House of Delegates

Policies Approved by the 2017 ASHP House of Delegates

1701
Ensuring Patient Safety and Data Integrity During Cyber-attacks
Source: Council on Pharmacy Management

To advocate that healthcare organizations include pharmacists in (1) assessing cyber-security systems and procedures for vulnerabilities, (2) implementing cyber-security strategies, and (3) reviewing cyber-security breaches and developing corrective actions; further,

To encourage the development of business continuity plans by pharmacy departments; further,

To advocate that healthcare organizations assess vendor systems to validate the security and integrity of data, including an assessment of the minimum amount of patient health information vendors require to provide services.

Rationale
As use of technology in healthcare has increased, so has the risk of cyber-attacks on this essential infrastructure. The digitization of patient records and the movement to enhance healthcare with technology has increased the risk of cyber-attacks; from 2015 to 2016, there was a 5.2% increase in such attacks against healthcare targets. Moreover, healthcare facilities made up 7.1% of the identified targets in July 2016, a 5.3% increase from the previous month. Maintaining the privacy of health information, in compliance with the Health Insurance Portability and Affordability Act (HIPAA), and ensuring patient safety in the face of cyber-attacks have become essential concerns for every healthcare organization. In July 2016, the U.S. Department of Health and Human Services released guidance on ransomware and HIPAA. Despite this guidance, there remains very little assistance to prevent data breaches or advice on how to respond when an attack occurs. Increased connectivity with vendor systems creates a mutual need to share access to patient information and other vital data, so risk mitigation must be considered at all points of access. Pharmacists and pharmacy departments need to contribute to organizational efforts to prevent and respond to cyber-attacks as well as develop business continuity plans to ensure they can meet patient needs and protect patient privacy in case of such attacks.

1702

Reduction of Unused Prescription Drug Products

Source: Council on Pharmacy Practice

To recognize that unused prescription drug products contribute to drug misuse, abuse, and diversion; further,

To advocate for research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, including but not limited to partial fills or refills; further,

To advocate that pharmacists take a leadership role in reducing excess quantities of unused prescription drug products.

Rationale

According to the Centers for Disease Control and Prevention (CDC), almost 5% of the U.S. population over 12 years old used prescription pain relievers for nonmedical reasons in 2010, resulting in 15,000 overdose deaths. A major source of diversion is unused prescription drug products, such as those left over after a patient has gained relief from temporary pain. Although prescribers and other healthcare providers have long been aware of the dangers of unused prescription drug products, incentives for overprescribing remain. The desire to minimize office visits, concern about undertreatment of pain, and prohibitions against partial fills and refills of controlled substances contribute to overprescribing.

ASHP recognizes the need for research on best practices to ensure appropriate quantities of drug products are prescribed, which will include study of the effectiveness of partial fills or refills of prescription drug products, among other solutions. ASHP has concerns about quantity and duration limits, because rigid restrictions on treatment options may result in adverse patient outcomes.

Appropriate community return and disposal of excess prescription drug products reduce diversion, accidental poisoning risk, and environmental harm. ASHP advocates for pharmacist leadership in reducing excess quantities of unused prescription drug products through appropriate pain management practices and development and implementation of prescription drug product return and disposal programs.

1703

Pharmacist's Leadership Role in Anticoagulation Therapy Management

Source: Council on Therapeutics

To advocate that pharmacists provide leadership in caring for patients receiving medications for anticoagulant therapy management; further,

To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving medications for anticoagulation therapy management; further,

To encourage pharmacists who participate in anticoagulation therapy management to educate patients, caregivers, prescribers, and other members of the interprofessional

healthcare team about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

This policy supersedes ASHP policy 0816.

Rationale

As medication experts, pharmacists are well poised to play a key role in implementation, maintenance, monitoring, management of complications, risk assessment, and assurance of continuity of care for patients receiving medications for management of anticoagulation therapy. Inappropriate medication-related management of anticoagulants creates unnecessary preventable harm.

The Joint Commission 2008 National Patient Safety Goals for hospitals include a requirement for reducing the likelihood of harm associated with anticoagulant therapy. Healthcare facilities are instructed to assign leadership for ensuring compliance with this requirement, standardize therapeutic practices and protocols, establish monitoring procedures and a drug–food interaction program, individualize care for each patient receiving these treatments, and provide education on the appropriate management of these patients.

1704

Medical Aid in Dying

Source: Board of Directors

To affirm that a pharmacist's decision to participate or decline to participate in medical aid in dying for competent, terminally ill patients, where legal, is one of individual conscience; further,

To reaffirm that pharmacists have a right to participate or decline to participate in medical aid in dying without retribution; further,

To take a stance of studied neutrality on legislation that would permit medical aid in dying for competent, terminally ill patients.

This policy supersedes ASHP policy 9915.

Rationale

Medical aid in dying (also called physician-assisted dying, physician-assisted suicide, physician aid in dying, physician-assisted death, hastened death, medically assisted dying, and death with dignity) has been legal in some areas of the U.S. since Oregon passed its Death with Dignity Law in 1995. By 2016, one sixth of U.S. citizens lived in a jurisdiction in which medical aid in dying was available, and more states were contemplating legislation to legalize it. Experience in Oregon and elsewhere demonstrates that pharmacists in those jurisdictions may be confronted with the difficult ethical question of whether to participate in medical aid in dying.

For purposes of this policy position, ASHP adapts a common definition of medical aid in dying: the practice in which a physician provides a prescription for a lethal dose of medication

to a terminally ill, competent patient at the patient's request that the patient can self-administer at a time of his or her choosing to end his or her life. ASHP notes that many of the terms commonly used to describe this practice ignore the patient care and dispensing roles of pharmacists as well as the roles of other healthcare professionals, such as hospice nurses, in providing care for patients requesting medical aid in dying. ASHP recognizes the utility of a term such as "medical aid in dying" that addresses the roles of all healthcare providers involved in or affected by the practice but acknowledges the term's ambiguity regarding self-administration of the lethal dose. ASHP therefore explicitly distinguishes medical aid in dying from all forms of euthanasia, which is not the subject of this policy.

ASHP takes a position of studied neutrality on whether pharmacists should participate in medical aid in dying. Studied neutrality has been defined as "the careful or premeditated practice of being neutral in a dispute" and has as it goals "to foster a respectful culture among people of diverse views and to guide action that does not afford material advantage to a [particular] group." (Johnstone M-J. Organization Position Statements and the Stance of ''Studied Neutrality'' on Euthanasia in Palliative Care. *J Pain Symp Manag.* 2012; 44:896-907.) ASHP respects the diversity of views of its members and other pharmacists on medical aid in dying and adopts a position of studied neutrality to promote patient autonomy and access to care and to protect pharmacists' professional integrity and comity.

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 medical aid in dying, those principles may clash. Self-determination dictates that patients should be free to exercise their ethical and legal right to choose or decline any legally available treatment. Many healthcare professionals, and their organizations (including the American Medical Association, the American College of Physicians, and the American Nurses Association), question whether death is ever an acceptable therapeutic goal. Others (including the American Academy of Hospice and Palliative Medicine and the American Psychological Association) acknowledge in their statements of neutrality that society may determine that medical aid in dying falls within a spectrum of treatments and withholding of treatments that has as its goal the relief of suffering through a compassionately hastened death, even while recognizing the risks of such a practice.

Pharmacists, like other healthcare professionals, have a right to examine and act on the moral and ethical issues involved in providing care to patients. ASHP policy position 0610, Pharmacist's Right of Conscience and Patient's Right of Access to Therapy, outlines the rights and responsibilities of pharmacists and other pharmacy employees who decline to participate in therapies that they find morally, religiously, or ethically troubling, including the right to reasonable accommodation of their right to conscience in a nonpunitive manner. 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. In adopting its position of studied neutrality on pharmacist involvement in medical aid in dying, ASHP recognizes that adopting a position in favor of participation would infringe on the moral and ethical prerogatives of pharmacists. ASHP similarly recognizes that a stance against participation would make the same

infringement and in addition present the risk of legal or professional sanction for pharmacists who participate in medical aid in dying where it is legal.

ASHP also takes a position of studied neutrality on whether medical aid in dying should be legally permitted for competent, terminally ill patients. ASHP recognizes that society may interpret the principle of patient autonomy to include the right to therapies that some may find morally, religiously, or ethically troubling, including medical aid in dying. Recognizing as well the role of healthcare professionals as guardians against practices that would undermine patient autonomy, ASHP advocates that, when permitted, medical aid in dying only be available to competent, terminally ill patients who freely and knowledgeably make that choice.

ASHP joins other healthcare professional organizations in noting that medical aid in dying is inextricably linked with hospice, palliative, and other end-of-life care. ASHP will therefore continue to advocate that patients receive appropriate pharmacist care at the end of life, including pain management (ASHP policy 1106), support in dying (ASHP policy 0307), and hospice and palliative care.

1705

Workforce Diversity

Source: Council on Education and Workforce Development

To affirm that a diverse and inclusive workforce contributes to health equity and health outcomes; further,

To advocate for the development of a workforce whose background, perspectives, and experiences reflect the diverse patients for whom pharmacists provide care.

Rationale

As the U.S. becomes more heterogeneous, the pharmacy workforce should reflect and respond to this increasingly diverse patient base. An inclusive pharmacy workforce is best able to positively impact the health and wellness of patients for whom pharmacists provide care. According to the Institute of Medicine, increasing 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.[1,2] Diversity in the pharmacy workforce includes, but is not limited to, the categories of sexual orientation and gender expression, age, national origin, socioeconomic origin, ethnicity, culture, gender, race, religion, and persons with disabilities.[3] A diverse pharmacy workforce will provide the best care for all patients.

[1] Smedley 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.

[2] Cohen JJ, Gabriel, BA, Terrell C. The case for diversity in the health care workforce. *Health Aff*.2002;21(5):90-102.

[3] American Medical Association. AMA policies on LGBT issues. http://www.ama-assn.org/ama/pub/about-ama/our-people/member-groups-sections/glbt-advisory-committee/ama-policy-regarding-sexual-orientation.page (accessed 2016 Oct 4).

1706

ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process

Source: Council on Education and Workforce Development

To encourage all educators of the pharmacy workforce to use ASHP statements, guidelines, and professional policies as an integral part of education and training.

This policy supersedes ASHP policy 0705.

Rationale

ASHP members create professional policy that reflect best practices and influence the future direction of the profession and patient care. ASHP's professional policies contain varying levels of detail, but all contain guiding principles for the profession. The use of professional policy should be incorporated into all forms of professional education, including pharmacy and technician students, residents, and practitioners and widely used across the pharmacy profession.

1707

Pharmaceutical Distribution Systems

Source: Council on Pharmacy Management

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

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

This policy supersedes ASHP policy 1016.

Rationale

Wholesaler and distributors have traditionally contracted with hospitals and health systems for basic drug product distribution and other services. Many wholesalers have made a large portion of their revenue through speculative buying and other business practices that are no longer desirable because of requirements for pedigrees, the risk of buying counterfeit or adulterated products, demands by manufacturers to limit product transactions, and the need to manage drug recalls. These changes, plus the vast diversification of many wholesaler distributors, have resulted in new business models that will affect how hospitals acquire and manage pharmaceuticals. These changing models for distribution may result in higher costs for hospitals and health systems, as current wholesaler distribution systems have become very efficient. Recently, some wholesalers have required that pharmacies ensure certain drugs are not used or

sold for use for particular purposes, and there are concerns that this practice could grow. ASHP supports wholesaler and distribution business models that meet the requirements of hospitals and health systems, which includes the ability for pharmacies to obtain drug products for established patient care uses without restriction.

1708

Mobile Health Tools, Clinical Apps, and Associated Devices

Source: Council on Pharmacy Management

To advocate that patients, pharmacists, and other healthcare professionals be involved in the selection, approval, and management of mobile health tools, clinical software applications ("clinical apps"), and associated devices used by clinicians and patients for patient care; further,

To foster development of tools and resources to assist pharmacists in designing and assessing processes to ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices; further,

To advocate that decisions regarding the selection, approval, and management of mobile health tools, clinical apps, and associated devices should further the goal of delivering safe and effective patient care and optimizing outcomes; further,

To advocate that mobile health tools, clinical apps, and associated devices that contain health information be interoperable and, if applicable, be structured to allow incorporation of health information into the patient's electronic health record and other essential clinical systems to facilitate optimal health outcomes; further,

To advocate that pharmacists be included in regulatory and other evaluation and approval of mobile health tools, clinical apps, and associated devices that involve medications or medication management.

Rationale

The use of mobile devices (e.g., smartphones, tablets) has become commonplace. Over 68% of adults own a smartphone, and 62% of those use their smartphones to access health information. In addition to these mobile devices, use of remote monitoring devices is also being rapidly integrated into healthcare. According to a 2015 survey, although only 16% of healthcare professionals currently use mobile health tools in caring for patients, 46% plan to do so in the next five years. With the proliferation of mobile health tools, clinical apps, and associated devices, healthcare organizations need to address the potential risks of application use. Particular concerns include (1) assessing the quality of mobile health tools, clinical apps, and associated devices; (2) standardizing choices and use across the organization; and (3) ensuring the security of data and data storage.

To maximize the effectiveness of mobile health tools, clinical apps, and associated devices, they must be selected, approved, and managed with the goal of improving care and with input from representatives of all affected parties, including patients, physicians,

pharmacists, and other healthcare professionals. In addition, their effectiveness is enhanced when they are interoperable (as described in ASHP policy 1302, Interoperability of Patient-Care Technologies) and the data stored within them can be incorporated into the patient's electronic health record and other essential clinical systems.

Providers and patients currently have little guidance regarding use of these resources or the management of the data they provide. The Food and Drug Administration and other regulatory agencies are just beginning to determine the scope of their oversight. As medication-use experts, pharmacists can contribute to the regulatory evaluation and approval of mobile health tools, clinical apps, and associated devices that involve medications or medication management. In addition, ASHP is committed to fostering development of resources to help pharmacists ensure safe, accurate, supported, and secure use of mobile health tools, clinical apps, and associated devices.

1709

Controlled Substance Diversion Prevention

Source: Council on Pharmacy Management

To encourage healthcare organizations to develop controlled substances diversion prevention programs and policies that delineate the roles, responsibilities, and oversight of all personnel who have access to controlled substances to ensure compliance with applicable laws and scopes of practice; further,

To encourage healthcare organizations to ensure that all healthcare workers are appropriately screened for substance abuse prior to initial employment and surveillance, auditing, and monitoring are conducted on an ongoing basis to support a safe patient-care environment, protect co-workers, and discourage controlled substances diversion.

Rationale

Abuse of controlled prescription drugs (CPDs) is on the rise in the U.S. According to the 2014 National Drug Threat Assessment Summary from the Drug Enforcement Administration (DEA), deaths involving CPDs 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 institutions that handle controlled substances are required to have storage and distribution systems in place to prevent diversion. Due to the numerous medication access points in most hospital distribution systems, diversion is sometimes difficult to detect. Theft of controlled substances by healthcare workers remains a serious problem that can lead to patient harm and jeopardize patient safety. Drug addiction among healthcare workers is well documented. One survey suggested 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 published in *AJHP*, 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.

Pharmacy managers and pharmacists-in-charge have increasing responsibility for ensuring controlled substance management and storage across large healthcare organizations. This expanded responsibility has increased the risk to organizations as aquisitions of physician office practices, clinics, and other nonhospital-based business units continue. To ensure compliance with applicable laws and scopes of practice, ASHP advocates that healthcare organizations develop controlled substances diversion prevention programs and policies to describe the roles, responsibilities, and oversight of all personnel who have access to controlled substances throughout the organization. ASHP supports pre-employment screening and ongoing surveillance, auditing, and monitoring of all healthcare workers to reduce the risk of controlled substances diversion.

1710
Revenue Cycle Compliance and Management
Source: Council on Pharmacy Management

To encourage pharmacists to serve as leaders in the development and implementation of strategies to optimize medication-related revenue cycle compliance, which includes verification of prior authorization, patient portion of payment, billing, reimbursement, and financial documentation for the healthcare enterprise; further,

To advocate for the development of consistent billing and reimbursement policies and practices by both government and private payers; further,

To advocate that information technology (IT) vendors enhance the capacity and capability of IT systems to support and facilitate medication-related purchasing, billing, and audit functions; further,

To investigate and publish best practices in medication-related revenue cycle compliance and management.

This policy supersedes ASHP policy 1205.

Rationale
Pharmacy has an increasingly important role in optimizing revenue capture and avoiding revenue erosion resulting from improper billing or inadequate documentation of medication-related charges. Pharmacy needs to be involved in aspects of medication-related billing, including not just pharmacy drug charges and billing but also contracting and negotiating for carve-outs. Pharmacy leaders need to actively engage senior leadership and collaborate with various departments to ensure organizational success in revenue cycle management.

Recently, organizations have experienced increasing compliance pressures. This pressure comes from many sectors, including Centers for Medicare & Medicaid Services (CMS) programs plus state-specific requirements, third-party payers, and financial intermediaries. These policies impact organizations in two ways: increased requirements before the insurers will pay for a claim, and increased audit pressure to be sure the organizations are billing accurately. The frequency and nature of audits has also been changing. Insurers have increased

the use of audits to control costs. Government agencies have also increased the use of audits. CMS has implemented Recovery Audit Contractor (RAC) audits, and the Office of the Inspector General is also auditing organizations. Results of the audits can have significant financial impact on the organization when money needs to be returned based on improper billing or lack of documentation.

Historically, pharmacy departments have great strength in managing supply chain issues. Drug expenditures are typically a significant portion of any hospital's budget. Pharmacy is a key leader in managing these expenses. However, pharmacy departments are involved in broader revenue cycle management in variable ways. In some organizations, the billing or patient accounting departments handle all billing issues with various degrees of pharmacy involvement. Accurate billing requires integration of the organization's clinical services, pharmacy, billing, and charge master functions. The required elements for proper billing may reside in several systems. As coverage decisions become more complex, pharmacy expertise is increasingly required in the clinical coverage decisions and information integration in order to be successfully reimbursed for services. For the healthcare enterprise to successfully manage compliance and optimize revenue capture there must be effective collaboration among various departments. Pharmacy knowledge and leadership is increasingly required to ensure organizational success in revenue cycle management.

Each insurer has different requirements for coverage determinations, and coverage decisions have become more complex. More drugs now require prior authorization processes. In some cases, even if the prior authorization process has been used, the charge is denied. Medicare has implemented requirements for self-administered drugs (SADs), and diabetic supplies are now handled under durable medical equipment (DME) requirements, which may require different data elements before a bill is processed. Medicaid requires the National Drug Code (NDC) prior to payment, and billing requirements for Medicare and Medicaid programs are not harmonized. Healthcare Common Procedure Coding System (HCPCS) codes also need to be attached where indicated. It is challenging to keep up with all the changes. International Classification of Disease 10 (ICD-10) codes further complicate required coding. Current IT solutions are inadequate and do not effectively facilitate effective billing. Current systems are often not designed to capture all necessary information required to properly document and bill. Even when necessary data is captured it often resides in different departmental computer systems that are not integrated and designed to share data. There is a need for better IT solutions to facilitate both billing and audits. Greater consistency in billing and reimbursement practices would facilitate greater compliance and enable the development of effective technology solutions to improve billing and reimbursement processes.

Since pharmacy leaders have had variable levels of engagement in revenue cycle management, there is a need for education, tools, and resources related to best practices. Some pharmacy departments have created a business manager position in part to deal with these issues. This position is often not a pharmacist, but a staff member with business training. New roles for pharmacy technicians have also emerged in this area. ASHP and the Section of Pharmacy Practice Managers are committed to developing and sharing best practices and providing education to support pharmacists in optimizing pharmacy's role in revenue cycle compliance.

1711

Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use

Source: Council on Pharmacy Practice

To advocate that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that regulators (e.g., the Food and Drug Administration) have the authority to impose requirements on pharmaceutical manufacturers to provide hazardous drug products intended for home use in ready-to-administer packaging; further,

To advocate that when hazardous drug products intended for home use are not available from manufacturers in ready-to-administer packaging, pharmacies repackage those drug products to minimize the risk of exposure; further,

To advocate that hazardous drug products intended for home use be labeled to warn that special handling is required for safety; further,

To advocate that pharmacists provide education to patients and caregivers regarding safe handling and appropriate disposal of hazardous drug products intended for home use.

Rationale

Home use of oral chemotherapy increases patient convenience and lowers healthcare costs, but it presents unique safety risks. In a hospital or clinic setting, healthcare professionals manage the risks posed by hazardous drugs, defined as any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing hazardous drugs in structure or toxicity (NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings). In the home environment, however, patients and caregivers must be prepared to fill that role. Ready-to-administer packaging of hazardous drugs minimizes patient, caregiver, and family exposure to hazardous drugs, promotes patient adherence, and enhances safe medication use. Ready-to-administer packaging is defined as packaging that provides the product in a way that requires no manipulation before that patient or caregiver can administer the medication. In contrast, ready-to-use packaging may require a small amount of manipulation (e.g., reconstitution). These definitions are consistent with United States Pharmacopeia and Institute for Safe Medication Practices terminology. ASHP advocates that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging, and that regulators have the authority to require manufacturers to (1) provide hazardous drug products intended for home use in ready-to-administer packaging, and (2) label hazardous drug products intended for home use to warn that special handling is required to ensure safety. ASHP further advocates that when hazardous drug products intended for home use are not available in ready-to-administer packaging, pharmacies repackage those drug products to minimize exposure risk for caregivers and others in the patient's household. For example, intravenous drug products should be dispensed in a container designed so the patient or

caregiver does not have to puncture a vial; tablets are split or crushed prior to dispensing; compounding of liquid medications is done by the pharmacy, if stability information for the drug product supports advanced compounding and transport; and all liquid medications are dispensed with a dispensing cap that can accommodate attachment of an oral syringe. Finally, ASHP advocates that patients and caregivers be provided education regarding safe handling of hazardous drug products from a qualified healthcare professional, preferably a pharmacist experienced in managing the risks of hazardous drug products.

1712

Expiration Dating of Pharmaceutical Products

Source: Council on Pharmacy Practice

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs and reducing healthcare costs; further,

To advocate that the Food and Drug Administration implement procedures to encourage pharmaceutical manufacturers to readily update expiration dates, for as long as possible while maintaining drug potency and safety, to reflect current evidence; further,

To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.

This policy supersedes ASHP policy 9309.

Rationale

Extending the expiration date of commercially available pharmaceutical products for as long as possible, while maintaining drug potency and safety, reduces healthcare costs and increases access. ASHP encourages pre- and post-marketing research on expiration dates and the use of the most current authoritative data on expiration dates in drug product management. However, the current process for updating expiration dates in drug product labeling presents barriers to timely revision and should be streamlined to allow for timely updates. Until such a process is implemented, regulators and accreditation agencies should permit healthcare organizations to rely on authoritative data when determining appropriate extended expiration dates for commercially available pharmaceutical products.

1713

Partial Filling of Schedule II Prescriptions

Source: Council on Public Policy

To advocate that state legislatures and boards of pharmacy create consistent laws and rules to allow partial filling of Schedule II drugs; further,

To advocate that public and private entities construct criteria for partial filling to minimize the additional burden on patients, pharmacists, and healthcare organizations; further,

To advocate that pharmacists educate prescribers and patients about options for filling prescriptions for Schedule II drugs, including the risks of overprescribing, while recognizing the patient or caregiver's rights to make their own care and management decisions.

Rationale

The issue of opioid abuse and addiction has been at the forefront of federal and state activity. Increasing addiction rates of patients taking powerful opioids have spurred calls for action to help address this growing problem. The issue has become national in scope and has generated discussion among policymakers and healthcare practitioners alike. In mid-2016, Congress passed the Comprehensive Addiction and Recovery Act of 2016, legislation aimed at curbing opioid abuse and enhancing access to addiction treatment. States have been considering their own legislative initiatives to address what is increasingly described as an epidemic.

One solution proposed by policymakers is to allow pharmacists to dispense only a portion of the quantity of a Schedule II drug prescribed (e.g., 7 days of the prescribed quantity of the drug rather than an entire 30-day supply). Such "partial filling" of Schedule II drug prescriptions reduces the potential of opioid addiction for the patient and the risk of diversion for others. Federal law has been changed to permit partial filling of Schedule II drugs, and Massachusetts and Maine have passed laws to allow for partial filling of Schedule II drugs. ASHP advocates that other state legislatures and boards of pharmacy amend pharmacy practice acts and rules to allow for partial filling of Schedule II drugs, and that such laws and rules be made consistent across states. However, ASHP has concerns about quantity and duration limits applied across the board and not on an as-needed basis. ASHP believes that each patient must be evaluated individually and that polices that allow for partial filling are not indiscriminately applied as an across-the-board mandatory rule. ASHP encourages public and private payers to recognize the additional burden placed on patients and pharmacies by partial filling and to minimize these burdens when possible, including providing appropriate reimbursement for pharmacist activities. ASHP encourages pharmacists to serve as patient advocates by educating prescribers and patients about options for filling prescriptions for Schedule II drugs.

1714

Restricted Drug Distribution

Source: Council on Public Policy

To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) are not supported by publicly available evidence that they are the least restrictive means to improve patient safety; (7) interfere with the professional practice of healthcare providers; or (8) are created for any reason other than patient safety.

This policy supersedes ASHP policy 0714.

Rationale

Restricted drug distribution systems (RDDSes) that are not created solely for patient safety reasons significantly restrict patient access to medications. These systems were justified as a

means to closely monitor patient use of medications that could potentially pose a safety risk. They were never intended to allow drug manufacturers to reduce pharmacists' access to medications through limited distribution networks. Using restricted distribution as a tool to gain marketplace advantage rather than for patient safety undermines the justification for such limited systems. ASHP opposes the use of RDDSes for anything other than patient safety and encourages the FDA or other appropriate authorities to investigate whether RDDSes are being used in a manner inconsistent with the original intent. In addition, RDDSes may compromise continuity of care or interfere with pharmacists' accountability for care to certain patient populations, such as when an RDDS prevents a patient's pharmacist from obtaining it. Some investigational drugs approved for marketing under an RDDS are no longer available for qualifying patients on admission through the institution, despite the institution having a history of managing the drug while it was investigational. Such circumstances force the patient to seek care elsewhere or require them and their healthcare providers to unnecessarily utilize additional resources to provide care. In addition, healthcare organizations, responsible for the total care of the patient, including maintaining the patient's medical records, may lose the established patient-care relationship when a patient must go to a specialty pharmacy for a drug the healthcare organization cannot access. RDDSes fragment the healthcare delivery system at a time when public and private payers are increasing incentives to integrate patient care.

1715
Collaborative Practice
Source: Council on Public Policy

To pursue the development of federal and state laws and regulations that authorize pharmacists as providers within collaborative practice; further,

To advocate expansion of federal and state laws and regulations that optimize pharmacists' ability to provide the full range of professional services within their scope of expertise; further,

To advocate for federal and state laws and regulations that would allow pharmacists to prescribe and transmit prescriptions electronically; further,

To acknowledge that as part of these advanced collaborative practices, pharmacists, as active members in team-based care, must be responsible and accountable for medication-related outcomes; further,

To support affiliated state societies in their pursuit of state-level regulations allowing collaborative practice for pharmacists.

This policy supersedes ASHP policy 1217.

Rationale

Although many states permit pharmacists to serve as providers in collaborative practice, there is great variability in the authority granted to pharmacists. ASHP supports collaborative practice and advocates its expansion to all states, in a variety of diverse practice settings, and at the highest level of pharmacy practice. As new pharmacy practice models emerge, collaborative practice should be a part of those innovations. One of the common barriers to the highest level of collaborative practice is the prohibition of pharmacists transmitting prescriptions electronically. The expansion of collaborative practice, including electronic transmission of prescriptions, will aid in moving the profession forward to the highest level of team-based practice and will enable pharmacists to practice at the top of their licenses, accountable to the patient and the team for medication-related outcomes.

1716

Greater Competition Among Generic and Biosimilar Manufacturers

Source: Council on Public Policy

To advocate for legislation and regulations that promote greater competition among generic and biosimilar pharmaceutical manufacturers.

This policy supersedes ASHP policy 0222.

Rationale

A healthy market for generic drug products and biosimilars increases patient access to drugs and lowers drug costs. ASHP recognizes several threats to the health of that market and advocates legislative and regulatory solutions: speeding FDA approval of generic drug applications, especially for lifesaving drugs; reducing drug monopolies by incentivizing competition for additional market entrants; targeting exclusivity protections to truly innovative products; and curbing abuse of risk evaluation and mitigation strategies (REMS). In 2015, the FDA faced a backlog of nearly 4,000 generic drug applications, with the approval process taking three years or more. ASHP advocates that the FDA be provided the resources needed to evaluate and approve generic drug applications in a safe and timely manner. ASHP also advocates government and market incentives to increase competition for expensive drugs where no competitors exist and encourage additional market entrants. ASHP has long recognized that agreements between generic and brand-name manufacturers when a product's market exclusivity is about to expire have the effect of delaying the marketing of competitor products and limiting patient access to affordable generic drugs. ASHP advocates for legislative and regulatory solutions to limit such agreements, as well as solutions to prevent brand-name manufacturers from extending market exclusivity and preventing market entry by generics by slightly altering the formulation of a product. ASHP further advocates legislation that would prevent frivolous patent infringement litigation by brand-name manufacturers, which is reported to have been initiated with the sole intent to extend market exclusivity. Another solution advocated by ASHP is curbing misuse of REMS, which are reported to have been used to prevent generic manufacturers from accessing drug products. In addition, ASHP advocates for more consumer-accessible information on drug prices, including an annual report on increases in drug prices, which would provide patients and their healthcare providers with the

information they need to make drug purchasing choices. Finally, ASHP encourages appropriate federal review of anticompetitive practices by pharmaceutical manufacturers.

1717
Drug Testing
Source: Council on Public Policy

To recognize the use of pre-employment and random or for-cause drug testing during employment based on defined criteria and with appropriate testing validation procedures; further,

To support employer-sponsored drug programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that employers use validated testing panels that have demonstrated effectiveness detecting commonly abused or illegally used substances.

This policy supersedes ASHP policy 9103.

Rationale
Controlled substance diversion and abuse has reached the attention at the highest levels in the U.S., with even the White House weighing in on the crisis. In the past 4-5 years, the Drug Enforcement Administration has levied large fines on chain drugstores, drug wholesalers, and even major hospitals. Pharmacy managers and pharmacists-in-charge have increasing responsibility of ensuring controlled substance management and storage across large healthcare organizations. There is an increased risk to organizations as acquisitions of physician office practices, clinics, and other nonhospital-based business units continue, and many challenges exist for healthcare institutions in managing controlled substances.
ASHP recognizes that drug testing job applicants and employees whose responsibilities may bring them into contact with controlled substances is an essential element of diversion prevention programs. Pre-employment and random or for-cause drug testing should be performed based on defined criteria, with appropriate testing validation procedures, and have demonstrated effectiveness detecting commonly abused or illegally used substances. In addition, drug testing should be supported by an employee addiction recovery program, as outlined in the ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance.

1718
Therapeutic and Psychosocial Considerations of Transgender Patients
Source: Council on Therapeutics

To support medication and disease management of transgender patients as a part of care unique to this population; further,

To advocate that transgender patients have access to pharmacist care to ensure safe and effective medication use; further,

To promote research on, education about, and development and implementation of therapeutic and biopsychosocial best practices in the care of transgender patients; further,

To encourage structured documentation of both a patient's birth sex and self-identified gender in electronic health records.

Rationale

The transgender population is a small population that has unique healthcare and biopsychosocial needs. There are guidelines to help practitioners caring for the patients identify these needs and recommendations for practitioners to consider.

Patients electing to transition from their birth sex to their self-identified gender may have surgeries and take higher doses of hormones to change their physical appearance to reflect their self-identified sex. These patients have significant requirements for therapeutic drug monitoring, as certain lab values may to appear out of normal limits but are clinically appropriate for the transgender patient, and the risk of drug-drug interactions may be higher because medications may be taken at a higher than normal doses. These patients may be more at risk for adverse effects, including thyroid disorders, and may more frequently require anticoagulation and management of diabetes as a result of medication therapy. Other unique needs of these patients include cardiovascular and thrombotic risk assessment, screening for certain types of cancers should they elect to keep their gonadal organs, and other associated primary care screenings associated with their birth sex. Considerations for transgender patients who wish to have children will add the complexity of fertility as well as attention to use of teratogenic medications to their needs. Because of the unique and complex healthcare needs of transgender patients, it is essential that they have adequate access to appropriate care, including pharmacist care. To help ensure appropriate assessment and treatment, patients' birth sex and self-identified gender should be documented in a structured way in electronic health records. This documentation also helps healthcare providers address another of the unique biopsychosocial needs of transgender patients; like other healthcare providers, pharmacists should address transgender patients by their self-identified gender.

1719

Pharmacist's Leadership Role in Glycemic Control

Source: Council on Therapeutics

To advocate that pharmacists provide leadership in caring for patients receiving medications for management of blood glucose; further,

To advocate that pharmacists be a member of the interprofessional healthcare team that coordinates glycemic management programs; further,

To encourage pharmacists who participate in glycemic management to educate patients, caregivers, prescribers, and other members of the healthcare team about glycemic control medication uses, metrics, drug interactions, adverse effects, lifestyle modifications, the

importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

Rationale

As medication experts, pharmacists play a key role in implementation, maintenance, monitoring, management of complications, risk assessment, and assurance of continuity of care for patients receiving medications for management of blood glucose. Inappropriate medication-related management of diabetes creates unnecessary, preventable harm. There is a direct relationship between medication administration and harm from inappropriately managed glycemic agents. In 2014, the Accountability Measures Work Group identified the incidence of hypoglycemic and hyperglycemic events and evidence of poorly controlled diabetes (hemoglobin A1C value exceeding 9%) as clinical measures for pharmacist accountability. Given this responsibility, pharmacists need to provide leadership in caring for patients receiving medications for management of blood glucose, including education of patients and members of the interprofessional healthcare team. To enhance their ability to participate in the care of these patients, many pharmacists have elected to become certified diabetes educators. This training strengthens the value of pharmacists and permits them to be more aligned with the benchmarking tools linked with reimbursement models. The unknown adverse effects of sustained hyperglycemia in the inpatient and outpatient settings, as well as during transitions of care, demonstrate a continued need for pharmacist-led research in all settings.

1720

Drug Dosing in Conditions That Modify Pharmacokinetics or Pharmacodynamics

Source: Council on Therapeutics

To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic conditions; further,

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and electronic health record documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic conditions; further,

To collaborate with stakeholders in enhancing aggregation and publication of and access to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug dosing within these patient populations.

Rationale

The pharmacokinetic and pharmacodynamic properties of drugs found in drug information monographs are based on the drug's absorption, distribution, metabolism, and excretion in healthy, adult patients during Phase I of a drug's clinical trials. Many patients receiving medication therapy do not fit this profile, and many have compromised organ function. The medical community has long recognized the need for a standardized approach to evaluating organ system dysfunction. Although there are methods to determine organ function (e.g., the Cockcroft-Gault equation for renal function or the Child-Turcotte-Pugh Classification for Severity of Cirrhosis), there is debate as to whether these methods are true indicators of organ

function, as the components that comprise these equations may fluctuate based on severity and patient status. Traditional laboratory values used to evaluate organ dysfunction can be bidirectional and conflicting as well.

In addition, with the exception of adjustments for renal dysfunction, there is not much information regarding dosage adjustment for specific medications. Many organ systems are involved in a drug's absorption, distribution, metabolism, and excretion. Hepatic effects, for example, are a risk area, as those effects are slower to be seen and have not been the subject of as much research, and the number of drugs affected are smaller in number than renally excreted drugs. Both acute and chronic aspects of patient conditions may require monitoring and adjustment, including sepsis, encephalopathies, pregnancy, heart failure exacerbations, and cystic fibrosis, and certain protocols such as therapeutic hypothermia can also have clinically significant impact on a drug's pharmacokinetic and pharmacodynamic behavior. There is also need to promote research and utilization of biomarkers into practice, as these may reflect organ function and may provide pharmacists with a more complete clinical picture.

1721

Clinical Significance of Accurate and Timely Height and Weight Measurements

Source: Council on Therapeutics

To encourage pharmacists to participate in interprofessional efforts to ensure accurate and timely patient height and weight measurements are recorded in the patient medical record to provide safe and effective drug therapy; further,

To encourage drug product manufacturers to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,

To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes.

Rationale

Patients who have clinically significant changes in weight during an admission or between physician visits, or who are at an extreme high or low weight, have a higher risk of medication dosing errors that depend on weight body surface area. Accurate heights and weights in SI units (i.e., kilograms, grams, meters, and centimeters) are an integral part of a physical examination for pharmacists to ensure proper dosing of medications. Certain medications require dosing based on body surface area, and there is a need for healthcare organizations to consistently record patients' height, as estimation of height or weight can contribute to potential over- or underdosing.

Factors such as clinically significant changes in weight due to fluid overload and subsequent diuresis, patient growth, and weight changes due to changes in caloric consumption complicate the picture of an appropriate weight to record for dosing certain medications. Some healthcare organizations default to a dosing weight that is used for dosing medications alone, while other weight fluctuations recorded on a daily basis are not used to dose medications, whereas other organizations alert pharmacists to a clinically significant change in weight. Leveraging technology to ensure such safeguards are in place is essential, and providing interoperability between the patient's recorded dosing weight and smart pumps is ideal.

Pharmacists are also seeing an increase in the number of patients at both extremes of weight, and there is a lack of information regarding dosing medications for these populations. ASHP advocates that the Food and Drug Administration (FDA) develop guidance for voluntary drug dosing studies in these populations, as the need for this guidance is supported by the complexity of drug dosing that can vary based on drug and patient characteristics. Drug product manufacturers should be encouraged to complete pharmacokinetic and pharmacodynamic dosing studies, and to publicly report the results, especially for drugs for which significant weight extremes may have clinical impact.

1722

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 foster the development of educational resources on multimodal pain therapy, substance abuse and prevention of adverse effects; further,

To encourage the education of pharmacists, pharmacy students, and other healthcare providers regarding the principles of pain management and substance abuse that encourage holistic, supportive approaches and reduce stigma surrounding opioid-use disorders.

This policy supersedes ASHP policy 1106.

Rationale

Currently there are over 100 million adults in the United States affected by acute and chronic pain. Pain management requires ongoing assessment and reassessment of analgesia, activities of daily living, and adverse effects. Pharmacists are well poised to fill a key role in appropriate treatment and optimization of severe pain and chronic pain with multimodal treatment strategies. Pain therapies, in particular, have the potential for abuse if not used appropriately. ASHP is cognizant of the delicate balance between undertreatment of pain and barriers to patient access that can occur with the implementation of abuse-prevention strategies. ASHP advocates increased awareness of the abuse and misuse of some pain therapies and encourages 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) that encourage holistic, supportive care and reduce stigma surrounding opioid-use disorders.

1723

Clinical Investigations of Drugs Used in Elderly and Pediatric Patients

Source: Council on Therapeutics

To advocate for increased enrollment and outcomes reporting of pediatric and geriatric patients in clinical trials of medications; further,

To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in pediatric and geriatric patients to facilitate safe and effective dosing of medications in these patient populations.

This policy supersedes ASHP policy 0229.

Rationale

Pediatric and geriatric patients are populations in which the pharmacokinetic and pharmacodynamic properties of medications may differ from those typically seen in an adult patient. These differences can dramatically alter the behavior of drugs, producing supra- or subtherapeutic levels, which may result in adverse effects. While there has been legislation that provides incentive for drug manufacturers to study these effects, many drugs already approved by the FDA do not have such information or robust outcomes reporting for these at-risk populations. The need for this guidance is supported by the complexity of drug dosing for these patients, which varies based on drug and patient characteristics. A paucity of research in these patient populations is noted, which is similar to the lack of preapproval studies in obese patients. ASHP also encourages independent clinical and practice-based research to further define clinical use of drugs in the treatment of these patients, as well as clinician reporting of patient experience via published articles and clinical registries.

1724

Safe and Effective Therapeutic Use of Invertebrates

Source: Council on Therapeutics

To recognize use of medical invertebrates as an alternative treatment in limited clinical circumstances; further,

To educate pharmacists, patients, and the public about the risks and benefits of medical invertebrates use and about best practices for use; further,

To advocate that pharmacy departments, in cooperation with other departments, provide oversight of medical invertebrates to assure appropriate formulary consideration and safe procurement, storage, control, prescribing, preparation, dispensing, administration, documentation, clinical and regulatory monitoring, and disposal; further,

To encourage independent research and reporting on the therapeutic use of medical invertebrates.

Rationale

Medical invertebrates, including leeches and maggots, are increasingly used in practice, including in treatment of extravasation injury, post-plastic-surgery salvage, relief of vascular congestion, macroglossia, compartment syndrome, pain management, and debridement therapy. The use of medical invertebrates is not without risk. There have been reports of local and systemic infections with use of leeches and transmission of communicable disease if not handled properly, and use may mask coagulopathies. Antimicrobial prophylaxis may be required, and there are also drug-invertebrate interactions that may impact the effectiveness of invertebrate therapy. There is also limited research on the efficacy of these therapies that lead to varied practice and unsubstantiated claims.

1725

Drug Dosing in Extracorporeal Therapies

Source: Council on Therapeutics

To encourage research on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To support development and use of standardized models of assessment of the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To collaborate with stakeholders in enhancing aggregation of data on the pharmacokinetics and pharmacodynamics of drug dosing in extracorporeal therapies; further,

To encourage the education of the pharmacy workforce and other healthcare providers regarding the basic principles of and drug dosing in extracorporeal therapies.

This policy supersedes ASHP policy 1606.

Rationale

There are few resources and recommendations for drug dosing in patients receiving the varied forms of extracorporeal therapies, including renal replacement therapy, extracorporeal membrane oxygenation (ECMO) support, apheresis, plasmapheresis, molecular adsorbent recirculating system (MARS) support, single pass albumin dialysis (SPAD), fractionated plasma separation and adsorption (PROMETHEUS), therapeutic plasma exchange (TPE), extracorporeal liver assist device (ELAD) support, modular extracorporeal liver (MELS) support, peritoneal dialysis, and use of ventricular assist devices.

Appropriate dosing is very important in optimizing patient outcomes and achieving 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 receiving these therapies. 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.

Research on drug removal by these extracorporeal means is scarce, and ASHP encourages independent clinical and practice-based research to further define clinical use of drugs for patients receiving these modes of treatment as well as clinician reporting of patient experience via published articles and clinical registries. ASHP also encourages education of the pharmacy workforce and other healthcare providers regarding the basic principles of and drug dosing in extracorporeal therapies.

Policies 1701 -1703 were approved by the virtual House of Delegates in March. Policies 1704-1725 were approved at the June meetings of the House of Delegates.