pharmacists can support patient access through documentation required for coverage, provide education on how to use the device, monitor the device for safety and efficacy, and interpret results if applicable. Collaborative practice agreements and credentialing and privileging are two ways pharmacist can use data provided from the devices to help make necessary changes to the patient's medication plan. Pharmacists' expertise should be leveraged to help patients procure and manage their medical supplies and equipment, DME, and medical devices to provide all-encompassing comprehensive medication management.

**Background**

The Council considered the topic at the suggestion of ASHP members and staff. Council members each had a unique perspective on the topic but universally agreed that there is considerable variation in and challenges with navigating pathways to support patient access to medical supplies and equipment, DME, and medical devices. Potential actions that the Council agreed to include development of professional policy, dissemination of education and resources, and advocacy efforts. Overall goals of these activities are to advocate for appropriate, safe, and transparent criteria for use by insurers and suppliers; enhance patient care by streamlining patient access; and close loopholes that prevent pharmacists from reliably billing for DME in their institutions. Council members also agreed that pharmacy technicians should be leveraged to support pharmacists in their efforts based on their scope of duties.

**3. Standardized Documentation and Attribution of Clinical Interventions by Pharmacists**

- 1 To promote the use of standardized documentation of clinical interventions by
- 2 pharmacists in a patient's health record to improve patient outcomes and allow for the
- 3 attribution of pharmacist services across the continuum of care; further,
  
- 4 To advocate for the standardization in the measurement of clinical interventions by
- 5 pharmacists on patient outcomes.

**Rationale**

ASHP has advocated for the importance of documentation of pharmacist care in patient medical records to ensure accurate and complete documentation of the care and services provided to the patient. However, differences in pharmacy practice within and across health systems make it hard to standardize such documentation in the electronic health record (EHR). The differences are caused by diverse clinical practices, EHR permissions, and documentation elements of the clinical interventions made by pharmacists. Documentation by the pharmacist may change depending on care settings, the value of intervention, or in respect to reimbursement. As a result, it is hard to validate and evaluate pharmacists' impact on patient outcomes due to the incomplete measurement and attribution of such interventions and lack of standardized documentation.

Other healthcare providers have released similar statements on documentation within their fields. The American College of Physicians states that physicians should define professional standards regarding clinical documentation and use macros and templates appropriately (Kuhn T, Basch P, Barr M et al. Clinical documentation in the 21st century: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med.* 2015; 162:301-3). The American Nurses Association (ANA) Principles for Nursing Documentation states that if patient documentation is not timely, accurate, accessible, complete, legible, readable, and standardized, it will interfere with the ability of those who were not involved in and are not familiar with the patient's care to use the documentation (ANA's Principles for Nursing Documentation: Guidance for Registered Nurses. 2010).



[www.nursingworld.org/~4af4f2/globalassets/docs/ana/ethics/principles-of-nursing-documentation.pdf](http://www.nursingworld.org/~4af4f2/globalassets/docs/ana/ethics/principles-of-nursing-documentation.pdf)). The American Speech-Language-Hearing Association (ASHA) states that speech-language pathologists should participate in the development of the templates that they will use for billing and clinical documents so that the information that is necessary is provided (ASHA. Documentation in health care.

[www.asha.org/PRPSpecificTopic.aspx?folderid=8589935365&section=References](http://www.asha.org/PRPSpecificTopic.aspx?folderid=8589935365&section=References)).

Other healthcare providers have recognized the benefits of requiring their documentation to be recorded in a standardized form that allows other healthcare stakeholders to quickly access the information. Employing accessible, standardized documentation improves communication and knowledge sharing between providers. Pharmacists are valuable members of the healthcare team that contribute significantly to patient care. More consistency and standardization of a pharmacist's documentation can provide essential information on a patient's care, such as therapeutic drug monitoring, appropriateness and effectiveness of patient's medications, or pain and antibiotic management, for example. Standardized notes enable healthcare team members to review the pharmacist note and become aware of the medication plan. Implementing standardized documentation across all healthcare providers, especially pharmacists, will allow for increased interactions and information to be shared between healthcare providers to improve overall patient care.

Implementing a standardized clinical pharmacy documentation system will also inform and enable a measurement approach for evaluation of the impact of pharmacist services. Many institutions use different tools for operational internal and external benchmarking to meet these measures; however, the tools are limited in their use for clinical benchmarking (Rough SS, McDaniel M, Rinehart JR. Effective use of workload and productivity monitoring tools in health-system pharmacy, pt 1. *Am J Health Syst Pharm.* 2010; 67:300–11). Institutions have tried to implement their own clinical pharmacy productivity measures tools to help demonstrate the value of de-centralized pharmacists on patient care teams. However, no current measure or measure set accurately identifies the impact pharmacists have on patient care outcomes or allows comparison and benchmarking across institutions. In response to this need, the ASHP Pharmacy Accountability Measures (PAM) Work Group seeks to identify pharmacy-related clinical quality measures that institutions could use for benchmarking (Andrawis MA, Carmichael J. A suite of inpatient and outpatient clinical measures for pharmacy accountability: recommendations from the Pharmacy Accountability Measures Work Group. *Am J Health Syst Pharm.* 2014; 71:669–78).

The PAM Workgroup evaluated quality measures endorsed by the National Quality Forum (NQF) and curated those selected into six therapeutic areas, which include antithrombotic safety, cardiovascular control, glycemic control, pain management, behavioral health, and antimicrobial stewardship (Andrawis M, Ellison C, Riddle S et al. Recommended quality measures for health-system pharmacy: 2019 update from the Pharmacy Accountability Measures Work Group. *Am J Health Syst Pharm.* 2019; 76:874–87). Using the NQF-endorsed measures along with appropriate documentation of these interventions may allow institutions to more readily benchmark performance.

After determining the most appropriate pharmacy quality measures, the documentation of the interventions should be standardized and efficient. Implementing standardized

templates and more retrievable data fields in the documentation process has been shown to improve workflow for pharmacists. One study demonstrated that by implementing EHR note templates that allowed retrievable data to be incorporated, pharmacists increased the amount of time providing value-added services from 47% to 72% and in providing direct patient care from 27% to 53% (Ekstrand MJ, Kobany JM, Pestka DL. Leveraging quality improvement principles in comprehensive medication management pharmacy practice: a case example. *J Am Pharm Assoc.* 2020; 60:509-15.e1.).

Finally, pharmacists must also be properly educated on how to use a standardized pharmacy documentation system. In one study, a health system that had implemented an improved pharmacist clinical intervention documentation system found that a focused education initiative increased the number of pharmacy clinical interventions 120%, and associated cost avoidance dollars increased proportionally (Rector KB, Veverka A, Evans SK. Improving pharmacist documentation of clinical interventions through focused education. *Am J Health-Syst Pharm.* 2014; 71:1303–10). Overall, research has shown that focused education has helped increase the number of clinical interventions documented in a standardized way, leading ultimately to better care for patients and demonstrating the value of pharmacy services.

### **Background**

The Council considered the topic at the suggestion of ASHP members and staff. Dr. McConnell reviewed a presentation she gave on the topic at the 2019 Midyear Clinical Meeting. Dr. Pack also pointed to similar approaches used for clinical pharmacy services in the Indian Health Service. Council members reviewed ASHP Policy 1419, Documentation of Patient Care Services in the Permanent Health Record, and felt a new policy was still warranted based on the topic of interest. The Council saw a great deal of alignment between the work of the PAM Workgroup and efforts to implement standardized documentation of clinical pharmacist interventions. The Council also voted to work with other ASHP component bodies to establish a workgroup to develop standardized clinical pharmacy documentation and metrics (e.g., key performance indicators) and to write a commentary for submission to AJHP regarding the need for standardized clinical pharmacy documentation and metrics (see Other Council Activity).

#### **4. Influenza Vaccination Requirements to Advance Patient Safety and Public Health**

- 1 To advocate that hospitals and health systems require healthcare workers to receive an
- 2 annual influenza vaccination except when (1) it is contraindicated, or (2) the worker has
- 3 religious objections, or (3) the worker signs an informed declination; further,
  
- 4 To encourage hospital and health-system pharmacists to take a lead role in developing
- 5 and implementing policies and procedures for vaccinating healthcare workers and in
- 6 providing education on the patient safety benefits of annual influenza vaccination;
- 7 further,

8 To work with the federal government and others to improve the vaccine development  
9 and supply system in order to ensure a consistent and adequate supply of influenza  
10 virus vaccine.

*Note: This policy would supersede ASHP policy 0615.*

### **Rationale**

The Centers for Disease Control and Prevention (CDC) estimates that the 2019-2020 influenza season was associated with 38 million illnesses, 18 million medical visits, 405,000 hospitalizations, and 22,000 deaths. The economic burden of influenza-attributable illness is estimated at over \$83 billion, encompassing direct costs such as hospitalizations and outpatient visits and indirect costs such as lost productivity from missed days at work.

Influenza immunization of healthcare workers can improve patient safety and decrease morbidity and mortality by protecting vulnerable patients such as young children and elderly, immunocompromised, and critically ill patients. The CDC has recommended vaccination of healthcare workers since 1981. In its recommendation, the CDC considers healthcare workers as including (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from health care workers and patients. In the 2019-2020 season, approximately 80% of healthcare workers were immunized against influenza, with rates over 90% among hospital employees, despite the fact that only approximately 70% of hospitals currently require an annual influenza vaccination, according to the CDC. Pharmacists have a responsibility, as knowledgeable purveyors of evidence-based medication information, to lead by example in receiving annual influenza vaccinations and to educate other healthcare workers and patients about the importance of influenza vaccination.

### **Background**

The Council reviewed ASHP policy 0615, Influenza Vaccination Requirements To Advance Patient Safety and Public Health, as part of sunset review and voted to recommend amending it as follows (~~strikethrough~~ indicates deletions):

To advocate that hospitals and health systems require healthcare workers to receive an annual influenza vaccination except when (1) it is contraindicated, or (2) the worker has religious objections, or (3) the worker signs an informed declination; further,

~~To encourage all hospital and health-system pharmacy personnel to be vaccinated against influenza; further,~~

To encourage hospital and health-system pharmacists to take a lead role in developing and implementing policies and procedures for vaccinating healthcare workers and in providing education on the patient safety benefits of annual influenza vaccination;

further,

To work with the federal government and others to improve the vaccine development and supply system in order to ensure a consistent and adequate supply of influenza virus vaccine.

The Council recognized that pharmacy personnel are included in the first clause's description of "healthcare workers" and recommended that the second clause be struck because it could be read as contradicting the first. This contradiction was introduced when the House of Delegates changed "healthcare workers with direct patient care responsibilities" in the first clause to just "healthcare workers." The original language of the first clause could have been read as excluding some pharmacy personnel, making the second clause necessary. In addition, the Council observed that some states have removed the religious exemption from their mandates but declined to remove that exemption from the policy. Finally, the Council recognized the importance of addressing vaccine hesitancy in ASHP policy but recommended that the topic is better suited for inclusion in another ASHP policy position or the ASHP Guidelines on the Pharmacist's Role in Immunization, as this policy is focused on the healthcare workforce rather than on the public.

## 5. Safe and Effective Extemporaneous Compounding

1 To affirm that extemporaneous compounding of medications, when done to meet  
2 immediate or anticipatory patient needs, is part of the practice of pharmacy and is not  
3 manufacturing; further,

4 To support the principle that medications should not be extemporaneously  
5 compounded when they are commercially and readily available in the form necessary to  
6 meet patient needs; further,

7 To encourage pharmacists who compound medications to use only drug substances that  
8 have been manufactured in Food and Drug Administration-registered facilities that have  
9 been inspected within the past two years and that meet official United States  
10 Pharmacopeia (USP) compendial requirements where those exist; further,

11 To advocate that all compounding activities meet applicable USP standards and federal  
12 and state regulations; further,

13 To support the principle that pharmacists be adequately trained and have sufficient  
14 facilities and equipment that meet technical and professional standards to ensure the  
15 quality of compounded medications; further,

16 To encourage USP to develop drug monographs for commonly compounded  
17 preparations; further,

- 18 To educate prescribers and other healthcare professionals about the potential risks  
19 associated with the use of extemporaneously compounded preparations.

*Note: This policy would supersede ASHP policy 0616.*

### **Rationale**

The practice of compounding has evolved along with the profession of pharmacy and it remains an essential component of patient care and pharmacy practice. With advances in pharmaceutical manufacturing, the need for preparation of individualized medications based on a prescription or medication order has decreased but not disappeared. Extemporaneous compounding of medications, when done to meet immediate or anticipatory patient needs, will likely always be an essential part of the practice of pharmacy, and cannot be replaced by any manufacturing model currently envisioned. Commercially and readily available drug products in the form necessary to meet patient needs should always be preferred to extemporaneously compounded alternatives. When extemporaneous compounding is required, it should meet strict requirements to protect patients from receiving substandard or poor-quality medications that pose a safety risk to their health and well-being. In particular, extemporaneously compounded sterile preparations must ensure highest quality. Extemporaneous compounding should be performed only using drug substances that have been manufactured in Food and Drug Administration-registered facilities that have been inspected within the past two years and that meet official United States Pharmacopeia (USP) compendial requirements. Such compounding should only be performed by adequately trained pharmacists and pharmacy technicians, in facilities and with equipment that meet technical and professional standards to ensure the quality and integrity of the compounded medication, and in accordance with USP standards and other applicable federal and state regulations. To facilitate such a high level of compounding, USP should develop drug monographs for commonly compounded preparations. ASHP and its members have always devoted a great deal of effort to promoting safe extemporaneous compounding, through education of pharmacists and pharmacy technicians, publication of best practices, and advocacy, recognizing the inherent risks of any such endeavor. Pharmacists and pharmacy technicians have a responsibility to safely prepare and distribute compounded medications to meet the unique and customized therapeutic needs of their patients, and ASHP and pharmacists therefore have a responsibility to educate prescribers and other healthcare professionals about the potential risks associated with the use of extemporaneously compounded preparations.

### **Background**

The Council reviewed ASHP policy 0616, Safe and Effective Extemporaneous Compounding, as part of sunset review and voted to recommend amending it as follows (underline indicates new text; ~~strike through~~ indicates deletions):

To affirm that extemporaneous compounding of medications, when done to meet immediate or anticipatory patient needs, is part of the practice of pharmacy and is not manufacturing; further,

To support the principle that medications should not be extemporaneously compounded when they are commercially and readily available in the form necessary to meet patient needs; further,

To encourage pharmacists who compound medications to use only drug substances that have been manufactured in Food and Drug Administration-~~approved~~ registered facilities that have been inspected within the past two years and that meet official United States Pharmacopeia (USP) compendial requirements where those exist; further,

To advocate that all compounding activities meet applicable USP standards and federal and state regulations; further,

To support the principle that pharmacists be adequately trained and have sufficient facilities and equipment that meet technical and professional standards to ensure the quality of compounded medications; further,

To encourage USP to develop drug monographs for commonly compounded preparations; further,

To educate prescribers and other healthcare professionals about the potential risks associated with the use of extemporaneously compounded preparations.

The revisions suggested by the Council align with more contemporary standards and regulations that exist for compounding.

## **6. Universal Immunization Against Vaccine-Preventable Diseases in the Healthcare Workforce**

- 1 To support policies that promote universal vaccination against preventable infectious
- 2 diseases among healthcare workers, including all members of the pharmacy workforce,
- 3 as a safeguard to patient and public health; further,
  
- 4 To encourage the use of evidence-based risk assessments to determine inclusions and
- 5 exemptions for mandatory vaccine requirements; further,
  
- 6 To support employers in mandatory vaccine requirements if risk assessments determine
- 7 it would promote patient and public health; further,
  
- 8 To urge healthcare organizations to have policies that address additional infection
- 9 prevention practices required for exempted healthcare workers; further,
  
- 10 To foster the development of tools, education, and other resources to reduce vaccine

- 11 hesitancy, increase vaccination rates, and prevent vaccine-preventable diseases among
- 12 healthcare workers.

### **Rationale**

Vaccine-preventable diseases (VPDs) pose a threat to vulnerable patients, the healthcare workforce, and public health. Vaccines are effective in protecting the healthcare workforce and the patients they care for and with whom they interact. Although voluntary vaccination of healthcare workers (HCWs), supported by employer-offered strategies, increases vaccination rates to some extent, mandatory vaccination requirements carry heavier weight and can result in near-universal vaccination rates. The effectiveness of this approach has led to HCW vaccination requirements from the Occupational Safety and Health Administration, recommendations from the Centers for Disease Control and Prevention (CDC), policy endorsements from numerous professional organizations, and quality measures for federal and commercial payer reporting programs. For example, the CDC Advisory Committee on Immunization Practices proposes recommendations for the immunization of healthcare workforce based on (1) those diseases for which routine vaccination or documentation of immunity is recommended for healthcare personnel because of risks to them in their work settings and, should healthcare personnel become infected, to the patients they serve; and (2) those diseases for which vaccination of healthcare personnel might be indicated in certain circumstances. The current list of VPDs in which healthcare personnel are considered to be at substantial risk for acquiring or transmitting and in which vaccination is recommended includes hepatitis B, influenza, measles, mumps, rubella, pertussis, and varicella. In the future, this list may include vaccination against SARS-CoV-2.

The vaccination-related policies of various healthcare professional organizations contain similar themes. These policies recognize that mandatory vaccination policies improve vaccination rates, protecting patients and the healthcare workforce; acknowledge circumstances that may preclude an HCW from being vaccinated (e.g., medical contraindications, religious beliefs); express support for following evidence-based practices in determining which vaccines should be mandatory; and support education of the healthcare workforce on the benefits of vaccination.

### **Background**

The Council prioritized discussion of universal vaccination given recent authorization of COVID-19 vaccines and the urgency in protecting patients and HCWs from exposure risk of SARS-CoV-2. The Council felt it was important to broaden their consideration to include all VPDs rather than focusing on one. The Council concluded that, although this new policy may overlap slightly with ASHP policy position 0615, Influenza Vaccination Requirements to Advance Patient Safety and Public Health, ASHP should have policy addressing all VPDs and continue to advocate for influenza vaccination as a separate policy, due to the annual need for influenza vaccination.

## 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.)

- Ready-to-Use Packaging for All Settings (0402)
- Pharmacist Accountability for Patient Outcomes (1114)
- Just Culture (1115)
- Ethical Use of Placebos in Clinical Practice (1116)

## Other Council Activity

### Joint Meeting on Pandemic Preparedness

On Tuesday, September 22, members of all councils and the Commission on Affiliate Relations met to hear presentations from Don R. Boyce and Joe Pinto of the Mount Sinai Health System on the lessons learned from Mount Sinai's experience with the COVID-19 pandemic. Council and Commission members were asked to reflect on current evidence, the presentations, background reading, meeting discussion, best practices, and personal experience to advise ASHP on pandemic-related policy issues relevant to the Council's purview. Council members considered existing and potential pharmacist roles in both operational and patient care aspects of the pandemic, and how the lessons learned from the pandemic could be applied to future crises that present similar circumstances. Key objectives of the discussion included considering the need for new or revised ASHP professional policy regarding pandemic preparedness and response, and suggesting elements of that policy, as well as reviewing current pharmacy practice related to pandemic preparedness and response and providing advice on ways ASHP can help advance pharmacy practice through the development of member tools and resources, best practices, education, and other programmatic approaches.

### ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System

The Council voted to recommend approval of the ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System.

### ASHP Guidance on Pandemic Preparedness Planning

The Council voted to revise the ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness and to develop and maintain a web resource to assist the pharmacy workforce in pandemic preparedness planning.

### Standardized Clinical Pharmacy Documentation and Metrics

The Council voted to work with other ASHP component bodies to establish a workgroup to



develop standardized clinical pharmacy documentation and metrics. The Council also voted to write a commentary for submission to *AJHP* regarding the need for standardized clinical pharmacy documentation and metrics.

### **ASHP Guidance on Single Unit and Unit Dose Packaging**

The Council voted to consolidate into one guidance document and update the ASHP Statement on Unit Dose Drug Distribution, the ASHP Technical Assistance Bulletin on Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages, and the ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs.

### **Pharmacist and Pharmacy Technician Response to Withdrawal or Recall of Medications from the Market**

The Council voted to revise the ASHP Technical Assistance Bulletin on Hospital Drug Distribution and Control as an ASHP guideline and include guidance on the handling of medication withdrawals and recalls.

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# COUNCIL ON PUBLIC POLICY

## POLICY RECOMMENDATIONS

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*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.*

Nishaminy Kasbekar, *Board Liaison*

### **Council Members**

Steve Riddle, *Chair* (Washington)  
Rusol Karralli, *Vice Chair* (Texas)  
Charzetta James (Florida)  
Brian Kawahara (California)  
Bernice Man (Illinois)  
Emily McTish, *Student* (South Carolina)  
Luke Miller (Texas)  
Matthew Pond (Arizona)  
Adam Porath (Nevada)  
Jeffrey Schnoor (Vermont)  
Elizabeth Shlom (New York)  
Elizabeth Rodman (Maryland)  
Jillanne Schulte Wall, *Secretary*

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### **1. Pharmacist Engagement in and Payment for Telehealth**

- 1 To advocate for pharmacists' provision of telehealth in all sites of care; further,
- 2 To advocate that reimbursement for telehealth be sufficient to support the practice.

### **Rationale**

During the COVID-19 public health emergency, hospitals, health systems, and clinics quickly pivoted to providing patient services via telehealth. The Centers for Medicare & Medicaid Services, commercial payers, and state policymakers have indicated that they would like to maintain telehealth services post-pandemic. Because pharmacists are not Medicare-eligible, it has been a struggle to ensure that they can be reimbursed for services provided via telehealth. In particular, it is vital that services be reimbursed at a level commensurate with complexity and duration and at an amount sufficient to support the practice, to ensure that patients can maintain access to services.

### **Background**

The Council discussed the issue of telehealth broadly. They reviewed a number of current policies, including ASHP policies 2029, Preserving Patient Access to Pharmacy Services by Medically Underserved Populations; 2034, Staffing for Safe and Effective Patient Care; 2020, Care-Commensurate Reimbursement; 1301, Payer Processes for Payment Authorization and



Coverage; and 1808, Patient Access to Pharmacist Care Within Provider Networks.

Overall, the Council felt that the current policies addressed many of the issues related to pharmacist payment and engagement. However, after extensive discussion, they agreed that a policy specific to telehealth was warranted. Rather than enumerate multiple changes necessary for effective telehealth provision, including access to, and support for, technology and billing and coding at specific levels, the Council agreed that a general statement would best serve member needs, allowing flexibility to address technological and payment shifts in a fast shifting environment.

## 2. Pharmacy Services in a State of Emergency

- 1 To advocate that state boards of pharmacy grant temporary licensure to pharmacists and
- 2 temporary licensure, registration, or any other necessary state-mandated credential to
- 3 pharmacy technicians during states of emergency; further,
- 4 To advocate that state and federal regulatory agencies allow for flexibilities necessary to
- 5 provide patient care during a declared state of emergency.

### **Rationale**

During the COVID-19 pandemic, both state and federal policymakers scrambled to provide the regulatory flexibility necessary to allow patients to access pharmacist services. Although states are generally willing to be flexible about dispensing during a public health emergency, pharmacy services themselves are not subject to the same degree of flexibility. Specifically, pharmacists, more so than other clinicians, struggled to get temporary licensure across state lines. The lack of access to temporary licensure impeded the ability of pharmacists to move to areas of great need or to volunteer in states with patient surges. Further, pharmacy services require flexibility, particularly around inventory control and the ability to reallocate product and the ability to quickly establish alternate sites of care. During the COVID-19 public health emergency, remdesivir was allocated to the states, and then the state retained full control over distribution, which resulted in situations in which hospitals could not transfer product across state lines to other hospitals, even to related entities, that needed the product more.

### **Background**

During the Council's broad discussion of COVID-19 treatment and insurance, a number of members felt that a significant policy gap exists regarding how pharmacy services are treated during any state of emergency, including a public health emergency. In particular, they noted that although there is current ASHP policy addressing emergency dispensing, there is not policy focused on the ability of pharmacists to practice during an emergency. Similarly, they noted that COVID-19 has underscored the need for general flexibility that can be quickly built out prior to an emergency. In particular, Council members focused on the need for flexible practice across state lines, flexibility on inventory control, and flexibility to quickly establish alternate sites of care.

Regarding interstate practice, the Council felt that there is generally difficulty in establishing and maintaining licensure across state lines, and the pandemic merely highlighted the issue. Further, the Council was concerned that because that National Association of Boards of Pharmacy is doing away with its Passport Program, which is the established database for connectivity between states, the process would be even more complex. Additionally, regarding inventory control, the Council discussed issues of allocation and distribution for remdesivir. During the public health emergency, remdesivir was allocated to states, and hospitals did not have the ability to send the drug over state lines to meet patient needs, even when the out-of-state hospital was part of the same health system.

## 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.)

- Poison Control Center Funding (1121)
- Manufacturer Promotion of Off-label Uses (1620)
- Timely Board of Pharmacy Licensing (1621)
- Home Intravenous Therapy (1623)
- Ban on Direct-to-Consumer Advertising for Prescription Drugs and Medication-Containing Devices (1624)

## Other Council Activity

### Joint Meeting on Pandemic Preparedness

On Tuesday, September 22, members of all councils and the Commission on Affiliate Relations met to hear presentations from Don R. Boyce and Joe Pinto of the Mount Sinai Health System on the lessons learned from Mount Sinai's experience with the COVID-19 pandemic. Council and Commission members were asked to reflect on current evidence, the presentations, background reading, meeting discussion, best practices, and personal experience to advise ASHP on pandemic-related policy issues relevant to the Council's purview. Council members considered existing and potential pharmacist roles in both operational and patient care aspects of the pandemic, and how the lessons learned from the pandemic could be applied to future crises that present similar circumstances. Key objectives of the discussion included considering the need for new or revised ASHP professional policy regarding pandemic preparedness and response, and suggesting elements of that policy, as well as reviewing current pharmacy practice related to pandemic preparedness and response and providing advice on ways ASHP can help advance pharmacy practice through the development of member tools and resources, best practices, education, and other programmatic approaches.

## COVID-19 Treatment and Insurance

The Council undertook a comprehensive discussion of COVID-19 treatment and insurance, with a focus on identifying emerging issues that might require new policy.

The discussion then turned to the issue of vaccine hesitancy and concerns that the public might not be quick to adopt a new COVID-19 vaccine. The Council suggested that ASHP consider other options for combatting vaccine hesitancy, including working directly with federal agencies and/or other provider groups on vaccine outreach strategies, including public relations campaigns.

Finally, during the course of the COVID-19 treatment and insurance discussion, the issue of regulatory barriers impeding treatment arose. It was during this discussion that the problem of quickly getting temporary licensure across state lines was raised, which eventually resulted in the proposed new policy, Pharmacy Services in a State of Emergency.

## Sourcing Raw Materials for Drug Manufacturing

The Council considered whether new policy is needed specific to the sourcing of active pharmaceutical ingredient (API) from foreign countries. At the outset of the pandemic, major concerns arose about whether the concentration of API manufacturing in China and India would create global drug shortages.

The Council felt that ASHP should focus on global reinforcement of supply chains, meaning that investments should be made not only in domestic manufacturing but in strengthening manufacturing across the world. The Council noted that calls to focus solely on domestic manufacturing capacity could create shortage problems by concentrating the supply chain in a single geographic locale rather than building in redundancies. The Council recommended that the rationale for ASHP policy 1905, Mitigating Drug Product Shortages, be updated to note the importance of geographically and commercially diversified API manufacturing operations.

## Discriminatory Laws and Interference with the Patient/Provider Relationship

The Council formalized a recommendation to the Council on Education and Workforce Development (CEWD) and/or to the ASHP Task Force on Racial Diversity, Equity, and Inclusion to consider policy requiring implicit bias training for pharmacists. Specifically, the Council recommended that CEWD or the Taskforce consider the following items:

- Mandatory training on implicit bias, including education at the pharmacy school and workforce levels, for all healthcare providers;
- Supporting research on healthcare disparities; and
- Equipping patients for shared decision-making regarding treatment.

## 340B Sustainability and Manufacturer Actions

The Council discussed potential revisions to existing ASHP policy to address recent manufacturer actions that threaten the sustainability of the 340B Drug Pricing Program, including placing limits on contract pharmacies and requiring the use of third-party vendors to

access 340B discounts.

The Council recommended that ASHP survey members on the level of detail they are comfortable disclosing regarding their 340B savings and data and resolved to reconsider this issue at a future meeting.



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

1 **Position**

2 Leading hospitals and health systems must have a strategic and innovative pharmacy executive  
3 who plans and oversees the design and operation of the entire and complex medication-use  
4 process throughout the system. It is essential that this leader report to an executive who can  
5 help the leader execute the practice models of tomorrow that include business outside normal  
6 hospital practice.

7 As the most knowledgeable leader of the medication-use process, this leader (may be  
8 referred to as the “chief pharmacy officer” but hereafter “the pharmacy executive”) proactively  
9 aligns pharmacy goals with strategic organizational initiatives to advocate for pharmacy  
10 practice advancement and improved patient care. The intrinsic value a pharmacy executive  
11 brings to the organization’s enterprise and executive leadership includes the following:

- 12 • Ensuring the enterprise’s strategic planning leverages pharmacy services across the  
13 continuum of care to improve health outcomes.
- 14 • Ensuring pharmaceuticals and pharmaceutical benefit designs focus on total health through  
15 the formulary, with procurement driven by clinical efficacy.

- 1 • Collaborating with healthcare executives within and external to the health system to foster  
2 and build cross-functional relationships and to align interdisciplinary services with initiatives  
3 such as quality metrics and financial performance.
- 4 • Advancing patient care services through the promotion of pharmacy best practices by the  
5 creation and adoption of emerging technologies and innovative services.

6

## 7 **Background**

8 Significant changes in pharmacy practice, healthcare, and health-system management over the  
9 past 20 years have dramatically transformed the traditional role of the pharmacy director.<sup>1</sup>  
10 More widespread use of the title “chief pharmacy officer” was first proposed in 2000 in an  
11 attempt to meet these new transformations and to enhance the contribution pharmacy makes  
12 to patient care by creating organizational parity between the pharmacy executive and other  
13 executive officers (e.g., chief nursing, medical, and information officers).<sup>2</sup>

14

## 15 **Responsibilities and value of the pharmacy executive**

16 The pharmacy executive assesses the ever-changing healthcare environment for emerging  
17 trends and identifies opportunities to leverage the pharmacy team’s expertise to improve the  
18 value of care across the healthcare continuum. Success as a pharmacy executive is predicated  
19 on building and maintaining relationships with diverse groups of people in order to be part of  
20 setting the overall strategy for the organization. Navigating solid and dotted-line reporting  
21 relationships, such as in a matrix organizational structure, requires the pharmacy executive to  
22 exercise a wider range of influence and persuasiveness rather than relying on traditional



23 hierarchy and formal control to accomplish objectives. As it relates to patient care and clinical  
24 services, the pharmacy executive leads all pharmacists and pharmacy staff across the  
25 organization. The pharmacy executive ensures that pharmacists are optimally positioned and  
26 resourced to improve the quality, safety, and efficiency of medication management and  
27 patient outcomes in the most cost-effective manner. The pharmacy executive leads the  
28 pharmacy's financial performance within the context of the broader health system through  
29 the evaluation of medication expenditure patterns and reimbursement trends, including  
30 value-based reimbursement and purchasing. As reimbursement and revenue capture become  
31 increasingly complex, the pharmacy executive can provide leadership across multiple  
32 disciplines (e.g., finance, nursing, medicine, pharmacy) to optimize reimbursement from  
33 involved government and commercial payment programs and meet metrics for value-based  
34 contract requirements.<sup>3,4</sup> She or he is also responsible for medication access in their  
35 organization to ensure patients have the most effective and affordable medications.

36 In performing these responsibilities, the pharmacy executive must bring continuous and  
37 evergreen value to the pharmacy team, the health system's executive team, and the  
38 organization as a whole. The pharmacy executive establishes key relationships with both  
39 internal multidisciplinary executives and external vendors, group purchasing organizations, and  
40 manufacturers to elevate services and optimize the pharmaceutical supply chain, respectively.  
41 In addition to optimizing the supply chain, the pharmacy executive plays a key role in  
42 developing a vision for information and technology solutions in the medication-use process and  
43 must work collaboratively with the chief information officer to advance pharmacy informatics  
44 and technology. During all phases of a public health emergency or disaster event, pharmacy

45 executive presence in a hospital or health system’s emergency operations center is pivotal for  
46 proactive planning and maintaining secure, functional, and resilient health and public health  
47 critical infrastructure. The pharmacy executive is integral in advancing pharmacy services in the  
48 midst of rising competitors, ensuring the vitality of the organization as healthcare transforms.<sup>5-</sup>  
49 7 She or he must maintain a focused effort to acquire, share, and reinvest in their own self-  
50 development and the development of the leadership team striving for a continuous pursuit of  
51 practice advancement.

52

### 53 **Experience and education of the pharmacy executive**

54 The pharmacy executive is a professionally competent, legally licensed pharmacist with a broad  
55 level of experience in health-system pharmacy practice and management and with a strategic  
56 vision for the profession. Additional qualifications may include an advanced management  
57 degree; a clearly evident successful record of leading people, operations, finance, and clinical  
58 services; and completion of a pharmacy residency program accredited by ASHP (e.g., health-  
59 system pharmacy administration and leadership residency).

60 What distinguishes the pharmacy executive from the established director of pharmacy  
61 position is the increased breadth and depth of the involvement in the health system’s strategic  
62 planning and decision-making processes at the most senior levels. The pharmacy executive has  
63 experience in leading the medication-use process, including optimizing the pharmaceutical  
64 supply chain, making evidence-based systematic clinical decisions, supporting medication-  
65 management systems and policies, implementing technology to elevate patient care, and  
66 optimizing financial performance. The pharmacy executive, therefore, provides pharmacy’s

67 unique clinical and business perspectives in decisions related to changes in the medication-  
68 management system.<sup>8-10</sup> To support these changes, the pharmacy executive leverages  
69 technology to develop the most cost-effective labor model.

70

### 71 **Reporting structure**

72 The pharmacy executive has a market-competitive title internally consistent with others  
73 reporting at that organizational level, reports directly to the organization's principal executive  
74 (e.g., chief executive officer [CEO], chief operating officer [COO]), participates as a member of  
75 the medical executive committee, and routinely engages with the health system's executive  
76 leadership as well as the board of directors. By working collaboratively with others at this most  
77 senior executive level, the pharmacy executive ensures that health-system pharmacy services  
78 are optimally positioned to most effectively contribute to the organization's strategic initiatives  
79 and address systemwide opportunities. A structure in which pharmacy leadership reports  
80 directly to the principal executive rather than through layers of management allows the  
81 pharmacy executive to engage in critical decision-making and be more effective and influential  
82 in helping the health system anticipate and address rapid change.

83

### 84 **Conclusion**

85 Optimal patient care, quality health outcomes, and pharmacy practice advancement requires  
86 progressive hospitals and health-systems that have an educated pharmacy executive  
87 responsible for the strategic planning, design, operation, and improvement of the  
88 organization's pharmacy services across the care continuum. Because of these expected

89 contributions, the pharmacy executive must be properly positioned within the health system's  
90 senior executive management team to ensure that health-system pharmacy services are best  
91 leveraged to meet the ever-changing demands of the future of healthcare delivery.

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