House of Delegates

Policies Approved by the 2019 ASHP House of Delegates

1901
Suicide Awareness and Prevention
Source: Council on Education and Workforce Development, Council on Pharmacy Management, Council on Pharmacy Practice, Council on Public Policy, and Council on Therapeutics
To support the goal of zero suicides; further,

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

To acknowledge that optimal suicide awareness and prevention efforts focus both on patients and on the healthcare workforce; further,

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

To foster the use and development of clinically validated tools to aid the pharmacy workforce in assessing the influence of medications and other factors on suicidality; further,

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

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

To encourage efforts that support universal education and training of healthcare providers in suicide awareness and prevention; further,

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

To enhance awareness of local, state, and national suicide awareness and prevention resources, including the National Suicide Prevention Lifeline funded by the Substance Abuse and Mental Health Services Administration; further,

To foster education and research on suicide awareness and prevention.

Rationale

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

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

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

Given the leading role of pharmacists in overseeing safe medication use, the dangers of medications relating to suicide risk, and the high degree of pharmacist interaction with patients, pharmacists are well positioned to play a key role in suicide awareness and prevention efforts. The pharmacist's role could include, for example, ensuring appropriate use of medications in management of mental health and other medical conditions; identifying patients at risk for suicide, and evaluating that suicide risk; and recommending care, making referrals, and following up on referrals with patients and providers. Strategies could range from evaluating patients' prescribed medications and identifying those that increase risk for suicidality; to counseling patients, caregivers, and other healthcare providers about those risks; to educating the public about the dangers of unused medications and the need for proper disposal. Clinical pharmacy specialists trained in behavioral health could also be incorporated into behavioral health programs to serve as a resource to the healthcare team. Other pharmacy practitioners (student pharmacists and pharmacy technicians) could perform vital services in suicide awareness and prevention efforts as well, such as medication reviews. The goal of zero

suicides will also require a combined effort from individual healthcare workers and the healthcare system as a whole to sustain clinician well-being and resilience, as further described in ASHP policy 1825, Clinician Well-Being and Resilience.

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

1902

Safe Administration of Hazardous Drugs

Source: Council on Pharmacy Practice

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

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

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

Rationale

Hazardous drugs (HDs) present well-known risks to healthcare workers who handle them. Most HDs are administered orally or intravenously; however, other routes of administration are sometimes used, such as intrathecal, intraventricular, or intravesicular administration, or perfusion into a vessel or organ cavity. These procedures are becoming more common. Healthcare providers are required to use personal protective equipment and other protective devices, such as closed-system transfer devices (CSTDs), when the dosage form allows. The

protective precautions required for administration through these routes is well described in United States Pharmacopeia (USP) General Chapter 800, the ASHP Guidelines on Handling Hazardous Drugs, the Oncology Nursing Society's Safe Handling of Hazardous Drugs, and other sources.

HDs are sometimes administered through other routes (e.g., Ommaya reservoirs, intraperitoneal infusion) for which protective precautions are not as well described or CSTD use is not possible. ASHP encourages all healthcare settings to conduct an interprofessional, proactive assessment of the risk of such procedures to assess the potential exposure risks for healthcare providers and identify mitigating measures. Given their depth of knowledge regarding the handling of HDs, pharmacists should be involved in the development of policies, procedures, and operational assessments regarding administration of HDs in such circumstances. To reduce the risks to healthcare providers, ASHP encourages device and pharmaceutical manufacturers and the Food and Drug Administration to foster the development of CSTD-compatible, ready-to-administer HD drug products. The goal would be that CSTDs be utilized for all routes of administration of HD products as a best practice. However, when such use is not possible, an assessment of risk could identify gaps and ensure there are pharmacy-guided policies to address the handling, compounding, and administration for all healthcare staff coming into contact with HDs during administration via nontraditional routes. Such policies could also address any specialized training for staff in procedural areas, or the availability of a HD-specialized trained staff member to assist in the administration of the drug (e.g., a "chemo nurse").

1903

Compounded Sterile Preparation Verification

Source: Council on Pharmacy Practice

To advocate that health systems adopt automation and information technology to facilitate in-process and final verification of compounded sterile preparations (CSPs) to ensure CSP quality; further,

To advocate that, until such time as automation or technology can be implemented, independent in-process and final verification of CSPs be performed; further,

To oppose the use of the syringe pull-back method or other proxy methods of CSP verification.

This policy supersedes ASHP policy 1617.

Rationale

Adoption of automation and information technology for preparing and dispensing compounded sterile preparations (CSPs) is increasing but not evenly distributed among healthcare organizations. A 2017 ASHP survey showed that 64% of hospitals did not use any technology for sterile product preparation activities. Only 26.9% of health systems surveyed employed barcode verification in their IV medication preparation and verification process. The survey found that 12.8% of all health systems surveyed used drug workflow software to manage IV drug preparation, verification, and dispensing. There are many reasons for these disparate rates

of adoption. Each institution has a different break-even point of investment versus return, and challenges of implementation can be daunting. Some organizations have implemented automated compounding technology only to withdraw it later. These technologies may slow the preparation and verification process; however, the enhanced safety outweighs losses in operational efficiency.

Information technology and automation, including robotics, can be used to improve the safety of CSP compounding. Although IV workflow technologies continue to be developed and improved, the majority of pharmacy departments continue to compound manually without the assistance of barcode or other technologies. Health systems have been slow to adopt IV workflow technology, with only 27% of respondents to the 2017 survey indicating their departments use barcode scanning to verify the ingredients in CSPs. If automated procedures are not employed, there are only two methods of in-process or final verification: real-time, direct, and independent visualization, or retroactive, proxy verification (e.g., the syringe pull-back method). The dangers of the syringe pull-back method have been well demonstrated, and the 2016 Institute for Safe Medication Practices (ISMP) Guidelines for Safe Preparation of Compounded Sterile Preparations discourage its use.

1904

Notification of Drug Product Price Increases

Source: Council on Public Policy

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

To advocate for transparency in drug product pricing decisions.

Rationale

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

1905
Mitigating Drug Product Shortages
Source: Council on Public Policy
To advocate for ongoing federal evaluation of how drug product shortages present risks to national security and public health; further,

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

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

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

To advocate that FDA be required to publicly provide quality ratings for 503B outsourcing facilities preparing copies of drug products under the exemption for products on FDA's shortage list; further,

To advocate that the Federal Trade Commission be required to evaluate the potential for drug product supply chain interruptions when considering manufacturer consolidations.

Rationale
In November 2017, ASHP convened a meeting of healthcare professional organizations to review and identify new opportunities to address the ongoing supply chain and patient care challenges associated with drug product shortages. Participants at the meeting examined how the 2012 FDA Safety and Innovation Act (FDASIA) has impacted drug product shortages and made recommendations to prevent and mitigate future shortages. One of those recommendations was that the federal government undertake an evaluation of the risks drug product shortages could present to national security. Such an evaluation would need to consider the risks posed by sourcing of APIs and excipients, as well as by the location of manufacturing sites.

FDA's Strategic Plan for Preventing and Mitigating Drug Shortages recommends that drug product purchasers consider quality in making purchasing decisions. Information that purchasers would find helpful in prospectively assessing drug product quality includes the production and compliance history of a manufacturer, the specific name and location of the manufacturing plant, and the source of raw materials. Because approximately 80 percent of APIs used in U.S. drug product manufacturing comes from foreign sources, FDA has limited ability to inspect and certify that those APIs are unadulterated. In addition, although FDA publishes some quality information about manufacturers, it is sometimes difficult to know who the actual manufacturer is and which specific plant location produced the product, because drug companies may rely on contract manufacturers to produce drug products through licensing agreements. Requiring manufacturers to disclose that information publicly would

allow for improved evaluation of a manufacturer's integrity and alignment with current good manufacturing processes. Detailed knowledge of manufacturing sites would also allow the government and healthcare systems to plan for or avoid disruptions to the supply chain like those that followed Hurricanes Irma and Maria in 2017, when supplies of 40 critical pharmaceutical products went into shortage, in part because of disruption to the large number of pharmaceutical manufacturing facilities in Puerto Rico. Lack of information about such disruptions can also lead to hoarding, which exacerbates an existing shortage. To avoid similar disruptions, FDA should require manufacturers to have contingency plans for maintaining drug product supplies during events that could disrupt production, such as natural and manmade disasters (e.g., hurricanes, cyber-attacks, electricity failures, shipping disruptions).

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

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

1906

Emergency Supplies of Drug Products

Source: Council on Public Policy

To advocate for states to allow any pharmacist, during a declared emergency, to dispense without a prescription an emergency supply of a drug product in quantities that meet the needs of patients.

Rationale

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

Medical Association policy H-120.933, Emergency Prescription Drug Refills, calls for emergency refills beyond the 72-hour period, excluding controlled substances.

1907
Credentialing and Privileging by Regulators, Payers, and Providers for Collaborative Practice
Source: Council on Public Policy
To advocate expansion of collaborative practice agreements in which the prescriber and pharmacist agree upon the conditions under which the pharmacist initiates, monitors, and adjusts a patient's drug and non-drug therapy; further,

To support (1) the development (as a professional initiative by pharmacist associations rather than as a government activity) of national standards for determining a pharmacist's competence to provide medication management services and (2) the appropriate use of these standards by clinical privileging systems, government authorities, and public or third-party payers; further,

To advocate pharmacists be included as providers in medical staff bylaws; further,

To support the use of credentialing and/or clinical privileging by hospitals, health systems, and payers in a manner that is consistent with other healthcare professionals to assess a pharmacist's competence to engage in medication management services within the hospital or health system.

This policy supersedes ASHP policy 0905.

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

ASHP supports a professional initiative to develop national standards for determining pharmacist competence and the appropriate use of these standards by clinical privileging systems, governments, and public or third-party payers. ASHP continues to support the application of credentialing and/or clinical privileging processes to medication management services as practiced within hospitals and health systems and by payers, consistent with other healthcare professionals (e.g., by including pharmacists as providers in medical staff bylaws).

1908

340B Drug Pricing Program Sustainability

Source: Council on Public Policy

To affirm the intent of the federal drug pricing program (the "340B program") to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate for continued access to the 340B program in accordance with the intent of the program; further,

To advocate that reimbursement and contracting policies promote 340B program stability and to oppose reimbursement and savings reductions to covered entities; further,

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage 340B participants to provide appropriate stewardship of the 340B program; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators, risk managers, and pharmacists about the resources required to support 340B program compliance and documentation; further,

To encourage communication and education concerning the value of the 340B program; further,

To advocate that the Health Resources & Services Administration Office of Pharmacy Affairs have sufficient regulatory authority to enforce compliance for all stakeholders with the 340B program.

This policy supersedes ASHP policy 1817.

Rationale

Statutory and other policy changes to the federal drug pricing ("340B") program over the years have spurred an increase in the number of hospitals and other eligible entities that participate. Since the program's inception, the number of 340B-eligible and participating hospitals has continued to grow. In response, policymakers and other stakeholders have raised questions over how the discounts are used by covered entities and what value the program brings to their respective communities. Congress has held hearings, and bills have been introduced to reform the program. Among the items Congress is considering are transparency, increasing authority of the Health Resources & Services Administration (HRSA) to oversee the program,

reimbursement cuts imposed under Medicare Part B on 340B drugs, and examining policy that passes the discount along to the patient.

Expansion of Medicaid eligibility in 2014 (through provisions in the Affordable Care Act) allowed additional hospitals to participate in the program, further driving scrutiny and questions from policymakers and stakeholders. In response to policymaker and stakeholder concerns, ASHP recognizes the important intent and role of the 340B program and stresses the need for its continued sustainability. These developments demonstrate the need for pharmacy leaders to engage in a strategic response to this compliance environment.

The original intent of the 340B program was to "to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rept. 102-384, pt. 2, at 12 [1992]). ASHP emphasizes the need for clarification and simplification (to the extent possible) of the program in order to enable compliance and maintain program integrity. Further, there is a need for communication and collaboration with public and private payers to ensure optimization of benefits from the 340B program and related contract and reimbursement policies.

1909

Pharmacist Authority to Provide Medication-Assisted Treatment

Source: Council on Public Policy

To advocate for the role of the pharmacist in medication-assisted treatment (MAT) for opioid use disorder, including patient assessment, education, prescribing, and monitoring of pharmacologic therapies; further,

To pursue the development of federal and state laws and regulations that recognize pharmacists as providers of MAT for opioid use disorder; further,

To foster additional research on clinical outcomes of pharmacist-driven MAT; further,

To advocate for the removal of barriers for all providers to be able to provide MAT to patients.

Rationale

An estimated 2.5 million Americans suffer from opioid use disorder. In 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended that the U.S. increase screenings and treatment for opioid use disorder. Many pharmacists have the skills to provide direct care to patients with opioid addiction or assist other healthcare providers in caring for these patients. Although some states allow pharmacists to prescribe controlled substances under collaborative practice agreements, pharmacists are not eligible to obtain a waiver under the Drug Addiction Treatment Act of 2000 to prescribe buprenorphine or other drugs for opioid use disorder. Having such prescribing authority would allow pharmacists to fully exercise their expertise and expand the pool of MAT providers. ASHP advocates the removal of barriers for all providers to be able to provide MAT to patients and encourages additional research on the clinical outcomes of pharmacist-driven MAT.

1910
Therapeutic Use of Cannabidiol
Source: Council on Therapeutics
To support continued research and to provide education on the therapeutic uses, adverse effects, and drug interactions of cannabidiol (CBD); further,

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

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

Rationale
In June 2018, the Food and Drug Administration (FDA) approved Epidiolex, an oral solution containing cannabidiol (CBD), for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is the first prescription formulation of highly purified component of the Cannabis sativa plant. Because it does not contain a significant amount of tetrahydrocannabinol, the intoxicating substance in Cannabis sativa, in September 2018 the Drug Enforcement Administration placed Epidiolex in schedule V of the Controlled Substances Act (CSA), the least restrictive schedule of the Act.

Given the patchwork of state legislation regarding recreational and medical cannabis, there is a robust but largely unregulated industry in cannabis derivatives, including products promoted as containing CBD. These formulations range from lotions for topical application to oils for enteral consumption, and their components and CBD concentrations vary, leading to questions about their safety. FDA has issued over 40 warning letters to firms marketing products that allegedly contain CBD. As part of these actions, FDA has tested the chemical content of cannabinoid compounds in some of the products, finding that many do not contain the levels of CBD claimed.

With CBD's easy availability came spurious claims regarding its efficacy in treating a number of maladies. Faced with the unique challenge of regulating an approved drug and widely available formulations of a similar product, FDA is currently considering a two-pronged approach that would:

1) regulate products that make therapeutic claims as new drugs, evaluating them for both safety and efficacy (e.g., Epidiolex); and
2) allow the continued marketing of CBD-containing products that do not make therapeutic claims, with limited regulation for safety (e.g., as dietary supplements).

ASHP opposes use of CBD-containing products not regulated by FDA in research and patient care. Further, due to concerns that patients may substitute unapproved cannabis-derivative products for the FDA-approved drug or confuse the two, ASHP advocates for enhanced patient and public education regarding safe use of CBD-containing products, and encourages pharmacists take a leadership role in those efforts. ASHP encourages research on the potential therapeutic uses, adverse effects, and drug interactions of CBD, and is committed to providing education to pharmacists and other healthcare providers on those topics.

1911

Pharmacy Expertise in Sterile Compounding

Source: Council on Education and Workforce Development

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

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

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

This policy supersedes ASHP policy 0915.

Rationale

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

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

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

1912

Pharmacy Technician Training and Certification

Source: Council on Education and Workforce Development

To advocate for adoption of a national standard for accreditation of pharmacy technician education and training programs; further,

To advocate that a pharmacy technician education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required for all new pharmacy technicians by the year 2022; further,

To advocate that all pharmacy technicians be required to obtain and maintain Pharmacy Technician Certification Board certification; further,

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

This policy supersedes ASHP policy 1609.

Rationale

In January 2017, the Pharmacy Technician Certification Board (PTCB) suspended the condition that by 2020 the completion of an accredited technician education and training program would be required to be eligible for the PTCB certification exam. There is no indication that PTCB will reinstate that requirement; however, ASHP supports completion of an education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) as well as PTCB certification for all pharmacy technicians. Although education requirements have been added by PTCB to take the certification exam starting in 2020, completion of an accredited education and training program is only one pathway for eligibility for the exam; PTCB also recognizes equivalent work experience. If an applicant has completed an unaccredited program, there is a required attestation for the content of that program.

In 2018, ASHP and ACPE developed revised national standards that serve as a guide for the development of ASHP/ACPE-accredited pharmacy technician education and training programs. These standards serve as the criteria for the evaluation of new and established pharmacy technician training programs and will help ensure that pharmacy technicians possess the knowledge, skills, and abilities necessary for their critical role on the healthcare team. A number of environmental factors, including changes in state laws allowing for expanded roles, responsibilities, and authority for pharmacy technicians, prompted the reassessment of the standards, which were last revised in 2015. ASHP supports more uniform state statutes and regulations regarding pharmacy technicians. The anticipated increase in demand for enrollment in ASHP/ACPE-accredited training programs will require an expansion of the number and distribution of such programs, including innovative education and training formats.

The target date of 2022 was included to provide a goal for requiring that all new pharmacy technicians in hospitals and health systems complete a pharmacy technician education and training program accredited by ASHP and ACPE. The date is in line with the initiatives and timeline of the Stakeholder Advisory Committee (the Committee). This Committee continues to advance the recommendations of the Pharmacy Technician Stakeholder Consensus Conference (*Toward uniform standards for pharmacy technicians: Summary of the 2017 Pharmacy Technician Stakeholder Consensus Conference*), the national consensus conference that engaged all sectors of pharmacy to define basic knowledge, skills, and abilities of pharmacy technicians, to promote and define advanced competencies, and to promote national definitions and regulation of pharmacy technicians. The Committee uses the recommendations and consensus statements to guide their work. Two of these statements are as follows:

2.1 The profession of pharmacy should move urgently towards the development and adoption of national standards for pharmacy technician education.

2.2 The profession of pharmacy should set a target for implementation of the national standard for pharmacy technician education at 3 to 5 years after adoption of the standard.

The accreditation standard for the education and training of pharmacy technicians was revised and approved by both the ASHP and ACPE Boards in June of 2018. Consistent with recommendation 2.2, 2022 is a reasonable target to require accredited training for new pharmacy technicians as it is four years from the time new standard was developed. The new standard was developed based on a job analysis of more than 44,000 pharmacy technicians in the U.S. The group developing the standard included educators; representatives from community, hospital, and chain pharmacy practice; and members of the Pharmacy Technician Accreditation Commission. More than 500 public comments were received and evaluated for inclusion in the revised standard before it was sent to the Boards of ASHP and ACPE for approval. The revised standard is divided into entry level and advanced, as recommended at the Pharmacy Technician Stakeholder Consensus Conference. This differentiation allows practice settings to have different education and training requirements based on the needs of the position. Additionally, boards of pharmacy can develop requirements based on entry-level competencies as a minimum standard and the advanced level can be an added credential that can be pursued based on employer requirements.

The Committee is currently working with the National Association of Boards of Pharmacy (NABP) to modify the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. At the NABP national meeting in May 2019, a resolution was passed to convene a task force of stakeholders to evaluate and make recommendations to NABP regarding the education requirements, practice responsibilities, and competence assessments for pharmacy technicians.

Additionally, work is being done at the state level with individual boards of pharmacy to evaluate requirements for accredited education and training for new pharmacy technicians. This activity follows consensus statement 5.2: The level of urgency for achieving state-to-state consistency in regulation of pharmacy technicians' scope of practice, education, certification, and licensure or regulation is high.

At the state level, advocacy will include several specific issues for boards of pharmacy to include as they consider regulations for technicians:

- There should be clear distinctions between pharmacy technicians and student pharmacists. Technician requirements should not be applied to student pharmacists.
- There should be a provision for a "technician in training" that would allow a technician who is enrolled in an accredited education and training program to be eligible to work in a pharmacy as long they complete the program in some prescribed amount of time (e.g., 12-18 months).

1913

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 restricting or making availability of drug products contingent on how those products are used; further,

To encourage selection of a wholesale distributor that (1) purchases products only from a manufacturer before distribution to the purchasing end user; (2) is licensed in the state where it is conducting business; (3) complies with the requirements of the Drug Supply Chain Security Act; (4) is accredited under the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors program; and (5) uses information systems that are interoperable with common types of pharmacy systems.

This policy supersedes ASHP policy 1707.

Rationale

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

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

ASHP supports using strict vendor vetting policies to prevent sales from nonreputable or gray market vendors. Vendors should purchase products only from a manufacturer, not a secondary source; should be licensed in the state in which it operates; comply with the requirements of the Drug Supply Chain Security Act; be accredited under the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors (VAWD) program; and use information systems that are interoperable with common types of pharmacy systems. VAWD accreditation requires a rigorous criteria compliance review to

ensure that a wholesale distribution facility operates legitimately, is licensed in good standing, and employs security and best practices for safe prescription drug distribution from manufacturers to pharmacies. As of 2018, 23 states had recognized VAWD accreditation.

1914

Safe Medication Preparation, Compounding, and Administration in All Sites of Care

Source: Council on Pharmacy Management

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

Rationale

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

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

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

1915

Pharmacy Department Business Partnerships

Source: Council on Pharmacy Management

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

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

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

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

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

This policy supersedes ASHP policy 1416.

Rationale

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

1916

Intimidating or Disruptive Behavior

Source: Council on Pharmacy Management

To affirm the professional responsibility of the pharmacist to ensure patient and workplace safety by communicating with other healthcare personnel to clarify and improve medication management; further,

To advocate that hospitals and health systems adopt zero-tolerance policies for intimidating or disruptive behaviors in their institutions; further,

To encourage hospitals and health systems to develop and implement education and training programs for all healthcare personnel to encourage effective communication, set expectations for standards of conduct, promote use of de-escalation techniques, and discourage intimidating or disruptive behaviors; further,

To encourage colleges of pharmacy and residency training programs to incorporate training in communications and managing intimidating or disruptive behaviors; further,

To collaborate with other organizations to advocate codes of conduct that do not allow intimidating or disruptive behavior in hospitals and health systems; further,

To encourage hospitals and health systems to adopt processes for identification and reporting of intimidating or disruptive behaviors to evaluate and mitigate unacceptable behaviors in a timely and effective manner.

This policy supersedes ASHP policy 0919.

Rationale

Intimidating or disruptive behaviors can lead to medical errors, contribute to poor patient satisfaction, increase costs, and cause staff turnover. Such behaviors range from passive behaviors such as providers refusing to answer questions or return pages to use of condescending language to overt actions such as verbal outbursts or physical threats. The Institute for Safe Medication Practices conducted a national survey regarding intimidation in the workplace in 2003 and conducted a follow-up survey in 2013 for comparison. There has been no reduction between 2003 and 2013 in the percentage of respondents who were aware of a medication error during the year in which disrespectful behavior played a role.

In addition, healthcare workers face an increased risk of work-related assaults resulting primarily from intimidating or disruptive behavior of patients and their caregivers or family members. Disruptive behavior, including interference with treatment plans, vulgar language, and threatening statements, can impede a healthcare worker's ability to provide safe and effective care. While such behavior is often overlooked, underreported, or considered to be part of the job, it can also lead to more serious confrontations. Unfortunately, there is no clear way to identify patients or family members who will be disruptive to healthcare personnel, so every patient and family member must be treated with the same level of caution.

According to the Bureau of Labor Statistics and National Crime Victimization Survey, more assaults occur in the healthcare and social services industries than in any other industry. For healthcare workers, assaults comprise 10-11% of workplace injuries involving days away from work, compared with 3% of injuries of all private sector employees. Further, it has been identified that workplace violence can harm a person's intrinsic sense of self-worth and confidence, which can result in physical symptoms including headaches, anxiety, and depression. The American Nurses Association and the American Medical Association have taken positions concerning violence against healthcare workers and are actively promoting solutions to address the issue.

ASHP believes organizations should develop training programs to discourage disruptive behaviors and to train employees in handling disruptive situations, including de-escalation techniques, and colleges of pharmacy and residency training programs should also provide such training. These organizational efforts will help with compliance with The Joint Commission leadership standard on disruptive behavior (LD.03.01.01), which suggests that healthcare organizations should "educate all team members – both physicians and non-physician staff – on appropriate professional behavior defined by the organization's code of conduct. The code and education should emphasize respect. Include training in basic business etiquette (particularly phone skills) and people skills."

1917

Pharmacy Technician Student Drug Testing

Source: Pharmacy Technician Forum

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

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

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

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

Rationale

Pharmacy technicians are essential members of the healthcare team and help ensure the health, safety, and welfare of patients. They have access to controlled substances and confidential information, and operate in settings that require the exercise of good judgment and ethical behavior. In addition, some state boards of pharmacy have reported that drug-abusing and -diverting persons are enrolling in pharmacy technician training programs to access drugs during experiential training and employment. Thus, an assessment of a pharmacy

technician student's possible impairment, which could diminish his or her capacity to function in such a setting, is imperative to promote the highest level of integrity in healthcare services. ASHP recognizes that drug testing pharmacy technician students, whose responsibilities may bring them into contact with controlled substances, is an essential element of diversion prevention programs. Pre-enrollment, random, and for-cause drug testing should be performed based on defined criteria, with appropriate testing validation procedures, and have demonstrated effectiveness detecting commonly abused or illegally used substances.

1918

Minimum Educational Qualification Standards for Pharmacists

Source: House of Delegates Resolution

To support minimum educational qualification standards for pharmacists to practice pharmacy that are consistent with the licensing standards of state boards of pharmacy; further,

To oppose the basic education requirement within the Office of Personnel Management Classification & Qualifications - General Schedule Qualification Standards - Pharmacy Series, 0660, requiring a Doctor of Pharmacy or Doctor of Philosophy degree as the minimum qualification to practice pharmacy.

Rationale

In September 2017, the U.S. Office of Personnel Management (OPM) issued a new qualification standard for pharmacists, GS-0660. The new standard lists the basic educational requirement for pharmacists as a Doctor of Pharmacy (Pharm.D.) or Doctor of Philosophy (Ph.D.) degree. To set this requirement, OPM must have determined that pharmacy cannot be performed by persons without one of these degrees, because Title 5 U.S.C. 3308 permits the establishment of minimum educational requirements only when OPM has determined that the work cannot be performed by persons who do not possess the prescribed minimum education.

All 50 states currently allow pharmacists with a bachelor's degree in pharmacy (B.S.Pharm.) to obtain licensure and practice pharmacy, which indicates that all state legislatures or regulators have concluded that pharmacists with a B.S.Pharm. degree can practice pharmacy safely and effectively. In the U.S., the B.S.Pharm. degree was awarded until 2005; in 2006, the Pharm.D. degree became the only entry-level degree awarded. A 2014 survey of the pharmacy workforce found that only 40% of pharmacists had earned a Pharm.D. The minimum educational requirements set by OPM would automatically disqualify 60% of pharmacists from entering the federal government workforce, an inequitable practice not seen outside the federal sector. The OPM minimum educational requirement also creates a monumental challenge to building and maintaining the pharmacist workforce the Department of Defense needs to support U.S. warfighting efforts and take care of veterans. ASHP recognizes that pharmacists must possess the education, training, and experience required to effectively, efficiently, and responsibly fulfill their roles. Further, ASHP supports licensure by a state board of pharmacy as the minimum requirement for pharmacy practice in its Minimum Standard for Pharmacies in Hospitals.

1919

ASHP Statement on the Role of the Medication Safety Leader

Source: Section of Inpatient Care Practitioners

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

This statement supersedes a previous version dated April 13, 2012.