

## Specific Practice Areas

### Safety of Intranasal Route as an Alternative Route of Administration (1601)

Source: Council on Therapeutics

To encourage the development of institutional guidance and advocate for further research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for intranasal administration; further,

To foster the development of educational resources on the safety of intranasal administration of drugs not approved for that route.

### Stewardship of Drugs with Potential for Abuse (1603)

Source: Council on Therapeutics

To advocate for the inclusion of a clinically appropriate indication of use, the intended duration, and the goals of therapy when prescribing drugs with potential for abuse; further,

To encourage pharmacists to engage in interprofessional efforts to promote the appropriate, but judicious, use of drugs with the potential for abuse, including education, monitoring, assessment of clinical progress, and discontinuation of therapy or dose reduction, where appropriate; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of drugs with potential for abuse, including engaging in strategies to detect and address patterns of use in patient populations at increased risk for adverse outcomes; further,

To facilitate the development of best practices for prescription drug monitoring programs and drug take-back disposal programs for drugs with potential for abuse.

### Appropriate Use of Antipsychotic Drug Therapies (1604)

Source: Council on Therapeutics

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

To support the participation of pharmacists in the management of antipsychotic drug use, which is an interprofessional, collaborative process for selecting appropriate drug therapies, educating patients or their caregivers, monitoring patients, continually assessing outcomes of therapy, and identifying opportunities for discontinuation or dose adjustment; further,

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

### Safety of Epidural Steroid Injections (1605)

Source: Council on Therapeutics

To encourage healthcare providers to 1) inform patients about the significant risks and potential lack of efficacy of epidural steroid injections, 2) request their informed consent, and 3) inform patients of alternative therapies and their risks and benefits; further,

To recommend pharmacist involvement in the medication-use process associated with epidural steroid injections when such injections are medically necessary.

### Drug Dosing in Renal Replacement Therapy (1606)

Source: Council on Therapeutics

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

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

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

### Use of Methadone to Treat Pain (1607)

Source: Council on Therapeutics

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

To oppose the payer-driven use of methadone as a preferred treatment option for pain; further,

To advocate that pain management experts, payers, and manufacturers collaborate to provide educational programs for healthcare professionals on treating pain with opioids, including the proper place in therapy for methadone; further,

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

### Controlled Substance Diversion and Patient Access (1614)

Source: Council on Pharmacy Management

To enhance awareness by pharmacy personnel, healthcare providers, and the public of drug diversion and abuse of controlled substances; further,

To advocate that the pharmacy profession lead collaborative efforts to reduce the incidence of controlled substance abuse; further,

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

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

To advocate establishment of programs to support patients and personnel with substance abuse and dependency issues.

### Naloxone Availability (1510)

Source: Council on Therapeutics

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

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

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

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

To support state efforts to authorize pharmacists' prescribing authority for naloxone for opioid reversal.

#### **Safety and Effectiveness of Ethanol Treatment for Alcohol Withdrawal Syndrome (1514)**

*Source: Council on Therapeutics*

To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,

To support hospital and health-system efforts that prohibit the use of oral or intravenous ethanol therapies to treat AWS; further,

To educate clinicians about the availability of alternative therapies for AWS.

*This policy supersedes ASHP policy 1010.*

#### **Chemotherapy Parity (1516)**

*Source: Council on Therapeutics*

To advocate that all insurance payers design plans so that patient cost sharing for chemotherapy be equivalent regardless of route of administration; further,

To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of chemotherapy agents regardless of route of administration.

#### **Documentation of Penicillin Allergy as a Component of Antimicrobial Stewardship (1517)**

*Source: Council on Therapeutics*

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

To advocate for documentation of penicillin allergy, intolerance, reactions, and severity in the medical record to facilitate optimal antimicrobial selection; further,

To recommend the use of penicillin skin testing in appropriate candidates when clinically indicated to optimize antimicrobial selection.

#### **Prescription Drug Abuse (1526)**

*Source: Council on Pharmacy Practice*

To affirm that pharmacists have leadership roles in recognition, prevention, and treatment of prescription drug abuse; further,

To promote education on prescription drug abuse, misuse, and diversion-prevention strategies.

#### **Pharmacist's Role in Urgent and Emergency Situations (1527)**

*Source: Council on Pharmacy Practice*

To affirm that pharmacists should participate in planning and providing emergency treatment team services; further,

To advocate that pharmacists participate in decision-making about the medications and supplies used in medical emergencies; further,

To advocate that pharmacists serve in all emergency responses, and that those pharmacists receive appropriate training and maintain appropriate certifications.

#### **Appropriate Use of Testosterone (1536)**

*Source: Council on Therapeutics*

To educate pharmacists, patients, and the public about the risks and benefits of testosterone use and about best practices for safe handling of testosterone, specifically regarding harmful effects of contact with another person; further,

To educate healthcare providers about the importance of including accurate testosterone levels and confirmed evidence of clinical symptoms in the evaluation of candidates for testosterone therapy; further,

To encourage additional research on the long-term effects of testosterone therapy.

#### **Safe Use of Radiopharmaceuticals (1402)**

*Source: Council on Pharmacy Practice*

To affirm that radiopharmaceuticals require the same standards for safe medication use as other medications, including but not limited to standards for procurement, storage and control, prescribing, preparation, dispensing, administration, documentation, clinical and regulatory monitoring, disposal, and formulary consideration; further,

To advocate that pharmacy departments, in cooperation with departments of nuclear medicine, radiology, and radiation safety, provide oversight of radiopharmaceuticals to assure safe use; further,

To advocate for incorporation of information on radiopharmaceuticals into college of pharmacy curricula and increased pharmacy continuing education on radiopharmaceuticals.

#### **Safe Use of Fentanyl Transdermal System Patches (1404)**

*Source: Council on Pharmacy Practice*

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

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

#### **Education About Performance-Enhancing Substances (1305)**

*Source: Council on Pharmacy Practice*

To encourage pharmacists to engage in community outreach efforts to provide education to athletes on the risks associated with the use of performance-enhancing substances; further,

To encourage pharmacists to advise athletic authorities and athletes on the dangers of performance-enhancing substances and other products that are prohibited in competition; further,

To advocate for the role of the pharmacist in all aspects of sports doping control.

*This policy supersedes ASHP policy 0710.*

**Pharmacists' Role in Immunization (1309)***Source: Council on Public Policy*

To affirm that pharmacists have a role in improving public health and increasing patient access to immunizations by promoting and administering appropriate immunizations to patients and employees in all settings; further,

To collaborate with key stakeholders to support the public health role of pharmacists and student pharmacists in the administration of adult and pediatric immunizations; further,

To advocate that states grant pharmacists and appropriately supervised student pharmacists the authority to initiate and administer all adult and pediatric immunizations; further,

To advocate that pharmacists and student pharmacists who have completed a training and certification program acceptable to state boards of pharmacy and meeting the standards established by the Centers for Disease Control and Prevention may provide such immunizations; further,

To advocate that state and federal health authorities establish centralized databases for documenting administration of immunizations that are accessible to all health care providers; further,

To advocate that state and federal health authorities require pharmacists and other immunization providers to report their documentation to these centralized databases, if available; further,

To strongly encourage pharmacists to educate all patients, their caregivers, parents, guardians, and health care providers about the importance of immunizations for disease prevention; further,

To encourage pharmacists to seek opportunities for involvement in disease prevention through community immunization programs; further,

To advocate for the inclusion of pharmacist-provided immunization training in college of pharmacy curricula.

*This policy supersedes ASHP policies 1220 and 0213.*

**Pharmacist's Role in Accountable Care Organizations (1214)***Source: Council on Pharmacy Practice*

To recognize that pharmacist participation in collaborative health care teams improves outcomes from medication use and lowers costs; further,

To advocate to health policymakers, payers, and other stakeholders for the inclusion of pharmacists as health care providers within accountable care organizations (ACOs) and other models of integrated health care delivery; further,

To advocate that pharmacist-provided care (including care coordination services) be appropriately recognized in reimbursement models for ACOs; further,

To advocate that pharmacists be included as health care providers in demonstration projects for ACOs; further,

To encourage comparative effectiveness research and measurement of key outcomes (e.g., clinical, economic, quality, access) for pharmacist services in ACOs; further,

To encourage pharmacy leaders to develop strategic plans for positioning pharmacists in key roles within ACOs.

**Criteria for Medication Use in Geriatric Patients (1221)***Source: Council on Therapeutics*

To support medication therapy management, including assessment of physiologic and pharmacokinetic factors, as a central component of providing safe and effective drug therapy to geriatric patients; further,

To oppose use of the Beers criteria or similar criteria by the Centers for Medicare & Medicaid Services and other accreditation and quality improvement entities as the sole indicator to assess the appropriateness of prescribing for geriatric patients based on known limitations in the evidence evaluating the association between use of medications listed in such criteria and subsequent adverse drug events; further,

To advocate for the development, refinement, and validation of new criteria that consider drug-, disease-, and patient-specific factors and demonstrate the ability to decrease the occurrence of adverse drug events in geriatric patients; further,

To support research to assess the clinical application of existing and proposed criteria, including assessment of their correlation to patient outcomes and strategies for implementation; further,

To encourage inclusion of validated criteria in clinical decision support systems and other information technologies to facilitate prescribing for geriatric patients; further,

To acknowledge that such criteria are intended as a guide and should not replace the clinical judgment of pharmacists and other clinicians.

**Tobacco and Tobacco Products (1224)***Source: Council on Therapeutics*

To discourage the use, distribution, and sale of tobacco and tobacco products in and by pharmacies; further,

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

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

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

To join with other interested organizations in statements and expressions of opposition to the use of tobacco and tobacco products.

*This policy supersedes ASHP policy 0713.*

**Safe and Effective Use of IV Promethazine (1105)***Source: Council on Therapeutics*

To recognize intravenous (IV) promethazine as a treatment alternative in limited clinical circumstances; further,

To support health-system efforts to restrict use of IV promethazine by encouraging alternate routes of administration or use of therapeutic alternatives when appropriate; further,

To encourage health systems to establish medication-use processes that reflect nationally recognized best practices to limit the potential for patient harm when IV promethazine use is medically necessary.

*This policy was reviewed in 2015 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**Pain Management (1106)**

Source: *Council on Therapeutics*

To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

To support the participation of pharmacists in pain management, which is a multidisciplinary, collaborative process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,

To encourage the education of pharmacists, pharmacy students, and other health care providers regarding the principles of pain management and methods to minimize drug diversion.

*This policy was reviewed in 2015 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**Pharmacist's Role in Providing Care for an Aging Population (0902)**

Source: *Council on Pharmacy Practice*

To encourage expansion of geriatric health care services; further,

To foster expanded roles for pharmacists in caring for geriatric patients; further,

To support successful innovative models of team-based, interdisciplinary geriatric care; further,

To increase training of pharmacists in caring for geriatric patients within college of pharmacy curricula, in ASHP-accredited postgraduate-year-one residencies, and through the expansion of the number of ASHP-accredited postgraduate-year-two geriatric pharmacy residency programs.

*This policy was reviewed in 2013 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Pharmacist Role in the Health Care (Medical) Home (0908)**

Source: *Council on Public Policy*

To advocate to health policymakers, payers, and other stakeholders for the inclusion of pharmacists as a care provider within the health care (medical) home model; further,

To ensure that there are appropriate reimbursement mechanisms for the care that pharmacists provide (including care coordination services) within the health care home model; further,

To advocate to the Centers for Medicare & Medicaid Services that pharmacists be included in demonstration projects for the health care home model; further,

To encourage comparative effectiveness research and measurement of key outcomes (e.g., clinical, economic, quality, access) for pharmacist services in the health care home model.

*This policy was reviewed in 2013 by the Council on Public Policy and by the Board of Directors and was found to still be appropriate.*

**Safe and Effective Use of Heparin in Neonatal Patients (0912)**

Source: *Council on Therapeutics*

To support the development and use of nationally standardized concentrations of heparin when used for maintenance and flush of peripheral and central venous lines in neonatal patients; further,

To advocate that hospitals and health systems use manufacturer-prepackaged heparin flush products to improve the safe use of heparin in neonatal patients.

*This policy was reviewed in 2013 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.*

**Pharmacist Support for Dying Patients (0307)**

Source: *Council on Professional Affairs*

To support the position that care for dying patients is part of the continuum of care that pharmacists should provide to patients; further,

To support the position that pharmacists have a professional obligation to work in a collaborative and compassionate manner with patients, family members, caregivers, and other professionals to help fulfill the patient care needs, especially the quality-of-life needs, of dying patients of all ages; further,

To support research on the needs of dying patients; further,

To provide education to pharmacists on caring for dying patients, including education on clinical, managerial, professional, and legal issues; further,

To urge the inclusion of such topics in the curricula of colleges of pharmacy.

*This policy was reviewed in 2012 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Interventions to Reduce High-Risk Behavior in Intravenous Drug Users (9711)**

Source: *House of Delegates Resolution*

ASHP supports the use of needle and syringe exchange programs, drug abuse treatment, and community outreach programs for substance abusers to reduce the risk of transmission of the human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus in intravenous drug users.

*This policy was reviewed in 2011 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

**Primary and Preventive Care (9407)**

Source: *Council on Professional Affairs*

To support primary and preventive care roles for pharmacists in the provision of pharmaceutical care; further,

To collaborate with physician, nursing, and health-system administrator groups in pursuit of these goals.

*This policy was reviewed in 2011 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.*

## ASHP Policy Positions 2009–2016 (with Rationales)

### Medication Therapy and Patient Care: Specific Practice Areas

#### 1601

##### **Safety of Intranasal Route as an Alternative Route of Administration**

*Source: Council on Therapeutics*

To encourage the development of institutional guidance and advocate for further research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for intranasal administration; further,

To foster the development of educational resources on the safety of intranasal administration of drugs not approved for that route.

##### ***Rationale***

Intranasal administration can be used for systemic drug delivery and is the delivery route of choice in specific circumstances. Intranasal administration is often the route of choice in the emergency department due to access issues, safety concerns, and the characteristics of specific patient populations (e.g., children). Soluble drugs such as naloxone can be converted for intranasal administration without altering the substance simply by use of an aerosolizer. The intranasal route is frequently used to treat pain when oral and intravenous routes are not optimal, and intranasal midazolam is often used for sedation in the pediatric population, although that route of administration is not FDA-approved. Certain rescue medications such as naloxone can also be administered intranasally and may be preferred for intravenous drug users. Vaccines are also commonly administered via the intranasal route.

Because many of these drugs are not approved for intranasal administration, there are varying degrees of evidence for use in specific cases. There is also varying evidence regarding the degree of systemic absorption of intranasally administered drugs that are not formulated for that route. A large number of characteristics may affect systemic distribution from the intranasal route, such as the presence of preservatives and viscosity of the agents. Given the interest in and potential benefits of intranasal administration, further research on the pharmacokinetics and pharmacodynamics of that route is needed.

#### 1603

##### **Stewardship of Drugs with Potential for Abuse**

*Source: Council on Therapeutics*

To advocate for the inclusion of a clinically appropriate indication of use, the intended duration, and the goals of therapy when prescribing drugs with potential for abuse; further,

To encourage pharmacists to engage in interprofessional efforts to promote the appropriate, but judicious, use of drugs with the potential for abuse, including education, monitoring, assessment of clinical progress, and discontinuation of therapy or dose reduction, where appropriate; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of drugs with potential for abuse, including engaging in strategies to detect and address patterns of use in patient populations at increased risk for adverse outcomes; further,

To facilitate the development of best practices for prescription drug monitoring 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.

Including a clinically appropriate indication of use, the intended duration, and the goals of therapy in the health record when drugs with potential for abuse are prescribed will foster the appropriate but judicious use of those drugs. Pharmacists, as medication-use experts, should engage in efforts to prevent inappropriate use of drugs with potential for abuse by promoting education, monitoring, assessment of clinical progress, and discontinuation of therapy or dose reduction, where appropriate, and should provide leadership in developing strategies to prevent adverse outcomes from drugs with potential for abuse and optimize prescription drug monitoring programs and drug take-back disposal programs for those drugs as well.

### **1604**

#### **Appropriate Use of Antipsychotic Drug Therapies**

*Source: Council on Therapeutics*

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

To support the participation of pharmacists in the management of antipsychotic drug use, which is an interprofessional, collaborative process for selecting appropriate drug therapies, educating patients or their caregivers, monitoring patients, continually assessing outcomes of therapy, and identifying opportunities for discontinuation or dose adjustment; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of antipsychotic drugs, including engaging in strategies to detect and address patterns 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.

## **1605**

### **Safety of Epidural Steroid Injections**

*Source: Council on Therapeutics*

To encourage healthcare providers to 1) inform patients about the significant risks and potential lack of efficacy of epidural steroid injections, 2) request their informed consent, and 3) inform patients of alternative therapies and their risks and benefits; further,

To recommend pharmacist involvement in the medication-use process associated with epidural steroid injections when such injections are medically necessary.

### **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, including pharmacist involvement in the medication-use process when such injections are medically necessary, to promote the safe use of epidural steroid injections.

## 1606

### **Drug Dosing in Renal Replacement Therapy**

*Source: Council on Therapeutics*

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

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

To collaborate with stakeholders in enhancing aggregation and publication of data on the pharmacokinetics and pharmacodynamics of drug dosing in renal replacement 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.



**1607****Use of Methadone to Treat Pain**

*Source: Council on Therapeutics*

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

To oppose the payer-driven use of methadone as a preferred treatment option for pain; further,

To advocate that pain management experts, payers, and manufacturers collaborate to provide educational programs for healthcare professionals on treating pain with opioids, including the proper place in therapy for methadone; further,

To advocate that all facilities that dispense methadone, including addiction 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 pain management experts, payers, and manufacturers collaborate to provide educational programs on best practices for prescribing opioids, including methadone.

#### **1614**

##### **Controlled Substance Diversion and Patient Access**

*Source: Council on Pharmacy Management*

To enhance awareness by pharmacy personnel, healthcare providers, and the public of drug diversion and abuse of controlled substances; further,

To advocate that the pharmacy profession lead collaborative efforts to reduce the incidence of controlled substance abuse; further,

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

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

To advocate establishment of programs to support patients and 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 acquisition 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.

## 1510

### NALOXONE AVAILABILITY

*Source: Council on Therapeutics*

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

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

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

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

To support state efforts to authorize pharmacists' prescribing authority for naloxone for opioid reversal.

### **Rationale**

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

Naloxone is a reversal agent that rapidly rescues patients from narcotic overdose by displacing mu<sub>2</sub> opioid receptors in the brain. Naloxone has an excellent safety profile. The World Health Organization includes naloxone on its model list of essential medications.

Evidence shows a clear public health benefit from expanding access to naloxone. Although naloxone requires a prescription, a number of states have implemented programs to

ensure liberal access to this lifesaving medication. As of 2014, there were 188 community-based programs operating in 26 states, and those programs had pronounced success in saving lives. In Massachusetts alone, almost 3000 overdoses were reversed. State laws authorizing pharmacists to prescribe naloxone for opioid reversal would remove one barrier to expanded access.

Healthcare professional organizations have endorsed expanded access to naloxone, including the American Medical Association. The Veterans Affairs administration has implemented a naloxone program, with 28,000 opioid reversal kits made available. Issues of legal liability for persons administering naloxone are being addressed as well: over 20 states have amended their laws to protect lay administrators of naloxone from civil or criminal liability. There is also substantial congressional support to allow police officers and first responders to carry naloxone. The Opioid Overdose Reduction Act of 2014 (S. 2092) would provide immunity from civil suits for individuals trained to administer naloxone for opioid overdose reversal.

Expanded access would require appropriate education for those administering the drug, training on safe administration, and recommendations on follow-up care with abuse treatment programs for treated individuals. The FDA-approved formulation for opioid reversal is administered via subcutaneous injection, something caregivers or peers may have difficulty doing properly. Several pilot and model programs, such as the Staying Alive program developed by the Baltimore City Health Department, have successfully offered training for drug abusers to respond to opioid overdose, however. A nasal device is also available, and data collected from emergency response situations have shown that intranasal naloxone is as effective as transdermal routes in rapid opioid reversal. It costs approximately ten times that of standard formulations, and may carry the same safety profile and concerns, but would be easier for lay people to administer.

#### **1514**

#### **SAFETY AND EFFECTIVENESS OF ETHANOL TREATMENT FOR ALCOHOL WITHDRAWAL SYNDROME**

*Source: Council on Therapeutics*

To oppose the use of oral or intravenous ethanol for the prevention or treatment of alcohol withdrawal syndrome (AWS) because of its poor effectiveness and safety profile; further,

To support hospital and health-system efforts that prohibit the use of oral or intravenous ethanol therapies to treat AWS; further,

To educate clinicians about the availability of alternative therapies for AWS.

*This policy supersedes ASHP policy 1010.*

#### ***Rationale***

Alcohol withdrawal syndrome (AWS), which can delay patient recovery and interfere with response to therapy, is often prevented or treated using oral or intravenous ethanol. Based on

a review of the available evidence, including treatment guidelines from the American Society of Addiction Medicine (ASAM), ASHP opposes the use of these therapies to prevent or treat AWS. Limited and conflicting evidence of effectiveness, inability to achieve accurate and consistent dosing and blood levels, and the availability of more effective and safer therapies are among the reasons to oppose use of ethanol to prevent or treat AWS symptoms. One evidence-based therapy for treatment of AWS is pharmacotherapy with benzodiazepines. Guidelines from the American Association of Family Physicians recommend benzodiazepines on a fixed schedule for AWS, outpatient detoxification, and enrollment in an alcohol treatment program. For these reasons, ASHP supports efforts to prohibit use of these therapies for AWS and advocates education to a variety of healthcare practitioner audiences to increase awareness of appropriate alternative therapies. ASHP continues to support the use of ethanol for the treatment of acute alcohol poisoning, which is described in evidence-based guidelines.

## 1516

### **CHEMOTHERAPY PARITY**

*Source: Council on Therapeutics*

To advocate that all insurance payers design plans so that patient cost sharing for chemotherapy be equivalent regardless of route of administration; further,

To continue to foster the development of best practices, including adherence monitoring strategies, and education on the safe use and management of chemotherapy agents regardless of route of administration.

#### ***Rationale***

Chemotherapy is traditionally thought of as intravenous agents, but the availability of oral chemotherapy agents has been steadily increasing. The FDA has approved 17 oral chemotherapy agents over the past 10 years. Thirty percent of the 900 current chemotherapy agents in development are oral agents. These agents play a significant role in treatment modalities and are sometimes the only agent of choice (e.g., oral imatinib mesylate for chronic myelogenous leukemia).

Unfortunately, cost sharing for these novel agents is not consistent across different types of medical coverage and prescription drug plans. Pharmaceutical manufacturers recoup research and development costs by charging more for novel agents, whose costs can soar as high as \$8,000 to \$12,000 per month. Well-established intravenous agents are less expensive and are often covered under systems such as Medicare Part B. Changing treatment from intravenous to oral agents can shift their billing to prescription drug benefits. Private health insurance typically contains varying tiers of copayment, with chemotherapy belonging to upper tiers. According to the Hematology/Oncology Pharmacists Association (HOPA), 25–33% of the cost of these agents is shared with patients. Cancer patients are over two-and-a-half times more likely to file for bankruptcy than patients with other conditions.

Given the expense, cost sharing can have a significant impact on patient access and adherence. A recent Health Affairs survey found that over 50% of practitioners agree that costs influence treatment decisions, but only 46% of practitioners discuss costs with patients. Although patient assistance programs can help some patients with the cost burden, the

requirements associated with such programs can be complex, and the programs typically do not cover gaps left by federally funded programs such as Medicare.

Since 2008, more than 26 states have passed oral chemotherapy parity laws to ensure equal insurance coverage of oral and intravenous chemotherapy agents and preserve patient access to these therapies. Federal chemotherapy parity legislation (H.R. 1801) has also been introduced. Ensuring parity between oral and intravenous chemotherapy reimbursement will expand patient access to needed medications and improve outcomes of care.

Pharmacists have a responsibility to assure safe, effective, and appropriate use of self-administered oral chemotherapy agents. Dispensing and administration of intravenous chemotherapy treatments has been reserved for clinics, where robust quality and monitoring processes address safety concerns. New oral chemotherapy agents can be self-administered in a variety of settings, where the safety checkpoints that are standard in infusion clinics are absent. All healthcare professionals involved in the collaborative care of cancer patients will require training to use these high-risk and costly oral chemotherapy agents safely and wisely. Pharmacists have been and will continue to be key leaders in addressing safety issues and evaluating the comparative effectiveness of chemotherapy across settings.

### 1517

#### **DOCUMENTATION OF PENICILLIN ALLERGY AS A COMPONENT OF ANTIMICROBIAL STEWARDSHIP**

*Source: Council on Therapeutics*

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

To advocate for documentation of penicillin allergy, intolerance, reactions, and severity in the medical record to facilitate optimal antimicrobial selection; further,

To recommend the use of penicillin skin testing in appropriate candidates when clinically indicated to optimize antimicrobial selection.

#### ***Rationale***

Antibiotic stewardship and the appropriate use of antibiotics are urgent public health concerns. Policymakers have emphasized the judicious use of antibiotics through proposed legislation such as the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) and Antibiotic Development to Advance Patient Treatment (ADAPT) acts, which have been incorporated into drafts of the 21st Century Cures legislation.

Evidence linking the inappropriate use of antibiotics and the emergence of drug-resistant organisms has been accumulating since the 1980s. According to a 2013 Centers for Disease Control and Prevention (CDC) report, 2 million people are infected with resistant bacteria each year in the U.S., and 23,000 die. *Clostridium difficile* infections alone cause 250,000 hospitalizations each year. It is estimated that 31–51% of vancomycin prescriptions are due to penicillin allergy. Cross-sensitivity between cephalosporins and penicillin is 8%, with anaphylactic reactions occurring in 0.4% of patients. Ninety percent of patients with a negative penicillin allergy skin test can be switched to penicillin, with additional minor determinants

adding another 30% of missed patients. At some institutions, 20% report penicillin allergy, while only 0.9% actually have the allergy.

The American Academy of Allergy and Immunology, as part of a Choosing Wisely campaign, recommends against the overuse of non-beta-lactam antibiotics in patients with a history of penicillin allergy, without appropriate evaluation. In a research abstract from the Canadian Society of Allergy and Clinical Immunology meeting in 2014, researchers found that only 15% of hospital-discharged patients notified a family physician of a negative penicillin allergy evaluation, and at the same time, 30% were still listed as penicillin allergic upon readmission to the hospital.

## 1526

### PRESCRIPTION DRUG ABUSE

*Source: Council on Pharmacy Practice*

To affirm that pharmacists have leadership roles in recognition, prevention, and treatment of prescription drug abuse; further,

To promote education on prescription drug abuse, misuse, and diversion-prevention strategies.

#### **Rationale**

Abuse of prescription opioid pain relievers caused more than 16,600 overdose deaths in 2010, a fourfold increase over 2000. Prescription drug abuse has also been linked to increased use of heroin; four of five recent heroin initiates had previously used prescription pain relievers nonmedically.

Pharmacy has been active in efforts to combat prescription drug abuse. ASHP and other pharmacy organizations [testified to the Senate Health, Education, Labor, and Pensions Committee](#) on strategies to address prescription drug abuse, including enhancing state prescription drug monitoring programs, making naloxone more available, and public education. As medication-use experts and accessible healthcare providers, pharmacists have a frontline, leadership role in curbing prescription drug abuse. Education of pharmacists, other healthcare professionals, and the public are critically important to these efforts.

## 1527

### PHARMACIST'S ROLE IN URGENT AND EMERGENCY SITUATIONS

*Source: Council on Pharmacy Practice*

To affirm that pharmacists should participate in planning and providing emergency treatment team services; further,

To advocate that pharmacists participate in decision-making about the medications and supplies used in medical emergencies; further,

To advocate that pharmacists serve in all emergency responses, and that those pharmacists receive appropriate training and maintain appropriate certifications.

**Rationale**

Pharmacists have a leadership role in many hospitals in planning for emergency treatment team services. ASHP National Survey data show that approximately 40% of hospitals have pharmacist participation in cardiopulmonary resuscitation (CPR) teams. This role includes developing policy on the contents of code carts and other supplies as well as establishing the role of the pharmacist in supporting these services. The literature demonstrates that pharmacists can make significant contributions to CPR and other emergency response teams as medication-use leaders and as participants, and there is evidence that better patient outcomes result when pharmacists participate. Pharmacists participating in this role should receive appropriate training and certification (e.g., Basic Life Support, Advanced Cardiopulmonary Life Support, and Pediatric Acute Life Support).

**1536****Appropriate Use of Testosterone**

*Source: Council on Therapeutics*

To educate pharmacists, patients, and the public about the risks and benefits of testosterone use and about best practices for safe handling of testosterone, specifically regarding harmful effects of contact with another person; further,

To educate healthcare providers about the importance of including accurate testosterone levels and confirmed evidence of clinical symptoms in the evaluation of candidates for testosterone therapy; further,

To encourage additional research on the long-term effects of testosterone therapy.

**1402****SAFE USE OF RADIOPHARMACEUTICALS**

*Source: Council on Pharmacy Practice*

To affirm that radiopharmaceuticals require the same standards for safe medication use as other medications, including but not limited to standards for procurement, storage and control, prescribing, preparation, dispensing, administration, documentation, clinical and regulatory monitoring, disposal, and formulary consideration; further,

To advocate that pharmacy departments, in cooperation with departments of nuclear medicine, radiology, and radiation safety, provide oversight of radiopharmaceuticals to assure safe use; further,

To advocate for incorporation of information on radiopharmaceuticals into college of pharmacy curricula and increased pharmacy continuing education on radiopharmaceuticals.

**Rationale**

Many hospitals utilize radiopharmaceuticals for diagnostic imaging tests or for treatment. Most hospitals outsource the preparation of injectable and oral radiopharmaceuticals to external suppliers. Because of the unique nature of these drugs and their narrow scope of use, the



pharmacy department is often not involved with their acquisition, handling, or disposal. Reports of improper handling, storage, and disposal suggest that these products should have similar oversight as other drug products used in hospitals, and that pharmacists, pharmacy students, and pharmacy technicians require education regarding their safe use.

**1404****SAFE USE OF FENTANYL TRANSDERMAL SYSTEM PATCHES**

*Source: Council on Pharmacy Practice*

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

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

***Rationale***

There have been many reports of errors, abuse, and misuse of the fentanyl patch, and while approaches to improving the safe use of the product have been considered, few have been implemented and fatalities related to this product continue. Better consumer education, specific to this unique dosage form, is an important activity, but is often overlooked. Manufacturers could also take additional steps to prevent misuse of the product, through changes to the formulation or to packaging. Pharmacists are in a unique position to help improve the safe use of fentanyl patches.

**1305****EDUCATION ABOUT PERFORMANCE-ENHANCING SUBSTANCES**

*Source: Council on Pharmacy Practice*

To encourage pharmacists to engage in community outreach efforts to provide education to athletes on the risks associated with the use of performance-enhancing substances; further,

To encourage pharmacists to advise athletic authorities and athletes on the dangers of performance-enhancing substances and other products that are prohibited in competition; further,

To advocate for the role of the pharmacist in all aspects of sports doping control.

*This policy supersedes ASHP policy 0710.*

***Rationale***

The risks of using performance-enhancing substances, more commonly called performance-enhancing drugs (PEDs), are well documented in sports medicine journals and other biomedical literature. The U.S. Anti-Doping Agency (USADA) maintains a comprehensive list of performance-enhancing substances that are banned for U.S. athletes competing in the

Olympics. In addition to anabolic steroids, the list includes hormones and hormone-like substances (e.g., insulin, tamoxifen); beta-2 agonists; diuretics; red blood cells (RBC) in any form and RBC enhancers; agents that alter genes or genetic expression; stimulants (including caffeine and nicotine); narcotics; cannabinoids; and glucocorticoids. Certain dietary supplements that are known to contain prohibited substances are also banned. The FDA has also identified dietary supplements that contain pathogens (e.g., *Salmonella*), contaminants (e.g., lead or mercury), or undeclared prescription drug ingredients (e.g., ephedrine, sildenafil, or dexamethasone).

Although such authorities as the National Collegiate Athletic Association and the USADA have implemented bans on use of these agents and drug testing policies to enforce them, these strategies have been only partially effective in curbing sports doping. Physical and emotional developmental changes during adolescence, as well as the desirable celebrity status of professional sports figures, place younger athletes at significant risk for PED use.

The incidence of PED use among young athletes and the lack of guidance on this topic prompted the American Academy of Pediatrics (AAP) to issue a [policy statement](#) in 2005 that provides a working definition of PEDs and strongly opposes their use. The statement also emphasizes the important role of health care professionals in educating younger athletes about the inflated claims and serious risks of sports doping products.

Use of PEDs has spread beyond professional athletes to military personnel, recreational body builders, professional entertainers, and others wishing to lose weight, increase muscle mass, improve alertness, and increase stamina. In 2011, an American College of Gynecology (ACOG) [opinion statement](#) addressed abuse of anabolic steroids, growth hormone, thyroid replacement products, and dietary supplements by women for cosmetic purposes. Risk factors among younger women (negative body image, social pressure to perform in high school or college sports, and risk-taking behaviors) may lead to steroid abuse as early as the late teens. While steroid use among women and girls is far less common than among men, abuse can lead to liver damage, hyperlipidemia, decreased glucose tolerance, increased cardiovascular disease, thrombotic events, psychosis, and infertility. ACOG recommended that health care professionals educate patients about the unfavorable benefit-to-risk ratio of steroid use, encourage cessation in suspected users, or refer them to substance abuse treatment programs.

### 1309

#### PHARMACISTS' ROLE IN IMMUNIZATION AND VACCINES

*Source: Council on Public Policy*

To affirm that pharmacists have a role in improving public health and increasing patient access to immunizations by promoting and administering appropriate immunizations to patients and employees in all settings; further,

To collaborate with key stakeholders to support the public health role of pharmacists and student pharmacists in the administration of adult and pediatric immunizations; further,

To advocate that states grant pharmacists and appropriately supervised student pharmacists the authority to initiate and administer all adult and pediatric immunizations; further,

To advocate that pharmacists and student pharmacists who have completed a training and certification program acceptable to state boards of pharmacy and meeting the standards established by the Centers for Disease Control and Prevention may provide such immunizations; further,

To advocate that state and federal health authorities establish centralized databases for documenting administration of immunizations that are accessible to all health care providers; further,

To advocate that state and federal health authorities require pharmacists and other immunization providers to report their documentation to these centralized databases, if available; further,

To strongly encourage pharmacists to educate all patients, their caregivers, parents, guardians, and health care providers about the importance of immunizations for disease prevention; further,

To encourage pharmacists to seek opportunities for involvement in disease prevention through community immunization programs; further,

To advocate for the inclusion of pharmacist-provided immunization training in college of pharmacy curricula.

*This policy supersedes ASHP policies 1220 and 0213.*

### **Rationale**

Increasing adult and pediatric patients' access to immunizations is an important public health challenge. Pharmacists' unique training and expertise in all aspects of the medication-use system can help expand patients' access to immunizations and promote disease prevention in all practice settings. Hospital and health-system pharmacists provide care to a patient population that is vulnerable and often critically ill, and such patients are especially dependent on herd immunity. Patients in rural areas, where a pharmacy may provide the only convenient access to a health care professional, will benefit from increased pharmacist immunization authority.

Although all states permit pharmacist administration of some vaccines, state laws differ in the range of vaccines pharmacists may administer and the patient populations they are permitted to vaccinate. Allowing trained and certified pharmacists, including student pharmacists, to initiate and administer all adult and pediatric vaccines (e.g., by eliminating the requirement that some pharmacist-provided immunizations to be conducted within a collaborative drug therapy management agreement) would encourage standardization of pharmacy immunization practice within and among states.

Only pharmacists and student pharmacists who undergo appropriate training and certification should be authorized by state boards to provide immunizations. To ensure their consistency and quality, those training and certification programs should meet Centers for

Disease Control and Prevention (CDC) standards. To aid in sharing important patient immunization information, centralized databases of patient immunizations should be established, and all authorized immunization providers, including pharmacists, should be required by law or regulation to document their immunizations in those databases when they become available.

Pharmacists, student pharmacists, and pharmacy educators should embrace their role in this important public health effort by providing education about the importance of immunization in disease prevention, participating in community immunization programs, and training immunization providers.

## 1214

### PHARMACIST'S ROLE IN ACCOUNTABLE CARE ORGANIZATIONS

*Source: Council on Pharmacy Practice*

To recognize that pharmacist participation in collaborative health care teams improves outcomes from medication use and lowers costs; further,

To advocate to health policymakers, payers, and other stakeholders for the inclusion of pharmacists as health care providers within accountable care organizations (ACOs) and other models of integrated health care delivery; further,

To advocate that pharmacist-provided care (including care coordination services) be appropriately recognized in reimbursement models for ACOs; further,

To advocate that pharmacists be included as health care providers in demonstration projects for ACOs; further,

To encourage comparative effectiveness research and measurement of key outcomes (e.g., clinical, economic, quality, access) for pharmacist services in ACOs; further,

To encourage pharmacy leaders to develop strategic plans for positioning pharmacists in key roles within ACOs.

#### ***Rationale***

The Affordable Care Act of 2009 encourages the formation of [accountable care organizations](#) (ACOs). Similar in concept to health maintenance organizations, these entities consist of alliances between physicians, other health care providers, and hospitals that provide comprehensive and coordinated health care to a population of patients. ACOs emphasize primary and preventive care, are provider-led, and receive reimbursement linked to increasing health care quality and lowering per capita costs. The ACO model is based on the premise that care coordinated in this manner and incentivized by a shared-risk reimbursement model will improve health care quality and slow the growth of health care spending. One significant deterrent to pharmacist participation in the fee-for-service care model, lack of provider status, is less of a barrier in the ACO model because reimbursement is tied to quality and reduced costs rather than specific services.

Integrated systems present an important opportunity for pharmacists to demonstrate their value to the quality of care. Pharmacists could contribute to the success of ACOs by providing the following patient care services:

- Developing, implementing, and monitoring patient-specific, evidence-based drug therapy as an active participant in team-based care.
- Improving transitions in care with coordinated MTM services for patients in the hospital as well as post-discharge in ambulatory clinics and physician practices.
- Monitoring the therapy of patients with multiple chronic conditions or complex medication regimens.
- Preventing and managing adverse drug events.

Although a number of ACOs have already evolved from existing disease management and medical home programs, not much is known about the elements of success for ACOs, and implementation is likely to be challenging. To establish these elements of success, pharmacists will need to be included in ACO demonstration projects and pharmacist services will need to be the subject of research on ACO effectiveness.

As pharmacists assume the expanded roles outlined in the PPMI recommendations, pharmacy leaders should use their expertise to explore innovative strategies to meet the broader goals of ACOs. This payment model is an opportunity to demonstrate how pharmacists can help these organizations reach clinical and financial performance targets set by the Centers for Medicare & Medicaid Services (CMS), i.e., improved patient results and lower health care costs. Pharmacy managers and other pharmacy leaders should prepare now to participate in emerging ACOs by developing strategic plans for positioning pharmacists in roles where their expertise can be best applied to these goals.

## **1221**

### **CRITERIA FOR MEDICATION USE IN GERIATRIC PATIENTS**

*Source: Council on Therapeutics*

To support medication therapy management, including assessment of physiologic and pharmacokinetic factors, as a central component of providing safe and effective drug therapy to geriatric patients; further,

To oppose use of the Beers criteria or similar criteria by the Centers for Medicare & Medicaid Services and other accreditation and quality improvement entities as the sole indicator to assess the appropriateness of prescribing for geriatric patients based on known limitations in the evidence evaluating the association between use of medications listed in such criteria and subsequent adverse drug events; further,

To advocate for the development, refinement, and validation of new criteria that consider drug-, disease-, and patient-specific factors and demonstrate the ability to decrease the occurrence of adverse drug events in geriatric patients; further,

To support research to assess the clinical application of existing and proposed criteria, including assessment of their correlation to patient outcomes and strategies for implementation; further,

To encourage inclusion of validated criteria in clinical decision support systems and other information technologies to facilitate prescribing for geriatric patients; further,

To acknowledge that such criteria are intended as a guide and should not replace the clinical judgment of pharmacists and other clinicians.

### ***Rationale***

Criteria have been developed to identify high-risk drugs that should be avoided in geriatric patients (i.e., those 65 years of age or older) based on the potential for these therapies to cause adverse drug events that can result in falls, hospitalizations, and other incidents that lead to significant morbidity and mortality in this patient population. Those criteria include the 2002 iteration of the [Beers criteria](#) (published in 2003) and the [Screening Tool of Older Persons' Potentially Inappropriate Prescriptions](#), or STOPP. Although ASHP supports the intent of these criteria to prevent patient harm, safe and effective use of medications in geriatric patients requires the more thorough assessment associated with pharmacist-provided medication therapy management. ASHP opposes adoption of the Beers criteria by the Centers for Medicare & Medicaid Services (CMS) and other accreditation and quality improvement organizations as a tool to assess prescribing in the long-term care and other settings, noting concerns about the development and validation of that tool. More importantly, studies evaluating the clinical application of the 2002 iteration of the Beers criteria have not demonstrated a reduction in adverse events when that tool is used. [*Note: The American Geriatric Society has published an update to the 2002 iteration of the Beers criteria ([DOI: 10.1111/j.1532-5415.2012.03923.x](https://doi.org/10.1111/j.1532-5415.2012.03923.x)).* Although the update addressed some concerns described by the Council (e.g., removal of drugs no longer available), some of the criteria's shortcomings (e.g., lack of validation) remain unresolved.] In that regard, STOPP, which is based on organ systems and accounts for patients' concomitant disease, is considered more useful. Studies evaluating STOPP, though small in number, project a favorable impact on patient outcomes. ASHP encourages additional work to develop, refine, and validate this and similar evidence-based criteria. Further, there is a need for practice-based research to evaluate the application of such criteria and inclusion of validated criteria in clinical decision support systems and other information technologies is necessary to facilitate the use of these criteria in clinical practice. Finally, these tools are intended to serve as a guide or screening tool and should not replace the clinical judgment of pharmacists and other clinicians.

## **1224**

### **TOBACCO AND TOBACCO PRODUCTS**

*Source: Council on Therapeutics*

To discourage the use, distribution, and sale of tobacco and tobacco products in and by pharmacies; further,

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

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

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

To join with other interested organizations in statements and expressions of opposition to the use of tobacco and tobacco products.

*This policy supersedes ASHP policy 0713.*

### **Rationale**

ASHP policy 0713, Tobacco and Tobacco Products, was revised to more clearly define the expanded role of pharmacists in recommending and managing drug therapy to support tobacco cessation, as described in the [ASHP Therapeutic Position Statement on Cessation of Tobacco Use](#). Newer therapies, including varenicline, are associated with more and evolving safety risks when compared to nicotine replacement therapies. Given the complexity of drug therapy, pharmacists should play a central role in ensuring the safe and appropriate use of these therapies. The revisions to this policy better reflect the important role of pharmacists in medication therapy management.

### **1105**

#### **SAFE AND EFFECTIVE USE OF IV PROMETHAZINE**

*Source: Council on Therapeutics*

To recognize intravenous (IV) promethazine as a treatment alternative in limited clinical circumstances; further,

To support health-system efforts to restrict use of IV promethazine by encouraging alternate routes of administration or use of therapeutic alternatives when appropriate; further,

To encourage health systems to establish medication-use processes that reflect nationally recognized best practices to limit the potential for patient harm when IV promethazine use is medically necessary.

### **Rationale**

The Council reviewed information regarding safety concerns with IV administration of promethazine. Promethazine is a known vesicant that has been associated with tissue damage and necrosis if extravasation occurs during IV administration. Recent changes in FDA-approved labeling advise against IV administration, and recommendations from the Institute for Safe Medication Practices (ISMP) promoting safe use have raised awareness about risks associated with IV promethazine administration. However, sporadic and significant patient harm continues to occur. The Council noted that although therapeutic alternatives are available for most indications, the alternative therapies are also not without risk and may not be as effective in

some clinical situations. The Council recognized that promethazine has demonstrated effectiveness and its use may be warranted in some clinical circumstances, and the Board and House concurred. The Council, Board, and House believed that these uses warranted continued availability and use of the product, but they recommended support for health-system efforts to restrict its use to these indications and encouraged implementation of processes that would limit the potential for patient harm.

## 1106

### PAIN MANAGEMENT

*Source: Council on Therapeutics*

To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

To support the participation of pharmacists in pain management, which is a multidisciplinary, collaborative process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,

To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,

To encourage the education of pharmacists, pharmacy students, and other health care providers regarding the principles of pain management and methods to minimize drug diversion.

*This policy supersedes ASHP policy 0306.*

### **Rationale**

The Council reviewed ASHP policy 0306, Pain Management, in light of data from the Centers for Disease Control and Prevention (CDC) that demonstrate a dramatic increase in the number of emergency department (ED) visits related to misuse of prescription and nonprescription therapies. Discussion focused on pain therapies, many of which have the potential for abuse if not used appropriately. Specifically, the rate of ED visits for misuse of prescription opioid therapies, including oxycodone, hydrocodone, methadone, morphine, and fentanyl, more than doubled between 2004 and 2008. Information from other sources describes an increased prevalence of opioid analgesic “pill sharing” (medications obtained from family and friends who have a legitimate prescription) and diversion by family members, especially among teens. Abuse of opioid analgesics and other prescription drugs among health care professionals is also on the rise. The Council, Board, and House were cognizant of the delicate balance between under-treatment of pain and barriers to patient access that can occur with the implementation of abuse-prevention strategies. However, the Council strongly believed that increased attention



to this issue was warranted, given the increasing abuse of these therapies, and the Board and House agreed. In revising the existing policy, the Council, Board, and House intended to increase awareness about the abuse and misuse of some pain therapies and encourage pharmacists to take a lead role in identifying and preventing inappropriate use through individual clinician efforts (e.g., prescriber and patient education on the potential for abuse) and system-based approaches (e.g., use of information technology systems to monitor for trends that suggest inappropriate prescribing or patient use).

## 0902

### PHARMACIST'S ROLE IN PROVIDING CARE FOR AN AGING POPULATION

*Source: Council on Pharmacy Practice*

To encourage expansion of geriatric health care services; further,

To foster expanded roles for pharmacists in caring for geriatric patients; further,

To support successful innovative models of team-based, interdisciplinary geriatric care; further,

To increase training of pharmacists in caring for geriatric patients within college of pharmacy curricula, in ASHP-accredited postgraduate-year-one residencies, and through the expansion of the number of ASHP-accredited postgraduate-year-two geriatric pharmacy residency programs.

#### ***Rationale***

The 2008 report from the Institute of Medicine, *Retooling for an Aging America: Building the Health Care Workforce*, predicts a pending crisis caused by an inadequate workforce for a rapidly increasing elderly patient population and highlights issues significant for pharmacy. Although older adults currently make up only about 12% of the U.S. population, they account for approximately 26% of all physician office visits, 35% of all hospital stays, 34% of all prescriptions, 38% of all emergency medical service responses, and 90% of all nursing-home use. By 2030, the number of adults age 65 and older will have doubled to 70 million, or 20% of total population, which will place even more demands on an already undermanned workforce.

The report recommends three major immediate actions to retool the workforce: enhancing the competence of all health care practitioners in geriatric care, increasing the recruitment and retention of geriatric specialists and caregivers, and redesigning models of care to broaden provider and patient roles to achieve greater flexibility. The report discusses the significant role of pharmacists in counseling, monitoring of medication-related problems, and support of medication adherence. Many elderly people have a number of drug-related issues as well as cognitive impairment and complex needs. These factors increase the amount of expertise, time, and attention required to deliver appropriate care. The pharmacist's role on patient care teams and in medication therapy management will become more important with increasing numbers of frail or chronically ill patients being treated with medication. Many pharmacists may not have received sufficient training to assume this role. While professional education for pharmacists provides basic competence for medication management in the

elderly, education in geriatrics may vary widely, and there are comparatively few geriatric pharmacy specialists, as only 10 programs currently offer ASHP-accredited geriatric pharmacy residency training.

**0908****PHARMACIST ROLE IN THE HEALTH CARE (MEDICAL) HOME**

*Source: Council on Public Policy*

To advocate to health policymakers, payers, and other stakeholders for the inclusion of pharmacists as a care provider within the health care (medical) home model; further,

To ensure that there are appropriate reimbursement mechanisms for the care that pharmacists provide (including care coordination services) within the health care home model; further,

To advocate to the Centers for Medicare & Medicaid Services that pharmacists be included in demonstration projects for the health care home model; further,

To encourage comparative effectiveness research and measurement of key outcomes (e.g., clinical, economic, quality, access) for pharmacist services in the health care home model.

***Rationale***

The concept of a “health care home,” also referred to as a “medical home,” was first described by the American Academy of Pediatrics in 1992. The health care (medical) home model emphasizes care coordination from a medical practice and uses an interdisciplinary health care team approach to managing a patient’s overall health. A recent Medicare Payment Advisory Commission (MedPAC) report discussed a health care home program in Medicare and stated that medication reviews conducted by a health care home would ideally be coordinated by a pharmacist. As the Centers for Medicare & Medicaid Services (CMS) begins health care home demonstration projects, it is important that a pharmacist be included in the health care home model and that pharmacists be factored into the compensation for services provided. To determine the effectiveness of the care that is delivered, research and measurement of key outcomes are important elements of any demonstration or permanent delivery model.

**0912****SAFE AND EFFECTIVE USE OF HEPARIN IN NEONATAL PATIENTS**

*Source: Council on Therapeutics*

To support the development and use of nationally standardized concentrations of heparin when used for maintenance and flush of peripheral and central venous lines in neonatal patients; further,

To advocate that hospitals and health systems use manufacturer-prepackaged heparin flush products to improve the safe use of heparin in neonatal patients.

**Rationale**

The preferential use of saline to maintain peripheral lines and devices in adult patients has largely become the standard of care, but use of heparin in neonates continues because of a lack of consensus and perceived and actual limitations in the evidence in published literature. However, fatal medication errors caused by the use of heparin in this patient population have brought to the forefront concern that the risks of using heparin for this purpose may outweigh the potential benefits. The ASHP Therapeutic Position Statement on the Institutional Use of 0.9% Sodium Chloride Injection to Maintain Patency of Peripheral Indwelling Intermittent Infusion Devices provides evidence for the use of sodium chloride as the preferred solution for maintaining peripheral lines in adult patients but does not address the use of sodium chloride versus heparin in patients younger than 12 years of age, because at the time of publication there was a lack of sufficient evidence regarding the effectiveness of sodium chloride solution for flushing peripheral lines or maintaining their patency in neonatal and pediatric patient populations.

ASHP's Council on Therapeutics has reviewed evidence from evaluations of the use of 0.9% sodium chloride and heparin to maintain and flush arterial and central lines in neonatal patients and reports of medication errors that involved heparin. The advantages of saline include greater compatibility than heparin with concurrently administered drug therapies, lower product costs, fewer potential adverse drug events (e.g., heparin-induced thrombocytopenia, a rare but potentially fatal event for neonatal patients), and prevention of potential medication errors related to improper selection or dilution of heparin products. Advantages of heparin use include extended line patency and a beneficial antithrombotic effect at the insertion site. The data are conflicting and insufficient to support the recommendation of a preferred solution for line maintenance in neonatal patients at this time. The development of standardized concentrations of heparin to decrease practice variation and the use of manufacturer-prepackaged products are the best ways to improve the safe use of heparin in neonatal patients.