

House of Delegates

Board of Directors Report on Policy Recommendations from ASHP Councils

April 11, 2016

COUNCIL ON THERAPEUTICS: POLICY RECOMMENDATIONS.....	3
1. Stewardship of Drugs with Potential for Abuse.....	3
2. Appropriate Use of Antipsychotic Drug Therapies	4
3. Safety of Epidural Steroid Injections	6
4. Drug Dosing in Renal Replacement Therapy	7
5. Use of Methadone to Treat Pain.....	8
6. Therapeutic Indication of Prescribing.....	10
COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT: POLICY RECOMMENDATIONS.....	15
1. Pharmacy Technician Training and Certification	15
2. Career Opportunities for Pharmacy Technicians.....	17
3. Developing Leadership Competencies.....	19
4. Interprofessional Education and Training.....	22
5. Cultural Competency and Cultural Diversity.....	23
COUNCIL ON PHARMACY MANAGEMENT: POLICY RECOMMENDATIONS.....	30
1. Controlled Substance Diversion and Patient Access	30
2. Surface Contamination on Packages and Vials of Hazardous Drugs	32
3. Pharmaceutical Distribution Systems	33
4. Patient Satisfaction	34

COUNCIL ON PHARMACY PRACTICE: POLICY RECOMMENDATIONS	41
1. Automated Preparation and Dispensing Technology for Sterile Preparations.....	41
2. Integrated Approach for the Pharmacy Enterprise	42
3. Preventing Exposure to Allergens	44
4. Accreditation of Compounding Facilities.....	45
COUNCIL ON PUBLIC POLICY: POLICY RECOMMENDATIONS	50
1. Off-Label Promotion by Pharmaceutical Manufacturers.....	50
2. Timely State Board of Pharmacy Licensing.....	51
3. Inclusion of Drug Product Shortages in State Price-gouging Laws.....	53
4. Home Intravenous Therapy	53
5. Drug Product Shortages	55
6. Direct-to-Consumer Advertising for Prescription Drugs and Implantable Devices.....	56

COUNCIL ON THERAPEUTICS: POLICY RECOMMENDATIONS

The Council on Therapeutics is concerned with ASHP professional policies related to the safe and appropriate use of medicines. 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.

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1. Stewardship of Drugs with Potential for Abuse

- 1 To encourage stewardship of drugs with potential for abuse; further,
- 2 To facilitate the development of best practices for prescription drug monitoring
- 3 programs and drug take-back disposal programs for drugs with potential for abuse.

Rationale

Drug abuse in the U.S. has reached epidemic proportions. In 2011, 110 people died every day from drug poisonings, and prescription drugs were involved in 41,300 deaths. According to the [CDC](#), almost 5% of the U.S. population over 12 years used opioid pain relievers for non-medical reasons in 2010. The CDC estimates the cost to insurance companies to be 70 billion annually. The Centers for Disease Control and Prevention (CDC) and White House continue to prioritize drug abuse issue as a national concern. SAMHSA has released a toolkit on opioid overdose, and state prescription drug monitoring programs are increasingly sharing information among states. In 2013, ASHP and others successfully advocated for the rescheduling of hydrocodone combination products due to safety concerns. ASHP has also [advocates broader access to naloxone for opioid reversal](#) as part of the nation's collective efforts to reduce harm from drugs of abuse.

Drugs of abuse consist of a variety of classes of medications and are not limited to opioids, however. The Substance Abuse and Mental Health Services Administration (SAMHSA) acknowledges that drugs of abuse include sedatives, stimulants, and antidepressants, in addition to opioids. Despite their risk for abuse, prescription medications for short-term symptomatic reliefs are often refilled well beyond recommended treatment time periods. Counseling on chronic long-term therapy is important for those prescribed these drugs, which may require well-planned titration schedules for safe and effective discontinuation. Patients may not have sufficient information on discontinuation of therapy and disposal of agents.

Encouraging stewardship of and disseminating information on use of these drugs, especially those with narrow therapeutic indices, will reduce ill effects and patient harm.

Background

Council members reviewed the [White House Initiative on Prescription Drug Abuse](#) and [National Drug Control Strategy](#). The Council discussed the concept of [corresponding responsibility](#), which can permit the Drug Enforcement Administration (DEA) to limit a pharmacy's inventory if the DEA suspects its pharmacists are not adhering to due diligence in reviewing opioid prescriptions. Council members noted there is a large disconnect between prescribers and the DEA.

The Council acknowledged that drug abuse is broader than simply opioid abuse. Council members noted that methylphenidate, amphetamines, and pregabalin are commonly abused in ambulatory care settings, and diversion of those drugs is a significant concern. The Council observed that components of strategies to discourage drug abuse include education of patients and family members, as well as proper disposal methods for controlled substances. The Council believed educating patients on risks could help decrease abuse, and that this education is an important opportunity for ambulatory care pharmacy practice. The Council considered mechanisms to discourage abuse, such as stewardship of medications. The Council noted that many studies on relief of low back pain showed no significant difference between opioids and non-narcotic agents and emphasized the importance of re-evaluation of patients on both short- and long-term therapy. Council members recognized the value of programs for stewardship of opioids and other drugs of abuse.

Ultimately, the Council concluded that it is important for leadership groups in ASHP (e.g., councils, the Section of Ambulatory Care Practitioners, and others) to collaborate internally and externally to educate vested parties and develop resources on stewardship and disposal of controlled substances and drugs of abuse. The Council suggested developing best practices and tools on assessment, prescription drug monitoring, and drug take-back programs, and stewardship of drugs with potential for abuse.

2. Appropriate Use of Antipsychotic Drug Therapies

- 1 To advocate for the documentation of appropriate indication and goals of therapy to
- 2 promote the judicious use of antipsychotic drugs and reduce the potential for harm;
- 3 further,

- 4 To support the participation of pharmacists in the management of antipsychotic drug
- 5 use, which is an interdisciplinary, collaborative process for selecting appropriate drug
- 6 therapies, educating and monitoring patients, continually assessing outcomes of
- 7 therapy, and identifying appropriate discontinuation; further,

- 8 To advocate that pharmacists lead efforts to prevent inappropriate use of
- 9 antipsychotic drugs, including engaging in strategies to detect and address patterns
- 10 of use in patient populations at increased risk for adverse outcomes.

Rationale

Antipsychotic drugs are often prescribed and continued in nursing homes after transition from other care settings without appropriate justification. Although there is currently no FDA-approved drug for behavioral and psychological symptoms of dementia (BPSD), antipsychotic drugs are consistently used off-label for BPSD. According to the Agency for Healthcare Research and Quality, there is medium-level evidence to suggest effectiveness of olanzapine, risperidone, and quetiapine to reduce agitation and behavioral disturbances for people with dementia. Some nursing homes are turning away patients with these conditions because of changes to the [CMS Five-Star Quality Rating System](#) for nursing homes, which includes two quality measures on antipsychotic drug use. These quality measures exclude patients with schizophrenia, Huntington's disease, and Tourette syndrome.

Antipsychotic drugs have a black-box warning for increased mortality in the elderly population. In certain patients there is a benefit for use, and these patients may require more intense monitoring and assessment. Some studies suggest a significant increase in cognitive function for Alzheimer's patients with aggressive behavior (Vigen 2011). Another study (Bonner 2015) looked at rationales for prescribing and found vague, generalized indications such as anger and agitation, which is not appropriate, according to guidelines. Nonpharmacological interventions are also supported in managing BPSD. These interventions may be more appropriate in the elderly population, despite being time consuming and labor-intensive.

Background

Council members described the current issues surrounding antipsychotic drug use and associated risks in the elderly population. For some drugs there are substantial risks of cardiovascular effects, such as QT interval prolongation for quetiapine. The Council acknowledged the continued work on revising the [ASHP Therapeutic Position Statement Use of Second-Generation Antipsychotic Medications in the Treatment of Adults with Psychotic Disorders](#). Council members felt this document primarily focused on classes of drugs, and there would be significant gaps in the statement if it were to cover the topic of use in long-term care settings. Some of the topics necessary would include documentation of goals of therapy, dose-reduction strategies, and communication across the continuum of care. The Council discussed how CMS standards may affect patients' admissions to nursing homes. The Council also discussed discontinuation of therapy for conditions originating in acute care settings, such as therapy for intensive care unit (ICU) delirium.

Council members reviewed a policy position from the American Society of Consultant Pharmacists (ASCP) that suggested support of appropriate use when clinically indicated and safe for the elderly population. Council members valued the importance of documenting goals and acknowledged specific rules and regulations associated with long-term care settings, such as requirements for indications for all medications. Council members were also concerned about inappropriately discontinuing medication at transitions in points of care.

3. Safety of Epidural Steroid Injections

- 1 To encourage healthcare providers to 1) inform patients about the significant risks
- 2 associated with epidural steroid injections, and 2) request their informed consent;
- 3 further,
- 4 To encourage healthcare organizations to prevent adverse events related to epidural
- 5 steroid injections by having pharmacists involved in the development of protocols that
- 6 promote the safe use of such injections.

Rationale

Use of epidural steroid injections to treat low back pain is increasing, despite not being a labeled indication and sparse literature confirming the safety and efficacy of the treatment. These drugs, in this route of administration, have narrow therapeutic indices, and there are quality assurance issues related to the compounding of the preparations used in epidural injections. The safety of epidural steroid injections has been referred to in the [FDA Safe Use Initiative](#) (SUI), in which 13 stakeholders were involved in assessing evidence of neurological complications of injections. Several recommended practices resulted, including a [controversial](#) preference for nonparticulate steroid injections for use in cervical transforaminal injections. In addition to the concerns about particulates in the injections, there are very significant safety concerns due to the proximity of intrathecal, epidural, and subdural spaces and how the injections are administered. Skillful technique is required to appropriately administer these drugs. Radiographic contrast is often used to guide the needle to injection sites. Improper technique can cause vasospasm and stroke, which is not related to particulates in the injection.

In April 2014 the FDA released a [drug safety communication](#) stating that rare and serious neurological effects can result from epidural steroid injections. The safety communication noted that “the effectiveness and safety of epidural administration of corticosteroids have not been established, and FDA has not approved corticosteroids for this use” and recommended that healthcare providers “discuss with patients the benefits and risks of epidural corticosteroid injections and other possible treatments.” ASHP concurs with those recommendations and encourages use of an informed consent process in addition to other institutional protocols to promote the safe use of epidural steroid injections.

Background

The Council discussed the compounding practices associated with epidural steroid injections as well as the prevalence of use for low back pain. The Council noted that millions of injections are administered each year in outpatient settings, often without pharmacist oversight or verification. These injections are covered by Medicare, but there is not an efficient and mandatory process for reporting adverse events. Council members stated that some insurers require patients to fail therapy with steroids before approving coverage for surgery. It was noted that cervical injections are the type most associated with adverse events, but one Council member stated that there is limited data and conclusions cannot be drawn on safety. Council members agreed on a need to focus on patient-specific assessment prior to therapy.

The Council also discussed the compounding practices associated with epidural steroid injections. The Council reviewed a 2015 [commentary](#) (Manchikanti and Falco, Pain Physician 18: E129-38) that criticized the development of the FDA SUI practices. The authors of that commentary pointed out that the group of experts representing stakeholders was different from those originally selected, the FDA SUI group had not achieved consensus on the recommendations, and the American Society of Interventional Pain Physicians left the group in 2013. The authors of the commentary also stated that no rigorous studies have been done to compare the safety of particulate and nonparticulate injections and that the FDA SUI neglected deaths associated with dexamethasone epidural injections.

Ultimately, the Council concluded that institutional support in the form of protocols is necessary to address the safety concerns associated with epidural steroid injections and that ASHP also needs to advocate for pharmacists involvement in the medication-use process associated with epidural steroid injections.

4. Drug Dosing in Renal Replacement Therapy

- 1 To encourage research on the pharmacokinetics and pharmacodynamics of drug
- 2 dosing in renal replacement therapy; further,

- 3 To support development and use of standardized models of assessment of the
- 4 pharmacokinetics and pharmacodynamics of drug dosing in renal replacement
- 5 therapy; further,

- 6 To collaborate with stakeholders in enhancing aggregation of data on the
- 7 pharmacokinetics and pharmacodynamics of drug dosing in renal replacement
- 8 therapy.

Rationale

There are few resources and recommendations for drug dosing in patients receiving forms of renal replacement therapy. Appropriate dosing is a very important issue to optimize patient outcomes and achieve goals of therapy. Often, drug properties are used to make educated guesses on appropriate dosing and are based on estimations of clearance. In the critically ill population, serious infections and renal issues often occur simultaneously. Solute removal has a significant impact on dosing and appropriate dosing. Many patient characteristics and device variables need to be considered when dosing patients undergoing renal replacement therapy. These factors include flow rate, membrane pore size, volume of distribution, and patient status. Protein binding helps sustain the drug in tissue, and drugs with a large molecular weight may clog the porous membranes.

Background

The Council discussed the specific definitions of *continuous renal replacement therapy*, *renal replacement therapy*, and *hemodialysis* and why the general term *renal replacement therapy* is

preferred. The Council also discussed the lack of information and guidance on dosing medications for renally compromised patients. Council members questioned whether end-stage renal disease dosing should be used as basis for patients with acute kidney injury if no other information is available. Bennet's renal dosing reference was mentioned as a guide. *Drug Prescribing in Renal Failure* (5th ed., Brier and Aronoff) is also available, and there is some gray literature on the topic.

Characteristics of effluents play a significant role in drug dosing. [Kidney Disease: Improving Global Outcomes \(KDIGO\) guidelines](#) attempt to calculate a sieving coefficient for agents. Council members recognized that European Medicines Agency has also been working on the issue. Some Council members mentioned that PhRMA might be aggregating data on drug dosing for specific medications but that this data may be proprietary and protected. Some members considered post-approval predictive modeling using tissue tests such as those for QT interval prolongation. One member stated that education at the college of pharmacy level is not done appropriately and often is overwhelming for students. Council members agreed that this topic is highly specialized.

Ultimately, the Council acknowledged that institution-specific guidelines are very valuable because of the differences in flow rates and effluents of renal replacement therapy. Not all institutions would have the resources for renal replacement therapy, and there are usually two or three different dialysis modes. The Council supported education and collaborative development of practice recommendations. Michael Blantly and Chris Bland were mentioned as experts on drug dosing in renal replacement therapy. The Council also felt development of educational programming should include chronic care issues and pearls of renal replacement therapy, including caveats to extracorporeal membrane oxygenation (ECMO).

5. Use of Methadone to Treat Pain

- 1 To acknowledge that methadone has a role in pain management and that its
- 2 pharmacologic properties present unique risks to patients; further,

- 3 To oppose the use of methadone as a preferred treatment option for acute and
- 4 chronic pain; further,

- 5 To advocate that all healthcare practitioners who prescribe or dispense methadone
- 6 complete a standardized educational program specific to the drug; further,

- 7 To advocate that pain management experts, payers, and manufacturers collaborate
- 8 to provide educational programs for healthcare professionals on treating acute and
- 9 chronic pain with opioids, including methadone; further,

- 10 To advocate that all facilities that dispense methadone, including addiction
- 11 treatment programs, participate in state prescription drug monitoring programs.

Rationale

Over 16,000 people die each year in the U.S. from opioid overdose. Although methadone accounts for only two percent of opioid prescriptions each year, it is estimated to be responsible for over one third of overdose deaths, according to a 2012 Mortality and Morbidity Weekly Report (MMRW) Vital Signs report. The use of methadone to treat pain and its contribution to overdose deaths is an urgent public health concern.

Methadone was approved in 1947 as an analgesic and antitussive, and in 1972 it received approval for use in treating opioid addiction. In 1995, over 100,000 people in the U.S. received addiction treatment with methadone.

There are significant risks associated with the use of methadone for pain management because of its pharmacokinetic and pharmacodynamic properties. Methadone has a long half-life and short duration of analgesic effect. The respiratory effects last longer, and there is also a risk of QT interval prolongation. In 2006, the FDA released a medication safety alert on the dangers of methadone use for the treatment of pain that included a black-box warning and increased the recommended dosing interval from 3 to 8 hours. In 2008, the Drug Enforcement Agency requested manufacturers to restrict distribution of high-dose formulations to addiction treatment programs and hospitals. Federal regulations restrict the dispensing of methadone; for example, dispensing for opioid addiction treatment is limited to programs certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and for emergency situations to bridge patients to a treatment program.

Despite these dangers, 30 state Medicaid programs include methadone on the preferred drug list for treatment of pain, primarily due to its low cost. The Centers for Disease Control and Prevention (CDC) has recommended that insurance companies and other payers remove methadone from the preferred lists for treating noncancer pain. Several organizations and federal agencies have recommended against the use of methadone as a first-line agent to treat pain, including the FDA, CDC, the American Academy of Pain Medicine (AAPM), and the American Society of Interventional Pain Physicians. In May 2015, the Energy and Commerce Committee of the U.S. Senate held a hearing to assess what the federal government is doing to combat the opioid abuse epidemic and identified use of methadone for treatment of pain as a concern.

ASHP joins AAPM in advocating that all healthcare practitioners who prescribe methadone complete an educational program specific to the drug, and that pain management experts, payers, and manufacturers collaborate to provide educational programs on best practices for prescribing opioids, including methadone.

Background

ASHP has a long history of advocating for the safe and appropriate use of opioids in pain management (e.g., ASHP policy 1106, Pain Management). The Council reviewed existing evidence on the detriments and negative sequelae associated with methadone use for the treatment of pain. The Council felt that ASHP needed a policy that recognizes the risks of using methadone to treat pain and advocates for best practices for methadone use, including education of healthcare providers involved in its use. The Council discussed the unique pharmacologic properties of methadone that contribute to unintentional overdose, such as a respiratory effect that outlasts the analgesic effects and a longer half-life. The Council noted that several organizations, government and private, have policies that discourage use for

methadone as a first-line agent in treating pain. There is significant support in the healthcare community for restricting such use and removing methadone from preferred drug lists for health insurance plans and state Medicaid programs. The Council concluded that education of providers is a key component of influencing inappropriate use and morbidity associated with methadone.

Although the Council concluded that methadone is not a preferred agent for treatment of acute or chronic pain, it recognized that there are specific and rare cases for which use is warranted, such as cancer patients. The Council agreed that a successful pain management plan incorporating methadone should not be altered. The Council also recognized that methadone should not be used for pain management by patients prone to drug abuse or on multiple agents such as benzodiazepines and other sedatives.

The Council was cognizant of the danger of increasing barriers to the appropriate use of methadone in addiction treatment programs. The Council noted that addiction treatment programs are well regulated and that in such controlled environments there are fewer opportunities for negative outcomes. Procedures for administering methadone to treat opioid addiction are rigorous. Patients are allotted an amount of oral liquid that is visibly swallowed at dispensing so that opportunities for diversion and abuse are reduced. Similar barriers are not present when oral methadone is prescribed, dispensed, and administered to treat pain.

Council members also noted that methadone is not required to be submitted to prescription drug monitoring programs but did not feel that language advocating for such a requirement would be an appropriate addition to the policy recommendation at this time.

6. Therapeutic Indication of Prescribing

- 1 To advocate that healthcare organizations optimize use of clinical decision support
- 2 systems by structuring them to include the indication for high-risk and problem-prone medications.
- 3

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, Equale¹ described the accuracy of indication information in electronic health records (EHRs). Galanter² 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 investigator conducted a trial of inpatient indication-based prescribing using computerized provider order entry (CPOE) with medications commonly used off-label.³ In a 60-day trial

¹ Equale T, Winslade N, Hanley JA et al. Enhancing pharmacovigilance with systematic collection of treatment indication in electronic prescribing. *Drug Saf* 2010;33: 559-67.

² Galanter W, Falck S, Burns M, et al. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc*. 2013;20:477-81.

³ Walton SM, Galanter WL, Rosencranz H, et al. A trial of inpatient indication based prescribing during computerized order entry with medications used off-label. *Appl Clin Inf*. 2011;2:94-103.

documenting indications in the CPOE system for lansoprazole, intravenous immune globulin, and recombinant Factor VII, the accurate diagnosis rates after validation by a clinician were 9, 16, and 24 percent, respectively. In a study in the *Joint Commission Journal on Quality and Patient Safety*, investigators tracked a total of 140,755 medications filled by pharmacy technicians over a seven-month period in an academic institution. A total of 5,075 (3.6%) contained errors, and 1,059 contained an error that was not detected by the hospital pharmacist. Just over 23 percent of the undetected errors were potential adverse drug events.⁴ Addressing these errors can have a large public health impact. Off-label prescription medication use without strong scientific evidence has also been associated with increased rates of adverse drug events, according to an article in *JAMA Internal Medicine*.⁵ The authors suggested that use of the electronic health record (EHR) and proper documentation of therapeutic indication can help improve surveillance and safety and decrease risk.

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 prescription 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.

A project funded by the National Institutes of Health (NIH) project in collaboration with the Agency for Healthcare Research and Quality is underway to assess, evaluate, and make recommendations on optimal communication of the purpose of prescribing. The goal of the project is to improve prescribing safety by redesigning CPOE to incorporate the medication indication into the prescription order. ASHP is a primary partner in this initiative, and almost 100 organizations have already joined the effort. Three phased goals are expected from this project. Phase one consists of a series of webinars. Phase two consists of the development of a white paper that outlines and specifies best practices and ideas obtained from the workgroups and webinars. Finally, phase three consists of the creation of simulated models of ideal systems that can reduce harm and increase efficiency. This project will focus on six domains: medication error prevention and mitigation, facilitating patient education, promoting prescribing drugs of choice, enhanced team communication, organizing the medication list for medication reconciliation, and enabling comparative outcomes research.

Background

⁴ Cina JL, Gandhi TK, Churchill W, et al. How many hospital pharmacy medication dispensing errors go undetected? *Joint Commission Journal on Quality and Patient Safety* 2006; 32:73-80.

⁵ Egualé T, Buckeridge DL, Verma A, et al. Association of off-label drug use and adverse drug events in an adult population. *JAMA Internal Medicine* 2016; 176:55-63. doi:10.1001/jamainternmed.2015.6058.

The Council reviewed several studies related to prevention of harm and usefulness of requiring indication in computerized provider order (CPOE) systems. The Council considered ASHP policy 0305, Expression of Therapeutic Purpose of Prescribing, and concluded that there may be significant gaps in the policy, which reads:

To advocate that prescribers provide or pharmacists have immediate access to the intended therapeutic purpose of prescribed medications in order to ensure safe and effective medication use.

Electronic prescribing has a prominent role that the current policy may not address. The Council focused on the importance of drug-disease and drug-drug interactions with listed indications. One Council member noted that the Iowa Board of Pharmacy proposed legislation and has made this issue a priority and steppingstone for provider status. Some Council members have implemented programs in their practice sites on high-risk and problem-prone medications, such as antibiotics, oral chemotherapy, and anticoagulants. Several Council members stated that they have used required indications for specific drug classes such as pain medication and for first doses. However, members also noted that compliance and validating accurate information was also a concern. Some Council members acknowledged that this policy would help support autonomy for practices such as discontinuing unnecessary medications by pharmacists after medication reconciliation. Council members noted that in many of the studies they reviewed, significantly fewer pharmacist interventions were needed on electronic prescriptions when indications were included. Council members also noted the importance of indication in documentation on admission to the hospital and as one component of medication reconciliation. One Council member noted from a recent project implementing CPOE in a critical care setting that physicians would bypass the proper procedure to document indication in efforts to get to the final order screen, often entering non-valid indications.

In general, the Council felt that most adverse events occur due to faulty communication and that education is the key to improving rates of adverse events. There are existing ASHP Guidelines on Pharmacy Planning for Implementation of CPOE Systems in Hospitals and Health-Systems. The Council members emphasized the importance of having the same process work with and across all systems in both inpatient and outpatient settings. There continues to be the potential for harm when prescribers select the wrong indication. There is significant evidence demonstrating financial incentives and savings attributable to correct selection of medications, specifically for antibiotics (i.e., correct duration of therapy). From an implementation perspective, the Council felt that high-risk and problem-prone medications warrant an extra level of review and would benefit from inclusion of indication on the prescription order. There are numerous contributing complexities based on billing codes and EHR caveats, and Council members agree the Section on Pharmacy Informatics could provide needed insight and be integrally involved in initiatives about documentation of indications for prescribing in health systems.

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.)

- [Universal Influenza Vaccination](#) (0601)
- [Minimum Effective Dose](#) (0602)
- [Agricultural Use of Hormone and Prohormone Therapies](#) (1102)
- [Direct to Consumer Clinical Genetic Tests](#) (1103)
- [Pharmacogenomics](#) (1104)
- [Safe and Effective Use of IV Promethazine](#) (1105)
- [Pain Management](#) (1106)
- [Patient-Reported Outcomes Tools](#) (1107)

Other Council Activity

CPIC Guidelines

The Council voted to recommend endorsement of the CPIC Guidelines on CYP2D6 and CYP2C19 genotypes and dosing of tricyclic antidepressants. The Council also voted to recommend endorsement of the CPIC Guidelines on CYP2D6 and CYP2C19 genotypes and dosing of selective serotonin reuptake inhibitors.

The Council reviewed two [Clinical Pharmacogenomics Implementation Consortium](#) guidelines. The Council acknowledged that the development of these recommendations closely adheres to Institute of Medicine recommendations on developing rigorous and trusted clinical practice guidelines. The Council appreciated the focus on interpretation of genetic tests rather than appropriateness of testing. Previous councils have found value in this type of guidance to aid in practice.

Tricyclic use is decreasing for psychological disorders because of side effects and is increasing for pain management. Genes for the CYP2D6 enzyme are very polymorphic, which creates variability in the level of pharmacokinetic effects. There are 30 subvariants identified for CYP2C19. This document provides scoring of activity for the diplotype of the cytochrome alleles. Phenotypes are then provided and classified as poor metabolizers, intermediate metabolizers, or extensive metabolizers. There is substantial evidence linking CYP2D6 and CYP2C19 genotypes to phenotype variability in side effects and pharmacokinetic profiles of tricyclics and selective serotonin reuptake inhibitors (SSRIs).

The CPIC guidelines for tricyclic antidepressants use amitriptyline and nortriptyline as a model but they suggest applying recommendations to others tricyclic antidepressants (e.g., clomipramine, desipramine, doxepin, imipramine, and trimipramine). The CPIC guidelines on CYP2D6 and CYP2C19 genotypes and dosing of selective serotonin reuptake inhibitors also suggest dose alterations based on phenotype. Supplemental evidence provides pharmacotherapy recommendations for paroxetine, fluvoxamine, citalopram, escitalopram,

and sertraline. The FDA suggests that fluvoxamine should be used cautiously in patients with reduced levels of CYP2D6 activity. For poor metabolizers of substrates for CYP2C19, an alternate SSRI is recommended. Clinical decision support tools can also be found in the supplement with additional information. The Council unanimously voted to recommend endorsement of these guidelines by ASHP.

Testosterone Replacement Therapy

The Council voted to develop an ASHP therapeutic position statement on the safe and appropriate use of testosterone therapy. The Council acknowledged that the forthcoming results of the National Institutes of Health [Testosterone Trial](#) would provide additional evidence on the risks associated with testosterone replacement therapy. The Council considered the value of additional educational resources on appropriate use, such as confirmed assessment through repeat serum levels taken in the morning. Council members provided their institutional appropriate-use protocols and discussed broader aspects, such as off-label use policies.

Council members agreed that guidance on appropriate therapy would be beneficial to ASHP members and other practitioners. One member also suggested education directed toward patients and family members regarding safe handling and the lack of data on long-term use. Council members had several other suggestions for topics to be addressed in the guidance, including conversions among agents, initiation of therapy, and safety precautions for contact with family members. It was also noted that the current Endocrine Society guidelines do not address transgender patients.

Pharmacist's Role in the Use of Biosimilars

The Council voted to develop an ASHP statement on the pharmacist's role in the use of biosimilars. The Council discussed the classification of agents as biosimilars, interchangeable biosimilars, and associated impacts on practice and potential drug acquisition and distribution costs. Council members discussed Europe's 10-year history with biosimilar availability, the [Biologics Price Competition and Innovation Act of 2009](#), and [associated FDA guidance](#), and the fact that biologics inherently have variability in make-up and effects on patients.

The Council considered the potential studies needed to characterize an agent as interchangeable with the reference biologic. The delineation between a biosimilar and interchangeable biosimilar can potentially be very narrow. There are significant safety concerns associated with biologics themselves because of the methods of manufacturing and lot-to-lot variability. All of these characteristics can affect immunogenicity. Council members discussed instances of delayed immune responses, such as red cell aplasia.

The Council acknowledged the parallel discussion by the Council on Public Policy on biosimilar naming and labeling requirements. Council members discussed the draft [2012 FDA guidance that provides factors for assessing biosimilarity](#). Manufacturers are required to submit pharmacovigilance plans as part of their marketing application. Members considered how use of the agents is moving toward outpatient settings and primary care.

The Council discussed the potential value of a formulary assessment tool for biosimilar amino acid comparability. Ultimately, the Council supported developing an ASHP statement on the pharmacist's role in the use of biosimilars and acknowledged that outcomes are specific to each individual product.

COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT: POLICY RECOMMENDATIONS

The Council on Education and Workforce Development is concerned with ASHP professional policies related to the quality and quantity of pharmacy practitioners in hospitals and health systems. 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.

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Joseph DiPiro (Virginia)
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Patricia Knowles (Georgia)
Richard Montgomery (Florida)
Mark Sinnott (New York)
Allison Vecchiet (Ohio)
Lanita White (Arkansas)
Whitney White (Alabama)
JoAnn Harris, *Secretary* (Maryland)

1. Pharmacy Technician Training and Certification

- 1 To advocate that Pharmacy Technician Certification Board (PTCB) certification be
- 2 required for all pharmacy technicians; further,

- 3 To advocate that all pharmacy technicians maintain PTCB certification; further,

- 4 To support the position that by the year 2020, the completion of a pharmacy
- 5 technician training program accredited by ASHP and the Accreditation Council for
- 6 Pharmacy Education (ACPE) be required to obtain PTCB certification for all new
- 7 pharmacy technicians; further,

- 8 To foster expansion of ASHP-ACPE accredited pharmacy technician training
- 9 programs.

(Note: This policy would supersede ASHP policy 1519.)

Rationale

The partnership between ASHP and the Accreditation Council for Pharmacy Education (ACPE) to accredit pharmacy technician training programs could be an important inflection point leading to profession-wide support for uniform education, training, and credentialing of pharmacy technicians. Such broad support may stimulate more uniform state statutes and regulations

regarding pharmacy technicians. The requirement that pharmacy technicians be graduates of ASHP-ACPE accredited training programs to be certified by the Pharmacy Technician Certification Board (PTCB) mirrors the profession's approach to the education (first) and licensure (second) of pharmacists. Consistent with this model, PTCB will, in 2020, require that an individual sitting for the pharmacy technician certification examination be a graduate of an ASHP-ACPE accredited training program. Although programs currently accredited by ASHP will be granted the joint accreditation, the anticipated increase in demand for enrollment in ASHP-ACPE accredited training programs will require an expansion of the number and distribution of such programs.

Background

The Council voted to recommend amending ASHP policy 1519, Pharmacy Technician Training and Certification, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To advocate that Pharmacy Technician Certification Board (PTCB) certification be required for all pharmacy technicians; further,

To advocate that all pharmacy technicians maintain PTCB certification; further,

To support the position that by the year 2020, the completion of a pharmacy technician training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required to obtain PTCB ~~Pharmacy Technician Certification Board~~ certification for all new pharmacy technicians ~~entering the workforce~~; further,

To foster expansion of ASHP-ACPE accredited pharmacy technician training programs.

The policy recommendation proposed by the 2014 Council that became policy 1519 was specifically intended to require *maintenance* of certification. In the amendment adopted by the 2015 House of Delegates, the requirement for maintenance was deleted. A 2015 House of Delegates recommendation suggested that the Council reconsider the addition for a requirement of maintenance of certification. The 2015 Council discussed the issue and there was strong consensus that maintenance is an important aspect to pharmacy technician competence. The Council specifically restated the intent of the 2014 Council was for pharmacy technicians to maintain their certification throughout their careers. This intent is also consistent with the [ASHP Statement on the Roles of Pharmacy Technicians](#).

2. Career Opportunities for Pharmacy Technicians

- 1 To promote the image of pharmacy technicians as valuable contributors to healthcare
- 2 delivery; further,

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

- 5 To support pharmacy technician career advancement opportunities, commensurate
- 6 with training and education; further,

- 7 To encourage compensation models for pharmacy technicians that provide a living
- 8 wage.

(Note: This policy would supersede ASHP policy 0211.)

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 achieve their goals for quality patient care without the support of competent pharmacy technicians. To support pharmacists, it is important that pharmacy technician positions be viewed as a career option and not just a job. As such, pharmacy technicians should be given opportunities for life-long advancement and should be compensated a living wage to ensure that being a pharmacy technician is a viable career option. (For the purposes of this policy, a living wage is defined as one sufficient to provide the basic things, such as food and shelter, needed to live an acceptable life.⁶)

The median annual salary of pharmacy technicians in the U.S., \$29,320 in 2012, falls short by approximately \$5,000 per year of the median annual salaries for other health technologists and technicians.⁷ Pharmacy technicians do not earn as much as dental hygienists (\$71,530) or radiologic technologists (\$56,760).⁸ If a wage and benefits, commensurate with skills and responsibility, were paid to pharmacy technicians, the pharmacy profession could expect a better return on employee investment and reduced turnover rates. Improving wages and benefits would encourage workers to make a career of being a pharmacy technician and reinforce their vital role on the healthcare team.

Background

The Council voted to recommend amending ASHP policy 0211, Image of and Career Opportunities for Pharmacy Technicians, as follows (underscore indicates new text):

⁶ Merriam-Webster online ([http://www.merriam-webster.com/dictionary/living wage](http://www.merriam-webster.com/dictionary/living%20wage)).

⁷ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, 2014-2015 Edition, Pharmacy Technicians. <http://www.bls.gov/ooh/healthcare/pharmacy-technicians.htm> (accessed 2015 Jul 23).

⁸ US News and World Report. Best Health Care Jobs 2015, Pharmacy Technician: Salary. <http://money.usnews.com/careers/best-jobs/pharmacy-technician/salary> (accessed 2015 September 8).

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

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

To support pharmacy technician career advancement opportunities, commensurate with training and education; further,

To encourage compensation models for pharmacy technicians that provide a living wage.

The Council agreed that ensuring pharmacy technicians a living wage was a more immediate issue than ensuring pharmacy technicians view their positions as a career with long-term opportunities, especially if ASHP advocates for licensure and certification.

In the retail setting, pharmacy technicians are compensated a median rate of \$13.50⁹ per hour, which is less than those who work in health systems. The large chain pharmacies are concerned with salary increases and turnover rates and are not convinced that if they invest in their technicians they will be able to retain them.

To advance the image of pharmacy technicians, the Council also discussed whether pharmacy technician position descriptions within the health system reflect the training, duties, and increased level of responsibility expected of pharmacy technicians. It was suggested that ASHP, perhaps through the Section of Inpatient Care Practitioners Section Advisory Group on Advancing Pharmacy Practice with Technicians, could encourage directors of pharmacy to work with human resource departments to promote increased recognition for the pharmacy technicians' level of responsibilities, including a higher pay scale for certification. There was some discussion of including mention of potential career ladders in the proposed policy, but the Council concluded that the proposed language should be more broadly worded to encourage career advancement opportunities for pharmacy technicians.

⁹ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, 2014-2015 Edition, Pharmacy Technicians, on the Internet at <http://www.bls.gov/ooh/healthcare/pharmacy-technicians.htm> (visited July 23, 2015)

3. Developing Leadership Competencies

- 1 To work with healthcare organization leadership to foster opportunities, allocate
2 time, and provide resources for pharmacy practitioners to move into leadership
3 roles; further,
- 4 To encourage leaders to seek out and mentor pharmacy practitioners in developing
5 administrative, managerial, and leadership skills; further,
- 6 To encourage pharmacy practitioners to obtain the skills necessary to pursue
7 administrative, managerial, and leadership roles; further,
- 8 To encourage colleges of pharmacy and ASHP state affiliates to collaborate in
9 fostering student leadership skills through development of co-curricular leadership
10 opportunities, leadership conferences, and other leadership promotion programs;
11 further,
- 12 To reaffirm that residency programs should develop leadership skills through
13 mentoring, training, and leadership opportunities; further,
- 14 To foster leadership skills for pharmacists to use on a daily basis in their roles as
15 leaders in patient care.

(Note: This policy would supersede ASHP policy 1518.)

Rationale

In their 2013 report, White and Enright anticipated a high rate in turnover of pharmacy directors and middle managers over the coming decade. Healthcare organizations must address this ongoing challenge if there are to be a sufficient number of new directors and managers to fill those positions. Factors that may contribute to a shortage of potential new leaders and managers include:

- New graduates frequently accept clinical positions or positions in drug distribution. After a few years, they may have a desire to assume managerial positions in health-system pharmacies, but training programs may not be convenient for them, and they may not have the resources to obtain training.
- Health-system pharmacy management positions do not turnover often. Prospective managers view those positions as unavailable for the near future, so there is little incentive to obtain training to be ready to move into those positions.
- Job satisfaction among pharmacy managers appears low to prospective managers.
- Frequent turnover in organizational administrative positions (above pharmacy) is frustrating to pharmacy directors, because they continually need to inform new

administrators about the organization's medication-use strengths and weaknesses and the pharmacy department's roles, strategic plans, and priorities for sustaining quality and making improvements. In those turnover circumstances, diligently achieved pharmacy service improvements can sometimes be eroded and reversed. The ensuing frustration can induce pharmacy directors to depart voluntarily from management positions and make those positions unattractive to others.

- Flattening of organizational structures in healthcare organizations has eliminated numerous managerial positions in pharmacies, leaving fewer pharmacists to serve as mentors for prospective managers. Without positive role models, it is difficult for pharmacists to gain good management experience.
- Pharmacy management positions that combine clinical and management responsibilities sometimes allow little time for clinical work.
- Many pharmacists, even those in managerial positions, have no training in personnel administration. Skills such as conflict resolution and negotiation are rarely taught in pharmacy curricula but are very important in leadership positions.
- In some healthcare organizations, managers receive raises predicated on overall organizational or departmental performance. However, the compensation of some staff may be based on individual performance. These differing bases can lead to instances in which the compensation of those supervised is higher than that of their managers. When that occurs, it can be a disincentive to individuals considering management positions.

Leadership and managerial potential in today's student pharmacists and new graduates is as high as it has ever been, but more effort is needed to nurture that potential and develop leadership and management skills in practice. Colleges of pharmacy, state associations, residency programs, and practitioners themselves need to foster the development of leadership and management skills. ASHP can help foster leadership competencies at all levels of practice through actions such as providing education about leadership and management roles, developing Web-based resources, and facilitating networking among leaders, managers, and those aspiring to such roles.

Leadership continues to be a critical area for development, as leadership is a necessary competency in the provision of patient care. There are multiple avenues available to pharmacists for leadership development and ASHP should take the lead in fostering this effort.

Background

The Council voted to recommend amending ASHP policy 1518, Developing Leadership Competencies, as follows (underscore indicates new text):

To work with healthcare organization leadership to foster opportunities, allocate time, and provide resources for pharmacy practitioners to move into leadership roles; further,

To encourage leaders to seek out and mentor pharmacy practitioners in developing administrative, managerial, and leadership skills; further,

To encourage pharmacy practitioners to obtain the skills necessary to pursue administrative, managerial, and leadership roles; further,

To encourage colleges of pharmacy and ASHP state affiliates to collaborate in fostering student leadership skills through development of co-curricular leadership opportunities, leadership conferences, and other leadership promotion programs; further,

To reaffirm that residency programs should develop leadership skills through mentoring, training, and leadership opportunities; further,

To foster leadership skills for pharmacists to use on a daily basis in their roles as leaders in patient care.

During the 2014 Regional Delegate Conferences, the Section of Pharmacy Practice Managers (SPPM) expressed concern with the proposed wording of the policy recommendation that became policy 1518 because they felt an important aspect related to development of opportunities to move into leadership roles was missing. The SPPM supported the policy recommendation; however, the Council agreed to review the newly approved policy to discuss whether revision was necessary.

The SPPM believed the training path for individuals who decide mid-career to pursue formal leadership positions may be less supported and structured than the paths for those who completed formal administrative residency training. The Council noted that ASHP and the ASHP Research and Education Foundation have a plethora of resources available for those interested in assuming leadership roles and that many other leadership training opportunities exist. The Council concluded that lack of time and financial support are significant barriers to individuals obtaining advanced leadership training. The Council decided that it was important that the policy encourage organizations to allocate time off from regular duties if needed as well as financial support for associated costs. The Council also reiterated that mentorship was a significant aspect of leadership development and an important component of this policy.

4. Interprofessional Education and Training

- 1 To support interprofessional education as a component of didactic and experiential
- 2 education in Doctor of Pharmacy degree programs; further,

- 3 To support interprofessional education, mentorship, and professional development
- 4 for student pharmacists, residents, and pharmacists; further,

- 5 To encourage and support pharmacists' collaboration with other health professionals
- 6 and healthcare executives in the development of team-based, patient-centered care
- 7 models; further,

- 8 To foster documentation and dissemination of outcomes achieved as a result of
- 9 interprofessional education of healthcare professionals.

(Note: This policy would supersede ASHP policy 1014.)

Rationale

Pharmacist involvement in team-based patient care improves medication-use safety and quality and reduces healthcare costs. For patient-care teams to be effective, they must possess unique skills that facilitate effective team-based interactions. Some pharmacists are exposed to team-based care models through interprofessional education and interaction with students of other disciplines when they are student pharmacists. Some colleges of pharmacy have very effective interprofessional didactic courses that include medical, pharmacy, nursing, and other health professional students. Additionally, most experiential rotations involve interaction with other members of the healthcare team and help students of all disciplines learn about the expertise of other team members. However, not all colleges and schools are effective in providing interprofessional education that facilitates team-based patient care. The reasons vary, but may include differences in teaching philosophies or a lack of access to other health professional schools at the university or campus.

The Hospital Care Collaborative (HCC) has described common principles for team-based care. The HCC principles recognize the knowledge, talent, and professionalism of all team members and support role delineation, collaboration, communication, and the accountability of individual team members and the entire team. The HCC principles note that collaboration of the healthcare team can lead to improved systems and processes that provide care more efficiently and result in better patient outcomes. The HCC states that current undergraduate and postgraduate professional education of team members is inadequate to promote true team functions.

ASHP believes that interprofessional education is important not only for student pharmacists but also throughout one's professional career. Similarly, it is important for other professionals on the team so that collaboration and synergistic relationships can develop. Failure to establish these collaborative working relationships early in one's career can result in

poor interactions in years to come. A positive working relationship, including interprofessional mentorship, with physicians and nurses is productive, while a bad working relationship can be counterproductive and devastating to all parties, including patients.

Background

The Council voted to recommend amending ASHP policy 1014, Interprofessional Education and Training, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To support interprofessional education as a component of didactic and experiential education in Doctor of Pharmacy degree programs; further,

To support interprofessional education, mentorship, and as a part of professional development for student pharmacists, residents, and pharmacists ~~y practitioners and to foster interprofessional collaboration to facilitate and promote programs that support this goal~~; further,

To encourage and support pharmacists' collaboration with other health professionals and healthcare executives in the development of team-based, patient-centered care models; further,

To foster documentation and dissemination of outcomes achieved as a result of interprofessional education of healthcare professionals.

The Council felt policy 1014 is still relevant but agreed new wording would strengthen the position. The Council acknowledged that interprofessional education and mentorship was important for the training of student pharmacists, residents, and pharmacists. The Council acknowledged the importance of mentorship and wanted to highlight the opportunities for interprofessional mentorship, which may not be thought of routinely. The Council reiterated its support for the HCC principles and suggested that ASHP should make members aware of their existence and seek ways to promote the adoption of team-based care by all hospitals.

5. Cultural Competency and Cultural Diversity

- 1 To endorse the development of cultural competency of pharmacy educators,
- 2 practitioners, residents, students, and technicians; further,
- 3 To educate providers on the importance of providing culturally congruent care to
- 4 achieve quality care and patient engagement; further,
- 5 To advocate for an ethnically and culturally diverse workforce.

(Note: This policy would supersede ASHP policy 1414.)

Rationale

The United States is rapidly becoming a more diverse nation. Culture influences a patient's belief and behavior toward health and illness. The representation of many of these diverse groups within the health professions is far below their representation in the general population. According to the Institute of Medicine, increasing racial and ethnic diversity among healthcare providers is associated with improved access to care for racial and ethnic minority patients, greater patient choice and satisfaction, and better educational experiences for health professions students.¹⁰

Cultural competence can significantly affect clinical outcomes. Research has shown that overlooking cultural beliefs may lead to negative health consequences.¹¹ According to the National Center for Cultural Competency, there are numerous examples of benefits derived from the impact of cultural competence on quality and effectiveness of care in relation to health outcomes and well-being.¹² Further, pharmacists can contribute to providing "culturally congruent care," which can be described as "a process of effective interaction between the provider and client levels" of healthcare that encourages provider cultural competence while recognizing that "[p]atients and families bring their own values, perceptions, and expectations to healthcare encounters which also influence the creation or destruction of cultural congruence."¹³

The underrepresentation of minorities among healthcare providers is often considered to be one of the contributing factors to health disparities in these populations.¹⁴ The [Report of the ASHP Ad Hoc Committee on Ethnic Diversity and Cultural Competence](#)¹⁵ and the [ASHP Statement on Racial and Ethnic Disparities in Health Care](#)¹⁶ support ways to raise awareness of the importance of cultural competence in the provision of patient care so that optimal therapeutic outcomes are achieved in diverse populations.

Background

The Council voted to recommend amending ASHP policy 1414, Cultural Competency and Cultural Diversity, as follows (underline indicates new text; ~~strike through~~ indicates deletions):

To ~~promote~~ endorse the development of cultural competency of pharmacy educators,

¹⁰Smedley BD, Butler AS, Bristow LR, eds. In the nation's compelling interest: ensuring diversity in the health-care workforce. Washington, DC: National Academies Press; 2004.

¹¹Administration on Aging. Achieving cultural competence. A guidebook for providers of services to older Americans and their families. Available at: <http://archive.org/details/achievingcultura00admi> (accessed October 17, 2013)

¹²Goode TD, Dunne MC, Bronheim SM. The evidence base for cultural and linguistic competency in health care. The Commonwealth Fund; 2006. Available http://www.commonwealthfund.org/usr_doc/Goode_evidencebasecultlinguisticcomp_962.pdf (accessed October 17, 2013)

¹³Schim SM, Doorenbos AZ. A Three-dimensional Model of Cultural Congruence: Framework for Intervention. *J Soc Work End Life Palliat Care*. 2010; 6:256–70.

¹⁴Smedley BD, Butler AS, Bristow LR, eds. In the nation's compelling interest: ensuring diversity in the health-care workforce. Washington, DC: National Academies Press; 2004.

¹⁵Report of the ASHP Ad hoc committee on ethnic diversity and cultural competence. *Am J Health-Syst Pharm*. 2005; 1924-30.

¹⁶[ASHP Statement on Racial and Ethnic Disparities in Health Care. Am J Health-Syst Pharm. 2008; 65:728–33.](#)

practitioners, residents, students, and technicians; further,

To educate providers on the importance of providing culturally congruent care to achieve quality care and patient engagement; further,

~~To foster awareness of the impact that an ethnically and culturally diverse workforce has on improving health care quality.~~

To advocate for an ethnically and culturally diverse workforce.

A 2015 House of Delegates recommendation urged the Council to consider a policy to promote, support, and advocate for developing a diverse workforce and addressing gaps in healthcare including, but not limited to, race and ethnicity as well as other gaps, such as socioeconomic and literacy gaps. The Council reviewed related ASHP policies 1414 and 0510 and decided to recommend amending policy 1414. The Council felt it important to note that the [ASHP Statement on Racial and Ethnic Disparities in Health Care](#) complements the ASHP policy positions, so all three must be considered when determining whether new or revised policy is needed.

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.)

- [Professional Development as a Retention Tool](#) (0112)
- [Quality of Pharmacy Education and Expansion of Colleges of Pharmacy](#) (1108)
- [Residency Equivalency](#) (1109)
- [Pharmacy Internships](#) (1110)
- [State-Specific Requirements for Pharmacist Continuing Education](#) (1111)
- [Innovative Residency Models](#) (1112)
- [Professional Socialization](#) (1113)

Other Council Activity

Experiential Education Event

The Council voted to assess the feasibility of and assess stakeholder interest in ASHP conducting a stakeholder event to examine standardization of experiential education experiences, introductory and advanced pharmacy practice experience rotations, and incorporating student learners into the healthcare team.

The Council discussed the impact of training students from different schools and the various specific requirements of each school. Because there is no standardization, it makes it difficult for organizations to utilize the student pharmacists as pharmacist extenders in a consistent manner. Rotation sites should not feel burdened by supporting the mission of training future practitioners. The Council felt strongly that if there were more standardization related to logistics (e.g., scheduling, evaluation, and learning objectives), it would be easier to incorporate student pharmacists into the healthcare team and would provide a better way to train future professionals. Because each school has its own specific requirements, ASHP policy advocating standardization is not sufficient. The Council that a high-level summit with all stakeholders, similar to the ASHP-ASHP Foundation Ambulatory Care Summit, may be the action needed to achieve this goal.

After discussing the lack of standardization of experiential educational evaluations, the Council felt strongly that there are significant barriers to standardization that are not easily overcome. In this recommendation, the Council suggests that ASHP convene a summit of thought leaders and stakeholders, including the American Association of Colleges of Pharmacy, the National Association of Boards of Pharmacy, and the Accreditation Council for Pharmacy Education, to collaborate on developing methods and models to address the following issues (among others):

- Standardizing rotation schedules
- Identifying and implementing universal experiential valuation tools
- Addressing the intersection of residency and student rotation sites
- Examining block rotations versus longitudinal models
- Developing models to integrate students into the healthcare delivery system

Pharmacist Oversight of Student Pharmacists

The Council voted to request that the Council on Public Policy consider developing policy that would advocate that the National Association of Boards of Pharmacy encourage standardization of state laws and board of pharmacy requirements regarding pharmacist oversight of student pharmacists.

As health-system pharmacies incorporate student pharmacists into the daily workflow, the definition of pharmacist oversight needs to be standardized. Oversight currently varies from state to state, ranging from direct line of sight to inside the four walls of the building. If, for example, student pharmacists are performing medication reconciliation, direct line of sight oversight is more difficult for the preceptor than a dispensing function would be, where direct oversight is more feasible.

Discussion regarding the methods to integrate student pharmacists into the healthcare setting workforce focused on the variety of models currently in place. Citing the Cleveland Clinic's recent effort to reorganize how care was delivered throughout its system, the Council agreed that addressing delivery of service and optimizing the student learner's experience as they transition into the workforce is needed. Several objectives were noted:

- Use students as extenders and make them accountable for patients while on rotation
- Introduce experiential learning early in the curriculum
- Adjust teaching methods from block style to rotational approach
- Broaden instruction for improving communication skills for interacting with patients
- Examine the practicality of the direct line of sight definition of supervision in health systems versus retail settings

The Council suggested that the Council on Public Policy consider developing policy that would advocate that the National Association of Boards of Pharmacy and states work to remove barriers for integrating students into the hospital and health-system workforce. The aforementioned suggestions could also be discussed during the stakeholder event proposed above.

Statement on Quality of Pharmacy Education and Expansion of Colleges of Pharmacy

The Council voted to draft an ASHP statement on the quality of pharmacy education and expansion of colleges of pharmacy. During sunset review of ASHP policy 1108, Quality of Pharmacy Education and Expansion of Colleges of Pharmacy, several Council members volunteered to develop an ASHP statement on the topic. The Council decided that when the statement is recommended for approval, policy 1108 should be re-evaluated.

Availability of Preceptor Resources

Greater awareness of and access to preceptor resources is needed. The Council discussed how models of learning that support the growth of residencies may also grow student opportunities. There remain concerns related to quality and consistency of some rotations. The importance of teaching residents how to teach as part of their training was noted. The Council discussed the growing need for standards around a teaching certificate earned during residency training.

Continuing Professional Development

The Council agreed that the vast majority of pharmacy professionals are not utilizing continuing professional development (CPD) to enrich their careers. An assessment tool should be developed to assess the continuous learning accomplishments of pharmacy professionals over the course of their career path. The Council encourages evaluation of the feasibility of developing a platform where members can upload details about scholarly activities, speaking engagements, and other self-directed, continuous learning accomplishments. This repository

could also serve as a place for background information that could showcase major milestones of the professional careers of ASHP members. Such a repository would be individually maintained and updated, and allow for portability so that a member could showcase their upward career trajectory and commitment to lifelong learning. Several Council members volunteered to explore opportunities to increase the visibility of continuing professional development among pharmacists.

Preceptor Development for Technician Training

A preceptor development resource for technician training could be modeled on the ASHP residency and pharmacy preceptor programs already in place and may be an attractive incentive for pharmacy technicians to become involved as ASHP members. The Council also noted that there is value in training pharmacy technician preceptors not only as preceptors for pharmacy technicians, but also as preceptors for student pharmacists, and that other types of precepting relationships exist, such as technician-student, technician-technician, and pharmacist-technician. The Council felt topics such as accountability, emotional intelligence, interpersonal communication, and leadership were important topics to be included in technician preceptor development. ASHP staff members in attendance at the Council meeting will take this request to the appropriate staff members at ASHP for further development.

2014 Workforce Report

The Council reviewed the 2014 National Pharmacy Workforce Survey, which outlined the following developments since its last edition in 2009:

- The profession is shifting from male- to female-dominated.
- More pharmacies are providing patient care.
- The percentage of pharmacists with Pharm.D. degrees has risen 49% since 2009.
- The increase in new roles and services has led to more stress and dissatisfaction.
- Pharmacists feel less able to change jobs than in the past.

In general, the Council felt the workforce report was positive information and not reflective of the “doom and gloom” perception currently held by some student pharmacists and prospective students. The Council felt it important that ASHP work to disseminate the positive message to counter the incorrect negative perceptions of qualified pharmacy school candidates. The Council encouraged ASHP staff to identify information from the survey to include in news summaries to the membership and the general public by a variety of communication methods, including social media.

Succession Planning

The Council discussed the importance of succession planning as a wave of retirements may be forthcoming in next few years. It was noted that succession planning is closely related to leadership development. ASHP currently has resources available on succession planning,

including a webinar planned for January 2016 and a position statement. In addition, ASHP hosts a [repository of information on leadership](#) on the ASHP website. In addition, because succession planning should begin early, this topic might be appropriate for inclusion in student leadership programs.

Generational Differences in the Workforce

The Council discussed how the following groups, with some general attributes, will soon represent five distinct generations working together in the labor force:

- Traditionalists -- Born 1935-46: They have been described as valuing hard work and self-sacrifice, and likely work for one organization for their entire career.
- Baby Boomers -- Born 1946-65: They number upward of 72 million and have witnessed significant social changes, including civil rights, more women in the workforce, and increasing educational requirements (e.g., the pharmacy degree advance to a five-year degree).
- Generation X -- Born 1965-80: This is a relatively small population, which has been described as possessing independence and problem-solving skills, striving to become entrepreneurs and innovators, and seeking well-paying jobs but valuing a work-life balance.
- Millennials -- Born 1980-2000: They have been described as upbeat and team-oriented, close to their parents, and having high expectations for speed and efficiency, having grown up in the mobile digital age.
- Homelanders -- 2000-2020: They were born after 9/11. They are the most ethnically diverse generation to date, and the use of active learning will impact their job expectations.

The Council discussion centered mainly on older pharmacists who may not have kept up on technology and other aspects of patient care and may have limited their careers as a result. Ideas to address the generational issues included educational programming on reverse mentoring, utilizing new practitioners as reverse mentors, or a modified PGY1-type program for seasoned pharmacists with limited direct patient care training and skills.

COUNCIL ON PHARMACY MANAGEMENT: POLICY RECOMMENDATIONS

The Council on Pharmacy Management is concerned with ASHP professional policies related to the process of leading and directing the pharmacy department in hospitals and health systems. 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.

Lea S. Eiland, *Board Liaison*

Council Members

Roger Woolf, *Vice Chair* (Washington)
Mohammed Abdulwahhab, *New Practitioner* (Florida)
Andrew Albanese (Oregon)
Rachel Booze, *Student* (Indiana)
Sam Calabrese (Ohio)
W. Lynn Ethridge (South Carolina)
Christine Marchese (Rhode Island)
Tricia Meyer (Texas)
Robert Oakley (Kentucky)
Cynthia Williams (Virginia)
David Chen, *Secretary* (Maryland)

1. Controlled Substance Diversion and Patient Access

- 1 To enhance awareness by pharmacists, healthcare providers, and the public of drug
- 2 diversion and abuse of controlled substances; further,

- 3 To advocate that pharmacists take a leadership role in national efforts to reduce the
- 4 incidence of controlled substance abuse; further,

- 5 To advocate that pharmacists lead collaborative efforts by organizations of
- 6 healthcare professionals, patient advocacy organizations, and regulatory authorities
- 7 to develop and promote best practices for preventing drug diversion and
- 8 appropriately using controlled substances to optimize patient access and therapeutic
- 9 outcomes; further,

- 10 To advocate that the Drug Enforcement Administration and other regulatory
- 11 authorities interpret and enforce laws, rules, and regulations to support patient
- 12 access to appropriate therapies, minimize burdens on pharmacy practice, and
- 13 provide reasonable safeguards against fraud, misuse, abuse, and diversion of
- 14 controlled substances; further,

- 15 To encourage healthcare organizations to establish programs to support patients and
- 16 personnel with substance abuse and dependency issues.

Rationale

Pharmacy managers and pharmacists-in-charge (PICs) have increasing responsibility for ensuring controlled substance management and storage across large healthcare organizations. This responsibility has increased as aquisition of physician office practices, clinics, and other non-hospital business units continue.

Controlled substance abuse is rising in the United States. According to the Drug Enforcement Administration (DEA) [2014 National Drug Threat Assessment Summary](#), deaths involving controlled substances outnumber those involving heroin and cocaine combined. Additionally, the economic cost of nonmedical use of prescription opioids alone in the U.S. totals more than \$53 billion annually. All pharmacies and healthcare organizations that handle controlled substances are required to have storage and distribution systems in place that prevent diversion. Due to the numerous medication-access points embedded within hospital distribution systems, diversion can be difficult to detect. Theft of controlled substances by healthcare professionals remains a serious problem that can lead to patient harm and jeopardize patient safety. Drug addiction among healthcare workers is well documented. One survey found that nurses who reported a perception of easier availability of controlled substances were almost twice as likely as others to divert and use a controlled substance. In another survey, 19% of pharmacists reported use of a controlled substance without a prescription during the preceding 12 months. Even the most conservative estimates are that 8–12% of physicians will develop a substance abuse problem at some point during their career, although the exact rate of substance abuse among physicians is uncertain.

Many challenges exist for healthcare institutions in managing controlled substances. New laws and regulations, including DEA quotas and controlled substances monitoring requirements at retail outpatient dispensing facilities, are meant to decrease diversion and illegal activity but are also impacting patients and pharmacists. In addition, the DEA has allowed hospitals and clinics with an onsite pharmacy and status as an authorized collector to maintain collection receptacles onsite and administer mail-back programs for controlled substances, adding another layer of complexity to controlled substance disposal. Pharmacists in healthcare organizations must meet standards and comply with laws and regulations from a variety of sources, including the DEA, The Joint Commission, Det Norske Veritas, other accreditation organizations, and state and federal governments. The [ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance](#) offers detailed suggestions for pharmacists in addressing substance abuse in their institutions and communities.

Background

This topic was considered by the Council in response to the New Business Item from the June 2015 House of Delegates as well as suggestions by Council members and ASHP staff. This policy recommendation was expedited for Board consideration due to its importance to ASHP members, as indicated by the New Business Item, the experience of Council and Board members, and anecdotal evidence.

2. Surface Contamination on Packages and Vials of Hazardous Drugs

- 1 To advocate that pharmaceutical manufacturers eliminate surface contamination on
- 2 packages and vials of hazardous drugs; further,

- 3 To inform pharmacists and other personnel of the potential presence of surface
- 4 contamination on the packages and vials of hazardous drugs; further,

- 5 To advocate that the Food and Drug Administration require standardized labeling
- 6 and package design for hazardous drugs that would alert handlers to the potential
- 7 presence of surface contamination; further,

- 8 To encourage healthcare organizations to adhere to published standards and
- 9 regulations to protect workers from undue exposure to hazardous drugs.

(Note: This policy would supersede ASHP policy 0618.)

Rationale

The outer surfaces of vials of hazardous drugs have been shown to be contaminated with hazardous substances, and pharmacy and other personnel handling those vials may unknowingly be exposed. ASHP advocates that individuals involved in drug distribution, receiving, and inventory control adhere to safe handling guidelines to avoid undue exposure to hazardous substances but recognizes the limits of these best practices. Pharmaceutical manufacturers have a responsibility to provide vials that are devoid of surface contamination due to inadequate vial-cleaning procedures, and can reduce contamination by using decontamination equipment and protective sleeves during the manufacturing process.

The purpose of United States Pharmacopeia (USP) Chapter 800 is to establish standards for protecting personnel and the environment when handling hazardous drugs. Each year, approximately 8 million U.S. healthcare workers are potentially exposed to hazardous drugs, according to the Centers for Disease Control and Prevention. USP Chapter 800 includes definitions, processes, and worker responsibilities that enhance understanding of risk and limit exposure. To support workers in protecting their patients, themselves, and the environment, the FDA and manufacturers will need to develop new production and processing standards to mitigate exposures, including labeling and package design that alerts handlers to the possibility of contamination.

Background

The Council voted to recommend amending policy 0618, Elimination of Surface Contamination on Vials of Hazardous Drugs, as follows (underline indicates new text):

To advocate that pharmaceutical manufacturers eliminate surface contamination on packages and vials of hazardous drugs; further,

To inform pharmacists and other personnel of the potential presence of surface contamination on the packages and vials of hazardous drugs; further,

To advocate that the Food and Drug Administration require standardized labeling and package design for hazardous drugs that would alert handlers to the potential presence of surface contamination; further,

To encourage healthcare organizations to adhere to published standards and regulations to protect workers from undue exposure to hazardous drugs.

The Council discussed the proposed USP Chapter 800 and the best practices contained in the [ASHP Guidelines on Handling Hazardous Drugs](#). The Council reviewed the comments ASHP had submitted to the USP, which addressed many of the concerns of ASHP members and the Council. The Council felt there was additional advocacy necessary to aid handlers in identifying hazardous drug products, similar to FDA product labeling of high-concentration electrolytes. The Council suggested that a resource, such as an ASHP white paper or AJHP article, on the critical aspects of medical surveillance and potential impacts on the pharmacy department would be helpful.

3. Pharmaceutical Distribution Systems

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

- 7 To encourage wholesalers and other trading partners in the drug supply chain to
- 8 implement policies and procedures consistent with United States Pharmacopeia
- 9 Chapter 800 to mitigate the risk of exposure as hazardous drug products move
- 10 through the supply chain.

(Note: This policy would supersede ASHP policy 1016.)

Rationale

Wholesaler distributors have traditionally contracted with hospitals and health systems for basic drug product distribution and other services. Many wholesalers have made a large portion of their revenue through speculative buying and other business practices that are no longer desirable because of requirements for pedigrees, the risk of buying counterfeit or adulterated products, demands by manufacturers to limit product transactions, and the need to manage drug recalls. These changes, plus the vast diversification of many wholesaler distributors, have resulted in new business models that will affect how hospitals acquire and manage

pharmaceuticals. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient. ASHP supports wholesaler/distribution business models that meet the requirements of hospitals and health systems.

Background

The Council voted to recommend amending policy 1016, Pharmaceutical Distribution Systems, as follows (underscore indicates new text):

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

To encourage wholesalers and other trading partners in the drug supply chain to implement policies and procedures consistent with United States Pharmacopeia (USP) Chapter 800 in order to mitigate the risk of hazardous drug exposure as products move through the supply chain.

The Council discussed the proposed USP Chapter 800 and the best practices contained in the [ASHP Guidelines on Handling Hazardous Drugs](#). The Council reviewed the comments ASHP had submitted to USP which addressed many of the concerns of ASHP members and the Council. The Council felt there was additional advocacy necessary regarding hazardous drugs and how they are transported throughout the supply chain. The Council also recommended that ASHP create a resource paper with checklists regarding critical steps and processes pharmacy leaders should be assessing and implementing regardless of the approval timeline of USP Chapter 800.

4. Patient Satisfaction

- 1 To encourage pharmacists to evaluate their practice settings for opportunities to
- 2 improve the level of satisfaction patients have with healthcare services and with the
- 3 outcomes of their drug therapy; further,

- 4 To educate pharmacists and pharmacy personnel about the relationship between
- 5 patient satisfaction and positive health outcomes, further,

- 6 To develop or adopt tools that will (1) provide a system for monitoring trends in the
- 7 quality of pharmacy services to patients, (2) increase recognition of the value of
- 8 pharmacy services, and (3) provide a basis for making improvements in the process
- 9 and outcomes of pharmacy services in efforts to engage patients and improve
- 10 satisfaction; further,

- 11 To facilitate a dialogue with and education of national patient satisfaction database
- 12 vendors on the role and value of clinical pharmacy services.

(Note: This policy would supersede ASHP policy 0104.)

Rationale

A major component of quality of healthcare is patient satisfaction, which is critical to how well patients respond and adhere to healthcare. Research has identified a clear link between patient outcomes and patient satisfaction scores. Additionally, patient satisfaction is a key determinant of quality of care and an important component of pay-for-performance metrics. Pharmacy leaders need to continually assess how pharmacists and pharmacy services support improved patient satisfaction with their care across the continuum of practice sites, including how pharmacists contribute to team-based care.

Background

The Council discussed ASHP policy 0104 as part of sunset review. The Council considered the policy to still be relevant but recommended amending the policy as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To encourage pharmacists to evaluate ~~establish mechanisms within~~ their practice settings for opportunities to improve ~~measure~~ the level of satisfaction patients have with healthcare pharmacy services and with the outcomes of their drug therapy; further,

To educate pharmacists and pharmacy personnel about the relationship between patient satisfaction and positive health outcomes; further,

To develop or adopt tools ~~construct such mechanisms in a manner~~ that will (1) provide a system for monitoring trends in the quality of pharmacy services to patients, (2) increase recognition of the value of pharmacy services, and (3) provide a basis for making improvements in the process and outcomes of pharmacy services in efforts to engage patients and improve satisfaction; further,

To facilitate a dialogue with and education of national patient satisfaction database vendors on the role and value of clinical pharmacy services.

The Council felt the original policy was created when patient satisfaction measurement requirements were in the early stages of being required by payers, and pharmacy was focused on ensuring pharmacist's role and influence on these measures needed to be a uniquely captured set of data. With the continued evolution of patient satisfaction measures and understanding on its impact on patient outcomes, the tools in the marketplace have become more team-based and standardized. The Council noted that pharmacists' understanding of the

connection between patient outcomes and satisfaction needs to be enhanced, including knowledge of effective approaches to optimize patient outcomes, with satisfaction being one facet of measures to utilize. The Council also reviewed ASHP policy 1107, Patient-Reported Outcomes Tools, and concluded that that policy, although similar, is more specific to patient tools pertaining to research because it emphasizes that patient-centric reporting of outcomes (e.g., what lifestyle changes to reach certain clinical targets were acceptable) is an important tool to be utilized in any patient-care setting.

Board Actions

Sunset Review of Professional Policies

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

- [Pharmacy Benefits for the Uninsured](#) (0101)
- [Medication Formulary System Management](#) (0102)
- [Gene Therapy](#) (0103)
- [Computerized Prescription Order Entry](#) (0105)
- [Minimizing the Use of Abbreviations](#) (0604)
- [ASHP Statement on Leadership as a Professional Obligation](#) (1123)

Other Council Activity

Controlled Substance Diversion and Patient Access

The Council voted to explore the feasibility of ASHP conducting a stakeholder event to evaluate the needs of pharmacists managing controlled substances and providing comprehensive and appropriate care for patients; further, to consider the issues to be addressed by such an event, including: (1) needs assessment on types and level of resources and education for pharmacy leaders, healthcare providers, and the public, (2) evaluation of controlled substance laws and regulations and the impact they have on providing legitimate patient care, (3) establishing best practices to minimize diversion, (4) identifying risk points and lack of harmonization among laws and regulations for improvements and/or advocacy, and (4) best mechanisms to improve sharing of ideas and information between stakeholder groups.

The Council also voted to develop ASHP guidelines describing best practices for controlled substance diversion management and risk reduction, including programs to support patients and personnel with substance abuse and dependency issues.

Controlled substance diversion and abuse has reached the attention at the highest levels in the United States, with even the White House weighing in on the crisis facing the country. In the past 4-5 years, the DEA has levied large fines on chain drugstores, drug wholesalers, and most recently, major hospitals. Pharmacy managers and pharmacists-in-

charge (PICs) have increasing responsibility for ensuring controlled substance management and storage across large healthcare organizations.

The Council discussed the increased risk to organizations as acquisitions of physician office practices, clinics, and other nonhospital-based business units continue, and the many challenges that exist for healthcare institutions in managing controlled substances. Council members also discussed their concern that many pharmacy leaders do not proactively manage controlled substance diversion and that, for those that do have proactive processes, it is tremendously time-consuming and requires strict policies, an interdisciplinary team, and a higher level of understanding of laws and legal ramifications of diversion discovery.

The Council also discussed how new laws have been implemented, including what were described as “DEA quotas” and the controlled substances monitoring requirements at the retail outpatient dispensing facilities that are meant to decrease diversion and illegal activity but which are impacting ASHP members in serving their patients. Pharmacists in healthcare institutions must meet standards and comply with regulations and laws from a variety of sources, including the DEA, The Joint Commission, and state and federal authorities. The Council felt ASHP should take a leadership role in developing best practices on diversion, taking into consideration models in which states have organized coalitions to research the problem of controlled substance diversion and develop best practices. Currently there are no national best practices or guidelines that institutions can adopt to improve controlled substance diversion detection systems.

Impact of Rising Drug Costs on Pharmacy Budgets and Patient Care

The Council discussed the escalation of drug prices and how they have increased steadily over the past few years. This increase is a multifactorial issue, including the introduction of new medications on the market, drug shortages, and the effect of rising prices of generic drug products. As a result, drug products that used to cost a few dollars a month have increased to sometimes hundreds of dollars a month, causing undue burden on patients who are struggling to afford their therapy. Although some drug companies have introduced patient assistance programs, the significant remaining expense can create a barrier to proper care. Additionally, the high prices of new drugs entering the marketplace can create access issues for patients through large copays or health plan prior authorization requirements. These high costs and barriers to care present not only a formulary and cost management issue for hospitals and health systems but also are rapidly becoming an ethical issue as medications become unaffordable for vulnerable populations. Hospital and health-system leaders have become more concerned about the financial implications of higher outpatient drug costs for patients as health plan deductibles, coinsurance, and copays increase, and some drugs come to market with limited or uncertain benefits for patients. Increases in prices have changed how formularies are discussed and managed at the pharmacy and therapeutics committee level. Strategies to mitigate costs include requiring medications that reach a threshold cost to be triggered for review, proof of efficacy or superiority over an existing formulary agent, and utilizing patient’s-own medication policies. Additionally, pharmacy leaders are often faced with the challenge of managing their budgets as many of these medications are impacting outpatient populations.

The Council acknowledged and reviewed the ASHP policies and guidelines on mitigating drug prices and formulary strategies. The Council suggested that the [ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems](#) be updated. The Council discussed the need for education and resources for best practices and innovations that could be used to mitigate the impact of rising costs (e.g., alternative therapies), management of hospital committees as more facilities include requirements to review certain drug use based on patient setting and end-of-life care, and management of risks and liability when rising prices and shortages are emergent-care drugs. Additionally, the Council requested that ASHP study the need for policy or advocacy on parity across all drug classes and not just oncology medications.

Management of Pharmacy Workforce Supply and Demand and Impact on Salaries

The Council discussed how the growth in the number of pharmacy graduates, increased use of pharmacy technicians and technology in retail and institutional dispensing operations, and other factors have converged to produce an ample supply of pharmacists for health-system entry-level positions nationwide. Council members also discussed evidence that there is a downward trend in salaries in parts of the country.

The Council felt ASHP policies were mainly focused on education and preparation of the workforce and not on supply and demand of pharmacists. During the discussions, the Council decided it was not ASHP's role through policy to address supply and demand directly, but it was the quality of the workforce and educating pharmacy leaders on ways to engage colleges of pharmacy to ensure the best-qualified candidates and graduates were created to meet the demands of pharmacy and healthcare.

The Council also discussed the current technician workforce and the pending 2020 Pharmacy Technician Certification Board requirements. The Council expressed concerns that the requirement could have unintended impact on students and potential students for colleges of pharmacy, especially in light of the lack of access and cost of ASHP-accredited technician training programs. The Council suggested ASHP investigate distance learning programs and develop resources to promote the development of ASHP-accredited technician training programs through hospitals and health systems.

Impact of Bundled Service Payments and Site of Care Trends with Payer

The Council noted that since the passage of the Affordable Care Act, the Centers for Medicare & Medicaid Services (CMS) and other payers have been rapidly moving from a fee-for-service reimbursement system to bundled payment arrangements and alternative payment models. Bundled payment models have been expanded to long-term care, inpatient rehabilitation, skilled nursing, and home health by CMS, and the 2016 inpatient prospective payment system proposed rule contains policies that will continue to increasingly shift Medicare payments from volume to value. Additionally, in a March 2012 Report to Congress, the Medicare Payment Advisory Commission recommended that CMS equalize the rate paid for evaluation and

management visits in hospital outpatient departments and freestanding physician offices. The Department of Health and Human Services Office of the Inspector General has said that CMS could save billions of dollars if the agency reduces hospital outpatient department payment rates for ambulatory surgical center-approved procedures to ambulatory surgical center payment rates.

The Council also noted that while CMS is moving toward bundled payments in the ambulatory care environment, pharmacy chains such as CVSHealth and Walgreens are expanding into primary care. CVS MinuteClinics, staffed by nurse practitioners and physician assistants, are the largest retail medical clinic provider in the United States. Walgreens is utilizing video technology to offer 24/7 access to physicians, while also allowing a health system in Oregon to own and operate its in-store healthcare clinics. Both companies are providing competition in the ambulatory care market, in part by increasing their ability to capture patient prescriptions.

Sites of care that are likely to be impacted by these changes include ambulatory care clinics, federally qualified health centers, patient-centered medical homes, and medication therapy management services performed electronically.

Impact of ICD-10 on Pharmacy Practice and Quality of Data and Reimbursement

The Council discussed the implementation of International Classification of Diseases, 10th Revision (ICD-10) codes and the impact they will have on health-system pharmacy practice. ICD-10 coding has been in existence since the early 1990s, but its use has been restricted to death certificates and mortality data. However, starting October 1, 2015, ICD-10 will be used nationwide for coding diagnosis and inpatient procedures in all U.S. health systems and settings. As with most new systems, the pressure to implement and be compliant is daunting, especially if there isn't a feeling of readiness.

Unlike its predecessors, ICD-10 codes are very different from ICD-9 codes, resulting in significant work being required to change to the new standard. For example, ICD-9 has just over 13,000 diagnosis codes, whereas ICD-10 has over 60,000. The new standard will require updates to almost every clinical and administrative process in all healthcare settings. Moreover, the updated codes will include changes in the reimbursement service and how insurance coverage is defined.

The Council noted pharmacy leaders and their informatics experts will need to ensure they are engaged in the implementation of ICD-10 within their organizations, as the implementation will have ramifications for clinical decision support, quality and outcomes reporting, and reimbursement. For example, performance measures are based on ICD-9 and will be converted to more granular and specific ICD-10 codes. Additionally, with many health systems owning and operating prescription benefit management-based outpatient pharmacy services, engaging with payers reliant on National Council for Prescription Drug Programs-based systems will be critical.

The Council felt existing ASHP policy, statements, and guidelines expressed the advocacy and guidance needs for ASHP, but there was significant education necessary for health-system pharmacists to understand the benefits and risks associated with not having pharmacy

representation included in the establishment of new policies and procedures at their organizations. Representatives from the Section of Pharmacy Informatics and Technology (SOPIT) were present during discussions and acknowledged they would develop FAQs and resources for ASHP members, including how ICD-10 coding impacts the revenue cycle, patient safety, automation of prior authorization, and refinement of diagnosis.

COUNCIL ON PHARMACY PRACTICE: POLICY RECOMMENDATIONS

The Council on Pharmacy Practice is concerned with ASHP professional policies related to the responsibilities of pharmacy practitioners in hospitals and health systems. 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.

Ranee M. Runnebaum, *Board Liaison*

Council Members

Julie Groppi, *Chair* (Florida)
Tate Trujillo, *Vice Chair* (Indiana)
Lindsey Amerine (North Carolina)
Abigail Brooks, *New Practitioner* (Minnesota)
Mark Dunnenberger (Illinois)
Michael Ganio (Ohio)
Meghan Garrett, *Student* (Tennessee)
Sandra Leal (Arizona)
Christina Martin (Pennsylvania)
Lisa Mascardo (Iowa)
LeeAnn Miller (Connecticut)
Elizabeth Wade (New Hampshire)
Steven Nelson, *Secretary* (Iowa)

1. Automated Preparation and Dispensing Technology for Sterile Preparations

- 1 To encourage health systems to adopt automation and information technology for
- 2 preparing and dispensing sterile preparations when such adoption is (1) planned,
- 3 implemented, and managed with pharmacists' involvement; (2) implemented with
- 4 adequate resources to promote successful development and maintenance; and (3)
- 5 supported by policies and procedures that ensure the safety, effectiveness, and
- 6 efficiency of the medication-use process; further,

- 7 To foster further research, development, and publication of best practices regarding
- 8 automation and information technology for preparing and dispensing sterile
- 9 preparations.

Rationale

Adoption of automation and information technology for preparing and dispensing sterile preparations is increasing but not evenly distributed among healthcare organizations. A 2014 ASHP survey showed that 40-60% of larger health systems used automated IV compounding technology in compounding nutrition support preparations. Less than 20% of all health systems surveyed employed barcode verification in their IV medication preparation process. A 2013 survey found that less than 10% of all health systems surveyed used drug workflow software to manage IV drug preparation, verification, and dispensing.

The reasons for these disparate rates of adoption are numerous. Each institution has a different break-even point of investment versus return, and challenges of implementation can be daunting. Some organizations have implemented automated compounding technology only

to withdraw it later. The probability of successful adoption of automation and information technology for preparing and dispensing sterile preparations is increased when it is planned, implemented, and managed with pharmacists' involvement and when adequate resources (including time) are planned for and provided not only to develop but also to maintain the technologies. Upfront costs and ongoing investments need to be clear from the start. Use of such technology also requires well-crafted policies and procedures to ensure the safety, effectiveness, and efficiency of the medication-use process. Research, development, and publication of best practices regarding automation and information technology for preparing and dispensing sterile preparations will require efforts not only from vendors but also from those who have experience with the process.

Background

The Council considered this topic upon suggestion from an ASHP member who expressed concern that the highest-risk products that pharmacy handles, injectable drugs, have a lower rate of automation safeguards, such as barcode verification, than oral medications. Council members suggested that more research needs to be done, which could include demonstration grants from manufacturers. Council members also suggested that ASHP could provide case studies or lessons learned and perhaps coordinate virtual site visits (e.g., via Webex).

2. Integrated Approach for the Pharmacy Enterprise

- 1 To advocate that pharmacy department leaders promote an integrated team
- 2 approach for all pharmacy professionals involved in the medication-use process;
- 3 further,

- 4 To advocate a high level of coordination of all components of the pharmacy
- 5 enterprise across the continuum of care for the purpose of optimizing (1)
- 6 medication-use safety, (2) quality, (3) outcomes, and (4) the value of drug therapy;
- 7 further,

- 8 To encourage pharmacy department leaders to develop and maintain patient-
- 9 centered practice models that integrate into a team all pharmacy professionals
- 10 engaged in the medication-use process, including general and specialized clinical
- 11 practice, drug-use policy, product acquisition and inventory control, product
- 12 preparation and distribution, and medication-use safety and other quality initiatives.

(Note: This policy would supersede ASHP policy 0619.)

Rationale

In November 2004 the Joint Commission of Pharmacy Practitioners adopted a vision for pharmacy practice that states that "pharmacists will be the healthcare professionals responsible for providing patient care that ensures optimal medication therapy outcomes." At the time, ASHP envisioned the pharmacy department as an integrated entity serving as the

nucleus for direct and team-based engagement of all pharmacists who work in the institution in an open feedback loop among various areas that support the overall pharmacy enterprise, including drug-use policy, product acquisition and inventory control, frontline and specialized clinical practice, product preparation and distribution, and medication-use safety and quality. Support for such an integrated model is based on recognition that the medication-use process is a tightly linked continuum in which the activities of one area affect other upstream and downstream processes.

In the decade since, the healthcare enterprise has continued its evolution from single hospitals to integrated systems and networks. These systems have become even more complex as they expand into new businesses, such as physician practices and outpatient care sites. As these organizations seek to standardize operations and gain economies of scale, pharmacy leaders have recognized that the evolving pharmacy enterprise is more far-reaching and sophisticated than in the past, and pharmacy leaders at all levels have to manage their pharmacy services in the context of the overall goals and needs of the organization across a wide array of business units, care settings, and organizations. ASHP continues to believe that the integrated model will optimize the value of drug therapy (i.e., obtaining the most benefit from the resources invested in drug products, taking into account both the cost of drug products and appropriate use of the products); medication-use safety (i.e., avoiding preventable adverse drug events, including medication errors); patient and economic outcomes, and healthcare quality.

Management of pharmacy services is no longer confined to drug distribution and clinical pharmacy but also includes human resources management, integrity of the electronic health record and related patient-care information, and oversight of various business partners. Pharmacy leaders within these evolving health systems confront many new challenges, ranging from communication among the pharmacy management team, decisions on pharmacy infrastructure purchases and contracting, identification of critical services and standardization, succession planning and workforce development, supply chain management, human resource coordination, and strategic planning across diverse healthcare sites within the system. Further challenging health system pharmacy leaders are coordinating pharmacy services across larger geographical regions and organizational boundaries. To cope with these new challenges, pharmacy department leaders need to develop and maintain patient-centered practice models that integrate into a team all pharmacy professionals engaged in the medication-use process of their organizations, including general and specialized clinical practice, drug-use policy, product acquisition and inventory control, product preparation and distribution, and medication-use safety and other quality initiatives.

Background

The Council considered ASHP policy 0619, Integrated Team-Based Approach for the Pharmacy Enterprise, as part of sunset review and recommended amending it as follows (underscore indicates new text; ~~strike through~~ indicates deletions):

To advocate that pharmacy department leaders promote an integrated team approach for all pharmacy professionals involved in the medication-use process; further,

To advocate a high level of coordination of all components of the pharmacy enterprise in hospitals and health systems across the continuum of care for the purpose of

optimizing ~~and~~ (1) medication-use safety (2) quality, (3) outcomes, and (4) the value of drug therapy; further,

To encourage pharmacy department leaders to develop and maintain patient-centered practice models that integrate into a team all ~~components of pharmacy professionals engaged in the pharmacy enterprise~~ medication-use process, including general and specialized clinical practice, drug-use policy, product acquisition and inventory control, product preparation and distribution, and medication-use safety and other quality initiatives.

The Council discussed the expansion of healthcare organizations into large systems with responsibility for managing healthcare for large numbers of patients across large geographical areas and many different settings. Council members recognized the challenge of integrating the activities of pharmacists and pharmacy technicians across such a broad spectrum, especially when these activities span business units, but the Council endorsed the vision of patient-centered practice models that integrate into a team all pharmacy professionals engaged in the medication-use process.

3. Preventing Exposure to Allergens

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

- 5 To advocate that pharmacy departments actively review allergens pertinent to
- 6 medication therapy and minimize patient and healthcare worker exposure to known
- 7 allergens, as feasible; further,

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

- 10 To advocate that pharmacy departments be actively involved soliciting information
- 11 about patient food and environmental allergies that may indicate a potential for
- 12 medication interaction or adverse event; further,

- 13 To encourage pharmacist education on medication-related allergens.

Rationale

In 2005, ASHP adopted policy 0501, Mandatory Labeling of the Presence of Latex, and in 2008 adopted policy 0808, Excipients in Drug Products (now ASHP policy 1528). The common theme in these policies is that patients may be exposed to potentially life-threatening allergens in items encountered in the medication-use process (i.e., natural rubber latex, drugs, drug product excipients, devices, and supplies). Pharmacist involvement in 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 and clinical decision support systems, some well-known cross-sensitivities are good candidates to be included in medication-related databases.

Background

In 2014, the Council reviewed and reaffirmed ASHP policy 0501, Mandatory Labeling of the Presence of Latex, and recommended a revised policy that became ASHP policy 1528, Excipients in Drug Products. After an ASHP member suggested strengthening pharmacy vigilance regarding latex, the Council decided to broaden their perspective on the issue and recommend a policy that addresses pharmacy vigilance regarding allergens throughout the medication-use process.

4. Accreditation of Compounding Facilities

To discontinue ASHP policy 0617, Accreditation of Compounding Facilities, which reads:

- 1 To encourage facilities where extemporaneous compounding of medications occurs
- 2 to seek accreditation by a nationally credible accreditation body.

Background

The Council discussed the policy as a result of sunset review and concluded that changes in law, regulation, practice, and ASHP policy make ASHP policy 0617 redundant. The Council noted that the intent of encouraging accreditation was to foster uniform standards of compounding practice. The Drug Quality and Security Act (DQSA) of 2013, and implementing guidance from the FDA that created the 503A and 503B regulatory scheme for compounding facilities, accompanied by more stringent state oversight of compounding following the New England Compounding Center tragedy, have achieved the goals that the Council hoped would be achieved through accreditation. In addition, ASHP policy 1406, Federal and State Regulation of Compounding, calls for state adoption of United States Pharmacopeia (USP) compendial standards and mandatory state registration of compounding facilities, further helping address the gaps the Council was concerned about in 2005, when policy 0617 was initially developed. Finally, the different focus of accrediting organizations and the differences in their accreditation standards makes the benefit of meeting such accreditation standards questionable.

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.)

- [Influenza Vaccination Requirements to Advance Patient Safety and Public Health](#) (0615)
- [Safe and Effective Extemporaneous Compounding](#) (0616)
- [Elimination of Surface Contamination on Vials of Hazardous Drugs](#) (0618)
- [Pharmacist Accountability for Patient Outcomes](#) (1114)
- [Ethical Use of Placebos in Clinical Practice](#) (1116)
- [Pharmacist's Right of Conscience and Patient's Right of Access to Therapy](#) (0610)
- [ASHP Position on Assisted Suicide](#) (9915)
- [Safe Disposal of Patients' Home Medications](#) (0614)
- [Just Culture](#) (1115)
- [Pharmacists' Role in Medication Reconciliation](#) (1117)

Other Council Activity

Pharmacist's Right of Conscience and Patient's Right of Access to Therapy

The Council reviewed ASHP policy 0610, Pharmacist's Right of Conscience and Patient's Right of Access to Therapy, in response to a recommendation from the House of Delegates that ASHP "should revise position 0610 to remove the requirement of referral and replace it with 'transfer care' in order to place decision-making regarding ethically troubling therapies in the hands of the patient and remove the burden of cooperation on the part of the pharmacist." The Council reviewed the conscientious objection policies of other organizations of healthcare providers and concluded that existing ASHP policy is adequate but that the terms "referral" and "transfer of care" could be clarified in a rationale for the existing policy, which is the following paragraph.

ASHP affirms pharmacists' right to decline to participate in therapies they consider to be morally, religiously, or ethically troubling but recognizes that a right of conscience must balance a pharmacist's deeply held beliefs with his or her professional duty and the patient's right to access legally prescribed and medically indicated treatments. To achieve this balance, systems to protect the patient's right to timely access to therapy should be developed in advance of the presentation of a prescription to a pharmacist or other employee who might exercise the right of conscience. The right of conscience therefore creates an affirmative responsibility on the part of the pharmacist to proactively notify his or her employer about therapies of concern. In addition, a pharmacist exercising the right of conscience must respect and serve the legitimate healthcare needs and desires of the patient and must provide a referral without any actions to persuade, coerce, or otherwise impose on the patient the pharmacist's values, beliefs, or objections. For the purposes of this policy, "referral" is defined in manner similar to that used by the [American Academy of Family Physicians](#) (Consultations, Referrals, and Transfers of Care;

2012 COD): a referral is a request from one pharmacist to another to assume responsibility for management of one or more of a patient's specified problems, for a specified period of time, until the problem(s)' resolution, or on an ongoing basis, and represents a temporary or partial transfer of care to another pharmacist for a particular condition. When conscience requires a pharmacist also to decline to refer the patient to a specific provider who can provide the legally prescribed and medically indicated treatment, the pharmacist should offer impartial guidance to patients about how to inform themselves regarding access to the therapy. The [National Catholic Bioethics Center](#) suggests that healthcare providers declining to refer may assist patients with accomplishing a transfer of care to another provider or institution of the patient's choosing by providing a general list of other providers or institutions based on geographic vicinity or area of specialty, so long as the list is not developed based on the criterion of whether the providers are known or believed to offer the therapy in question. Institutions should have processes in place to ensure that the transfer of care process does not interfere with the patient's right to obtain legally prescribed and medically indicated treatments. Any accommodations made on the basis of a pharmacist's decision to exercise the right of conscience should be nonpunitive.

ASHP Position on Assisted Suicide

The Council reviewed ASHP policy 9915, ASHP Position on Assisted Suicide, in response to a recommendation from the House of Delegates that ASHP "should revise position 9915 to clearly oppose pharmacists' participation in assisted suicide on the basis that it is not consistent with the pharmacists' role in affirming life and assisting patients in making the best use of medications." This issue has also grown in significance with the recent passing of laws legalizing assisted suicide along with court decisions decriminalizing the practice. In the United States this has occurred in Oregon (1997), Washington (2008), Montana (2009), Vermont (2013), and New Mexico (2014). The California legislature recently passed a law legalizing assisted suicide which is currently pending the Governor's decision. The Council considered the ASHP Statement on Pharmacist's Decision-making on Assisted Suicide, the Code of Ethics for Pharmacists, and the positions of the American Medical Association and American Nurses Association in reaffirming the existing policy. The Council concluded that the existing policy was relevant and appropriate, but that it would benefit from a rationale, which is the following two paragraphs.

The [Code of Ethics for Pharmacists](#) states that "a pharmacist promises to help individuals achieve optimum benefit from their medications [and] to be committed to their welfare" and that "a pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health." In pharmacist decision-making about participation in legal assisted suicide, those principles may clash. Patient autonomy dictates that they be free to exercise their ethical and legal right to choose or decline treatment. When legal treatment options conflict with the pharmacist's perceived obligations to the patient, it is essential for him or her to examine the moral and ethical issues of participating in the patient's treatment, but it remains incumbent on the pharmacist to place concern for the well-being of the patient at the center of professional practice, regardless of whether they agree with the values underlying a patient's choice of treatment or decision to forgo any particular treatment. The healthcare provider's duty to provide care and affirm life is interpreted by some to include ensuring the right of competent

patients to receive any legal treatment option, including assistance in dying. The [ASHP Statement on Pharmacist's Decision-making on Assisted Suicide](#) provides an overview of the guiding principles for the pharmacist's decision-making in assisted suicide, including professional tradition, respect for the patient, and professional obligations.

As more fully explored in ASHP policy 0610, Pharmacist's Right of Conscience and Patient's Right of Access to Therapy, pharmacists retain their right to refuse to participate in morally, religiously, or ethically troubling therapies, without retribution. Procedures should be in place to ensure that healthcare organizations can provide mission-compatible care to patients, and that healthcare providers practicing there are not a barrier to the organization's ability to provide that care.

Safe Disposal of Patients' Home Medications

The Council voted to develop an ASHP resource (e.g., a toolkit or web resource page) for pharmacists on implementing dropbox receptacles or mail-back medication disposal programs. During the sunset review of ASHP policy 0614, Safe Disposal of Patients' Home Medications, the Council identified the need to assist pharmacists in implementing patient-friendly medication disposal programs and voted to recommend development of an ASHP resource (e.g., a toolkit or web resource page) on the subject. The Council suggested that the following topics could be included in the resource: identifying community partners; generating funding; addressing liability; educating patients, prescribers, and administrators; and reducing over-prescribing. Council members suggested that sharps programs could serve as an example.

The Council also voted to request that the Council on Public Policy consider developing policy that would encourage state and federal legislation and regulation that would permit pharmacists to accept controlled substances as part of patient medication disposal programs regardless of onsite pharmacy status.

The Council noted that current DEA regulations limit hospital and clinic participation in patient medication take-back programs to those with an onsite pharmacy ([DEA Rule on Disposal of Controlled Substances \[79 FR 53519\]](#)). This restriction limits the ability of other health-system pharmacists, such as those practicing in clinic pharmacies without an onsite or retail pharmacy, from effectively participating in such patient medication disposal programs (e.g., mail-back programs and collection receptacles). The Council voted to request the Council on Public Policy to consider developing policy that would advocate that hospital and health-system pharmacies be allowed to participate, regardless of onsite pharmacy status.

Just Culture

The Council voted to request that the Council on Public Policy consider developing policy that would advocate that state boards of pharmacy adopt a *just culture* response when medication errors are reported.

During sunset review of ASHP policy 1115, Just Culture, the Council noted several examples of extreme punishments imposed by state boards of pharmacy in response to medication errors. The Council noted that Just Culture principles encourage the reporting of medication errors by reserving harsh punishments for reckless behavior rather than human or system errors and expressed concern that severe punishments for errors may discourage medication error reporting.

Council members noted that there is a lack of understanding of just culture and that an ongoing educational initiative also may be needed. Council members encouraged ASHP to review current educational offerings (meeting presentations and webinars) and AJHP articles to determine if this need has been addressed adequately by ASHP.

USP General Chapter 800: Hazardous Drugs – Handling in Healthcare Settings

The Council discussed the implications for members and ASHP of the pending publication of USP Chapter 800, Hazardous Drugs—Handling in Healthcare Settings. According to USP the purpose of the new proposed general chapter is to provide standards to protect personnel and the environment when handling hazardous drugs. The new proposed general chapter defines processes intended to reduce exposure to hazardous drugs to as low a limit as reasonably achievable.

The Council discussed the implications of implementing proposed Chapter 800. Council members recalled that when implementing USP Chapter 797, the ASHP gap analysis tool was very useful and wondered whether a checklist, a set of performance standards, or a similar tool is possible. Council members also expressed support for developing a diagram of the effects on Chapter 800 on the medication-use process. The questions Council members thought should be answered by the ASHP resource included:

- whether organizations should use the National Institute for Occupational Safety and Health (NIOSH) list of hazardous drugs or conduct an individual safety analysis;
- when the NIOSH list will be updated, and how organizations should respond to updates;
- how organizations should address new drugs not on the NIOSH list;
- how to construct a medical surveillance list (i.e., to include everyone who may handle hazardous drugs at any stage;
- whether distributors could be required to label totes that contain hazardous drugs (currently, the contents are not known until they're opened, which presents a hazard or a burden on practice);
- educational resources for staff (e.g., technicians and facilities staff);
- potential disparate impacts on small, rural, and critical access facilities;
- prioritization of risk-reduction actions (i.e., the relative value of specific actions), which could be expressed as a difficulty/resource rating and incorporated into a gap analysis tool, perhaps as add-on feature);
- how to communicate with vendors (i.e., a “Cliff Notes” version of Chapter 800 in “contractor speak”);
- how to implement the Chapter in alternative sites (e.g., physician offices); and
- education of and advocacy with accreditation organizations (e.g., TJC, DNV), administrators, and state board of pharmacy.

Council Guidance Documents

The Council reviewed the current schedule for development of guidance documents recommended by the Council and made several recommendations regarding continuing, suspending, or discontinuing development.

COUNCIL ON PUBLIC POLICY: POLICY RECOMMENDATIONS

The Council on Public Policy is concerned with ASHP professional policies related to laws and regulations that have a bearing on pharmacy practice in hospitals and health systems. 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.

Kelly M. Smith, *Board Liaison*

Council Members

John D. Pastor, *Chair* (Minnesota)
Gloria P. Sachdev, *Vice Chair* (Indiana)
Joe R. Anderson (New Mexico)
Anna Legreid Dopp (Wisconsin)
Emily L. Dyer (Virginia)
Ewa M. Dzwierzynski (Rhode Island)
Melissa A. Ortega (Massachusetts)
Kelley L. Ratermann, *New Practitioner*
(Kentucky)
Matthew P. Schneller, *Student* (Florida)
Maria D. Serpa (California)
Pamela L. Stamm (Georgia)
Joseph M. Hill, *Secretary*

1. Off-Label Promotion by Pharmaceutical Manufacturers

- 1 To advocate for authority for the Food and Drug Administration to regulate the
- 2 promotion and dissemination of information about off-label uses of medications and
- 3 medication-containing devices by manufacturers; further,

- 4 To advocate that such off-label promotion and marketing be limited to the responsible
- 5 dissemination of unbiased, truthful, non-misleading, and scientifically accurate
- 6 information based on authoritative, peer-reviewed literature not included in the New
- 7 Drug Approval process.

(Note: This policy would supersede ASHP policy 1120.)

Rationale

Congress is considering significant changes in the way drugs are developed, approved, and marketed in the United States. A provision in the House-passed 21st Century Cures bill (H.R. 6) would allow pharmaceutical manufacturers to promote off-label uses of their products to clinicians. This has raised concerns about the accuracy and sources of such information. Sources of such information, if unreliable, could put patient safety at risk. Despite these concerns about promotion of off-label uses by manufacturers, ASHP has suggested an amendment that would require Food and Drug Administration (FDA) oversight of such promotion and require promotional materials to be unbiased, truthful, non-misleading, scientifically accurate, and based upon peer-reviewed literature not included in the approved labeling of the drug. Materials would therefore require approval by the proper authority (FDA), meet certain requirements, and be truthful, non-biased and scientifically accurate.

Background

The Council voted to recommend revising ASHP policy 1120, Regulation of Off-Label Promotion and Marketing, as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To advocate for authority for the Food and Drug Administration to regulate the promotion and dissemination of information about off-label uses of medications and medication-containing devices by manufacturers; further,

~~To advocate that such promotion and dissemination be permitted only if manufacturers submit a supplemental new drug application for new use within a reasonable time after initial dissemination of information about off-label uses~~ off-label promotion and marketing be limited to the responsible dissemination of unbiased, truthful, non-misleading, and scientifically accurate information based on authoritative, peer-reviewed literature not included in the New Drug Approval process.

The Council was clear however, that it is generally concerned with the practice of off-label promotion by manufacturers and felt strongly that such concern be noted. These concerns are similar to those expressed in ASHP policy 1119, Direct-to-Consumer Advertising of Prescription and Nonprescription Medications, which opposes direct-to-consumer advertising of pharmaceuticals.

2. Timely State Board of Pharmacy Licensing

- 1 To advocate that state boards of pharmacy grant temporary licensure to pharmacists
- 2 who are relocating from another state in which they hold a license in good standing,
- 3 permitting them to engage in practice while their application for licensure reciprocity is
- 4 being processed; further,

- 5 To advocate that the National Association of Boards of Pharmacy (NABP) collaborate
- 6 with state boards of pharmacy to streamline the licensure reciprocity process; further,

- 7 To advocate that NABP collaborate with state boards of pharmacy to streamline the
- 8 licensure process through standardization and improve the timeliness of application
- 9 approval.

(Note: This policy would supersede ASHP policy 0612.)

Rationale

Pharmacists sometimes face challenges from delays in obtaining licensure by reciprocity when moving their practice from one state to another. Such delay may be due to the need for boards to review pharmacists' licensure records in all states in which they are licensed, administer a state pharmacy law exam, complete a criminal background check, and, in some cases, schedule an interview with the board. To address these challenges, boards of pharmacy should allow pharmacists in good standing to immediately practice in a different state when they change employment or enter a residency program. Granting pharmacists a temporary license for a period of up to six months while the state board completes its review would help meet

workforce demands while continuing to safeguard the public health. In some cases, pharmacists who are unable to obtain a license in a timely manner are unable to fully use the skills in which they have been trained. Without a license, the pharmacist may temporarily have to function as a technician or perform other tasks. For pharmacists participating in residency programs outside their state of licensure, several months of their residency program can elapse before they receive licensure reciprocity. Upon completion of a year-long residency program, many residents move to another state to practice and have to start the reciprocity process again.

Members in several states have reporting that in recent years state boards of pharmacy have been slow to issue pharmacy licenses. This is especially problematic for out-of-state residents who rely on state boards to grant them license prior to performing in a clinical capacity. Given that the licensing period can take several months, this has presented a problem for residents who have a limited timeframe to successfully complete their duties as pharmacy residents, typically one year. In some cases, state boards are urging residents to obtain a pharmacy technician license; however, this is inappropriate given the expertise and education residents have and the level of practice they're expected to engage in. Given its national scope, NABP is well-positioned to explore a broad solution to this problem rather than the current, incremental, state-by-state approach.

Background

The Council recommended amending ASHP policy 0612, Streamlined Licensure Reciprocity, as follows (underscore indicates new text):

To advocate that state boards of pharmacy grant temporary licensure to pharmacists who are relocating from another state in which they hold a license in good standing, permitting them to engage in practice while their application for licensure reciprocity is being processed; further,

To advocate that the National Association of Boards of Pharmacy (NABP) collaborate with state boards of pharmacy to streamline the licensure reciprocity process; further,

To advocate that NABP collaborate with state boards of pharmacy to streamline the licensure process through standardization and improve the timeliness of application approval.

The Council considered the policy in response to a recommendation from the House of Delegates that "ASHP develop a statement to NABP urging them to amend the model state pharmacy practice act to modernize and expedite initial licensing for pharmacists." In addition, the Council suggested that ASHP urge NABP to develop a task force to explore and make recommendations for improved licensing standards, including timeliness, access, and reciprocity.

The ASHP Accreditation Services Division will collaborate with ASHP Government Relations to provide outreach to NABP.

3. Inclusion of Drug Product Shortages in State Price-gouging Laws

- 1 To urge state attorneys general to consider including shortages of lifesaving drug
- 2 products within the definition of events that trigger application of state price-gouging
- 3 laws.

Rationale

Drug product shortages can lead to price gouging and trafficking in counterfeit and diverted drug products through gray-market distributors, which can ultimately result in adverse patient outcomes and increased healthcare costs. Strategies, including specific legislation with stiff penalties for price gouging during drug product shortages, are needed to deter these activities. Thirty-one states currently have price-gouging laws that prohibit price markups on life-sustaining products (e.g., food, water, fuel), usually during a time of disaster, natural or otherwise. In the absence of laws that specifically address price gouging during drug product shortages, ASHP urges state attorneys general to consider including shortages of lifesaving medications within the definitions of disaster or other trigger mechanisms for existing price-gouging laws.

Background

The Council considered the issue of price gouging during drug product shortages as it reviewed ASHP policy 1118, Drug Product Shortages. The Council concluded that encouraging state attorneys general to use existing laws against price gouging during shortages of lifesaving drug products was a strategy that could help reduce the impact of such shortages.

4. Home Intravenous Therapy

- 1 To support the continuation of a home intravenous therapy benefit under federal and
- 2 private health insurance plans, and expand the home infusion benefit under Medicare
- 3 at an appropriate level of reimbursement for pharmacists' patient care services
- 4 provided, medications, supplies, and equipment.

(Note: This policy would supersede ASHP policy 0414.)

Rationale

The Medicare Modernization Act of 2003 created an outpatient prescription drug benefit for Medicare beneficiaries, Medicare Part D. The new benefit provided prescription drug coverage for Medicare beneficiaries by private health plans and pharmacy benefit managers (PBMs). Although the law requires certain basic coverage packages across the plan continuum, it provides no coverage for services and supplies used in home infusion. The result is that the drug products used in home infusion may be covered, but the supplies (e.g., IV bags, tubing) and services related to providing and administering the drug products are not.

Over the years, efforts have been made to address this gap by moving coverage for the drug products from Part D to Part B, and including supplies and services within that coverage. Initially, this effort resulted in federal legislation to move home infusion coverage from Part D to Part B; however, projected costs to the Medicare program have prevented Congress from

passing the legislation. ASHP supports continuation of a home intravenous therapy benefit under federal and private health insurance plans and expanding the home infusion benefit under Medicare to include supplies and services related to providing and administering the therapy.

Background

The Council voted to recommend amending ASHP policy 0414, Home Intravenous Therapy Benefit, to strike “Part B” as follows (~~strike through~~ indicates deleted text):

To support the continuation of a home intravenous therapy benefit under federal and private health insurance plans, and expand the home infusion benefit under Medicare ~~Part B~~ at an appropriate level of reimbursement for pharmacists’ patient care services provided, medications, supplies, and equipment.

The Council on Public Policy reviewed the policy and agreed that a competing Part B “ask” would be detrimental to two policy objectives: expanding the home infusion benefit to cover related supplies and services as well as pharmacist provider recognition under Medicare Part B. Efforts by the pharmacy profession to obtain provider recognition within the Medicare program under Part B could be viewed as directly competing with the policy goal of Part B coverage of home infusion services and supplies, given that both would be funded through Medicare Part B and would require budget offsets to account for added costs in Part B of the Medicare Program.

In addition, the Council asked for input from ASHP’s Section of Ambulatory Care Practitioners Advisory Group on Home Infusion related to the sunset review of this policy. Those recommendations, and ensuing Council discussion, resulted in the suggestion that the reference to Part B be removed from the policy to keep the policy goal broad. This approach could allow for Part D plans to provide coverage for the supplies and services of home infusion therapy

5. Drug Product Shortages

To discontinue ASHP policy 1118, Drug Product Shortages, which reads:

- 1 To advocate that the Food and Drug Administration (FDA) have the authority to
- 2 require manufacturers to report drug product shortages and the reason(s) for the
- 3 shortage, and to make that information available to the public; further,

- 4 To strongly encourage the FDA to consider, in its definition of “medically necessary”
- 5 drug products, the patient safety risks created by use of alternate drug products
- 6 during a shortage; further,

- 7 To support government-sponsored incentives for manufacturers to maintain an
- 8 adequate supply of medically necessary drug products; further,

- 9 To advocate laws and regulations that would (1) require pharmaceutical
- 10 manufacturers to notify the appropriate government body at least 12 months in
- 11 advance of voluntarily discontinuing a drug product, (2) provide effective sanctions
- 12 for manufacturers that do not comply with this mandate, and (3) require prompt
- 13 public disclosure of a notification to voluntarily discontinue a drug product; further,

- 14 To encourage the appropriate government body to seek the cooperation of
- 15 manufacturers in maintaining the supply of a drug product after being informed of a
- 16 voluntary decision to discontinue that product.

Background

ASHP policy 1118 was last updated in 2010 to reflect ASHP’s efforts to address drug shortages through legislation. In 2010, there were a record number of drug product shortages nationwide, and many of them involved critical, life-saving medications. In response to the crisis, ASHP led a group of stakeholder organizations in an effort to pass legislation that would give FDA more authority to prevent drug shortages. The legislation has since been enacted and the Council concluded that the policy should be discontinued to reflect the passage of the [Food and Drug Safety and Innovation Act of 2012](#).

ASHP will continue to be involved in ongoing efforts to prevent drug shortages. Title X of the act requires FDA to develop a strategic plan aimed at preventing and mitigating shortages of critical medications. FDA must allow for input from the public on the strategic plan. Further, FDA must establish a task force to study and make recommendations on preventing shortages. The task force is also required to solicit public input from stakeholders, including pharmacy organizations. The Council believed that ASHP policy is not necessary to direct ASHP’s involvement and engagement with the FDA task force and development of the strategic plan.

6. Direct-to-Consumer Advertising for Prescription Drugs and Implantable Devices

- 1 To advocate that Congress commission an evidence-based review of direct-to-consumer
2 (DTC) advertising for prescription drugs and implantable medical devices in the United
3 States to determine the impact of such DTC advertising on the patient-prescriber
4 relationship, healthcare costs, health outcomes, and the public health; further,
- 5 To advocate that Congress ban DTC advertising for prescription drugs and implantable
6 medical devices until the results of such a review are publicly available; further,
- 7 To advocate, in the absence of a Congressionally mandated review, that the FDA, other
8 appropriate federal agencies, and the pharmaceutical and medical device industries
9 conduct or fund research on the effects of DTC advertising on the patient-prescriber
10 relationship, healthcare costs, health outcomes, and the public health, and make the
11 research results available to the public; further,
- 12 To oppose, in the absence of a ban, DTC advertising for prescription drugs and
13 implantable medical devices unless it is educational in nature about prescription drug
14 therapies for certain medical conditions, appropriately includes pharmacists as a source
15 of information, and is conducted so as to mitigate potential harmful effects on the
16 patient-prescriber relationship, healthcare costs, health outcomes, and the public
17 health.

(Note: This policy would supersede ASHP policy 1119.)

Rationale

Direct-to-consumer (DTC) advertising of prescription drugs and implantable medical devices has [both positive and negative potential effects](#). The positive potential effects include broader public awareness and use of therapies, increased patient engagement in their healthcare, and better return on investment in drug and medical device research. These potential benefits need to be weighed against the potential negative effects, which include increased adverse effects, higher drug and device costs, and inappropriate prescribing of more costly new drugs or devices without any justifying improvement in patient outcomes. In 2015, the American Medical Association (AMA) adopted a [policy](#) calling for a ban on DTC advertising of prescription drugs and implantable medical devices due to its impacts on drug prices and physician prescribing practices.

To properly assess the risks and benefits of DTC advertising, the nation needs an authoritative, evidence-based review of DTC advertising for prescription drugs and implantable medical devices to determine its impact on the patient-prescriber relationship, healthcare costs, health outcomes, and the public health. Until the results of such a review are publicly available, Congress should ban DTC advertising for prescription drugs and implantable medical devices in the interest of protecting the public health. In the absence of such a review, other

responsible stakeholders (e.g., FDA, public interest groups, and pharmaceutical and medical device manufacturers) should conduct research and make their findings publicly available.

In the absence of a ban, ASHP will oppose DTC advertising for prescription drugs and implantable medical devices unless it is educational in nature about prescription drug therapies for certain medical conditions, appropriately includes pharmacists as a source of information, and is conducted so as to mitigate potential harmful effects on the patient-prescriber relationship, healthcare costs, health outcomes, and the public health. The following are required to mitigate those potential harmful effects: (1) such advertising is delayed until postmarketing surveillance data are collected and assessed; (2) the benefits and risks of therapy are presented in an understandable format at an acceptable literacy level for the intended population; (3) such advertising promotes medication and device safety and allows informed decisions; (4) a clear relationship between the product and the disease state is presented; (5) no such advertising or marketing information is directed toward minors; (6) such advertising includes mechanisms that direct consumers to a medication or medical device adverse event reporting system (AERS); (7) the FDA review and pre-approve all such advertisements for prescription drug or implantable medical device products to ensure compliance with federal regulations and consistency with FDA-approved labeling before the advertisements are disseminated; and (8) that the FDA require an AERS reporting link in DTC advertising material available on the Internet.

Background

The Council recommended revising ASHP policy position 1119, Direct-to-Consumer Advertising of Prescription and Nonprescription Medications, which reads as follows:

To oppose direct-to-consumer advertising unless it is educational in nature about prescription drug therapies for certain medical conditions and appropriately includes pharmacists as a source of information; further,

To oppose direct-to-consumer advertising of specific prescription drug products unless the following requirements are met: (1) that such advertising is delayed until postmarketing surveillance data are collected and assessed, (2) that the benefits and risks of therapy are presented in an understandable format at an acceptable literacy level for the intended population, (3) that such advertising promotes medication safety and allows informed decisions, (4) that a clear relationship between the medication and the disease state is presented, (5) that no such advertising or marketing information for prescription or nonprescription medication is directed toward minors, and (6) that such advertising include mechanisms that direct consumers to a medication adverse event reporting system (AERS); further,

To advocate that the Food and Drug Administration require an AERS reporting link in direct-to-consumer advertising material available on the Internet; further,

To support the development of legislation or regulation that would require nonprescription drug advertising to state prominently the benefits and risks associated with product use that should be discussed with the consumer's pharmacist or physician.

In this revision, the Council is recommending adoption of policy similar to that of the AMA, which calls for a ban on DTC advertising but recognizes the need for strong policy regarding the content of such advertising in the absence of a ban. The Council chose to recommend joining AMA in calling for an authoritative study of the effects of DTC advertising and to place ASHP policy toward DTC advertising in that context. The Council also recommended that in the absence of such a study and a ban on DTC advertising, ASHP retain its policy in opposition to DTC advertising in clauses 1-3 of the current policy, placing some of the detail of clauses 2 and 3 in the rationale. The Council further decided to consider a separate new policy on DTC advertising of nonprescription medications at a future meeting, given the complexity of the recommended policy and the distinct regulatory regime for such advertising.

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.)

- [Regulation of Off-label Promotion and Marketing](#) (1120)
- [Poison Control Center Funding](#) (1121)
- [Generic Pharmaceutical Testing](#) (9010)
- [Redistribution of Unused Medications](#) (0611)
- [Importation of Pharmaceuticals](#) (0413)

Other Council Activity

Regulation of Dietary Supplements

A recommendation made by the 2015 ASHP House of Delegates asked ASHP to examine ASHP policy on the regulation of dietary supplements. Relevant ASHP policies include 0801, 1305, 0920, 0811, and 0415.

The Council concluded that existing ASHP policy on the regulation of dietary supplements is adequate. One area of potential concern is the growing use of homeopathic medicines. ASHP has had discussions with FDA on this issue and FDA would be concerned with categorizing homeopathic medications as a form a dietary supplement rather than a medication. After discussion, the Council decided that homeopathic medications are not entirely within the Council's purview and that the Council on Therapeutics may want to investigate this issue further. The discussion resulted in three recommendations:

- 1) The Council will investigate and gather additional information from the delegate who made the recommendation to the House of Delegates.

- 2) The Council will explore options to encourage more education on the use of dietary supplements, possibly through an article in *AJHP*.
- 3) The Council will further investigate the issues regarding homeopathic medications, through further discussion during its February call or by encouraging the Council on Therapeutics to examine the issue.

Hospital Pharmacy Budgets and Generic Drugs

There is growing concern over recent price spikes of previously low-cost, generic drug products and the impact the price increases is having on hospital pharmacy budgets. A number of national media outlets have been covering the issue as it has gained more attention in recent months. A suggestion by the House of Delegates that ASHP investigate this problem further underscores member concern over what they see as inappropriate price increases, or potential price gouging.

ASHP policy 0222 could be used as background as ASHP advocates for greater use of low-cost generic drug products. However, the policy does not address the pricing issue, but it could be interpreted broadly to link cost and access. In the event of price spikes, access to drug products may be compromised and thus elements of ASHP policy 0222 could be applicable from an access perspective.

In addition, the Council suggested that ASHP continue working with stakeholders such as the American Hospital Association to call attention to the issue and explore reasonable policy solutions. The Council also suggested beginning outreach to other potential stakeholder groups representing self-insured health plans, PBMs, and the health insurance industry to get input on how this issue impacts the payer community.

The Council decided that it needs more information about the subject. The Council also agreed with the House of Delegates recommendation that ASHP form a task force to provide more information on the following sub-topics:

- Pricing related to generic drugs
- Pricing related to brands, including specialty drugs
- Price gouging
- Price transparency