House of Delegates

Policies Approved by the ASHP House of Delegates March-June 2022 (with rationales)

2201
State-Specific Requirements for Pharmacist and Pharmacy Technician Continuing Education
Source: Council on Education and Workforce Development
To advocate for the standardization of state pharmacist and pharmacy technician continuing education requirements; further,

To advocate that state boards of pharmacy adopt continuing professional development as the preferred model to maintain competence.

This policy supersedes ASHP policy 1111.

Rationale
All 50 states require continuing education for pharmacists as a means of maintaining their competence, and many states have similar requirements for pharmacy technicians. State requirements for continuing education differ, in numbers of hours and the time frame within which they must be collected and reported, for example. Some state boards of pharmacy have established specific educational requirements for individual topic areas they concluded should be mandatory. These initially included topics such as state-specific pharmacy law and human immunodeficiency virus and acquired immune deficiency syndrome, but more recently, states have included requirements for education on topics such as medication and patient safety, pain and palliative care, patient management, and administration of injectables. Some states also specify the number of hours that must be obtained by "live" presentation rather than home-study courses. As more states develop unique requirements, many pharmacists who are licensed in multiple states are finding it difficult to meet the unique requirements of each individual state.

Pharmacy technician license and continuing education requirements vary widely by state, depending on whether the state requires national certification through the Pharmacy

Technician Certification Board (PTCB), completion of a state board-approved or accredited pharmacy technician training program, on-the-job training, or some other measure of competence. To maintain PTCB certification, pharmacy technicians must complete specific continuing education requirements including law, patient safety, or sterile compounding, depending on their level of certification.

For over a decade, ASHP has encouraged individuals, healthcare organizations, and states to embrace continuing professional development (CPD) as a means of maintaining and demonstrating competence. CPD involves personal self-appraisal, educational plan development, plan implementation, documentation, and evaluation, and has been endorsed by the Accreditation Council for Pharmacy Education and other pharmacy organizations for use by pharmacists and pharmacy technicians. Broader adoption of CPD into state CE requirements would facilitate its use and improve pharmacy practice.

2202
ASHP Statement on Professionalism
Source: Council on Education and Workforce Development
To approve the ASHP Statement on Professionalism.

This statement supersedes the ASHP Statement on Professionalism dated June 26, 2007.

2203
Preceptor Skills and Abilities
Source: Council on Education and Workforce Development
To collaborate with pharmacy organizations and colleges of pharmacy on the development of standards to enhance the quality of experiential education and pharmacy residency precepting; further,

To provide tools, education, and other resources to develop and evaluate preceptor skills.

This policy supersedes ASHP policy 1201.

Rationale
The quality and effectiveness of the pharmacy workforce can be positively influenced by the quality of pharmacy preceptors. Growth in the number and size of colleges of pharmacy has increased demand for teaching sites and for qualified preceptors to provide experiential training and residency rotations at those sites. Although nearly all colleges of pharmacy endeavor to provide robust preceptor training, efforts to develop preceptors may be inconsistent or ineffective due to resource constraints. In addition to improved training of preceptors, the profession needs a mechanism for evaluating the skills of preceptors and educators.

2204
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 patient-centered 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 consider patient usability, acceptability, and usefulness and should further the goal of delivering safe and effective patient care that optimizes 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; further,

To encourage patient education and assessment of competency in the use of mobile health technologies; further,

To enhance patient awareness on how to access and use validated sources of health information integrated with mobile health tools, clinical apps, and associated devices.

This policy supersedes ASHP policy 1708.

Rationale

Digital health technologies, including mobile health (mHealth) applications (apps), hold great potential to improve health and healthcare. There is nearly ubiquitous use of smartphones and an ever-growing and increasingly sophisticated suite of health apps. These apps are providing a wide range of medical functions that span the care continuum from prevention to diagnosis to care management. The adoption of these digital solutions is further amplified by their accessibility, low cost, and personalized features. In addition, their ability to provide practical functions such as health education, tracking of symptoms and side effects, appointment management, and social support make them compelling healthcare tools. With the proliferation of mHealth tools, clinical apps, and associated devices, healthcare organizations need to address the potential barriers and risks of application use. Particular concerns include (1) assessing the quality of mHealth tools, clinical apps, and associated devices; (2) standardizing choices and use across the organization; (3) ensuring the security of data and data storage; and (4) patient usability, acceptability, and usefulness (e.g., generational

differences in acceptance of technology). To maximize the effectiveness of mHealth 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 (EHR) 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 regarding standardized evaluation and validation processes. As medication-use experts, pharmacists can contribute to the regulatory evaluation and approval of mHealth tools, clinical apps, and associated devices that involve medications or medication management. For example, pharmacists can help assess the quality of information presented (e.g., incorrect or incomplete information, variation in content, incorrect or inappropriate response to patient needs) and mitigate inconsistencies with patient education resources provided by an organization (e.g., discharge education). ASHP is committed to fostering development of resources to help pharmacists ensure safe, accurate, supported, and secure use of mHealth tools, clinical apps, and associated devices. Patient engagement strategies include patient education and competency assessment and enhanced patient awareness of how to access and use validated sources of health information integrated with mHealth tools, clinical apps, and associated devices. Product customer assistance teams for mHealth tools, clinical apps, and associated devices should be leveraged to provide direct support to sustain these efforts. Patient engagement with these tools will: (1) increase communication between patient and providers, leading to increased patient satisfaction; (2) enhance sharing of health information using EHRs; and (3) enable patients to have access to their health data, which empowers them with the knowledge of their health conditions and helps them make informed treatment choices.

2205
Transitions of Care
Source: Council on Pharmacy Management
To encourage the pharmacy workforce to assume responsibility for medication-related aspects of ensuring the continuity of care as patients move from one care setting to another; further,

To encourage the development, optimization, and implementation of technologies that facilitate sharing of patient-care data across care settings and interprofessional care teams; further,

To advocate that health systems provide sufficient resources to support the important roles of the pharmacy workforce in supporting transitions of care; further,

To encourage payers to provide reimbursement for transitions of care services; further,

To encourage the development of strategies to address the gaps in continuity of pharmacist patient care services, including effective patient engagement.

This policy supersedes ASHP policy 1208.

Rationale

Continuity of patient care is a vital requirement in the appropriate use of medications. Changes in healthcare reimbursement have resulted in an increasing focus on transitions of care from the acute care environment to other settings (e.g., ambulatory care to inpatient care to home care or specialty settings). Pharmacy workforce engagement, as integral members of interprofessional care teams, is pivotal to support health systems focus on reducing readmissions, improving patient satisfaction, and effectively educating patients about their medications. It is important that ASHP advocate for improvements in technologies that facilitate sharing of patient information across various care settings. Further alignment of financial incentives and sufficient resource allocation that encourage and support patient care roles of the pharmacy workforce in the transition of care are also required.

2206

Continuous Performance Improvement

Source: Council on Pharmacy Management

To encourage the pharmacy workforce to establish multidisciplinary continuous performance improvement (CPI) processes within their practice settings to assess the effectiveness and safety of patient care services, adherence to standards, and quality and integrity of practice; further,

To encourage the pharmacy workforce to use contemporary CPI techniques and methods for ongoing improvement in their services; further,

To support the pharmacy workforce in their development and implementation of CPI processes.

This policy supersedes ASHP policy 0202.

Rationale

Pharmacy departments should continually strive for medication safety and quality by identifying and prioritizing quality improvement efforts that align with national and health-system goals. The pharmacy workforce can make use of a variety of methods to ascertain goals, aims, and interventions for the system and to influence medication-related goals, aims, and interventions in the pursuit of high-value care and improved patient outcomes. Some of these process improvement methodologies include Six Sigma, Lean Management, Lean Six Sigma, Agile Management, Total Quality Management, and Kaizen. All the process improvement tools share many common features and the philosophy that processes can always be improved. They share the assumption of measurement and statistics being a key to improvement and the faith in the power of the workers closest to a process to be able to improve it. The continuous performance or quality improvement program is structured to assess the effectiveness and

safety of patient care services, adherence to standards, and quality and integrity of the practice. It is aligned with the health system's overall plan and system for performance and quality improvement, accrediting organizations, and with payer contractual obligations for quality reporting. Pharmacy departments must have internal procedures for ongoing surveillance and reporting to assess overall appropriateness of services and implement quality improvements as needed to integrate quality metrics that drive quality improvement and refocus efforts on areas of need. The pharmacy department should have process and feedback loop in place that translates analysis to initiatives and initiatives to measured and improved outcomes using appropriate tools derived from implementation science.

2207
Institutional Review Board and Investigational Use of Drugs
Source: Council on Pharmacy Practice
To support mandatory education and training on human subject protections and research bioethics for members of institutional review boards (IRBs), principal investigators, and all others involved in clinical research; further,

To advocate that principal investigators discuss their proposed clinical drug research with representatives of the pharmacy department before submitting a proposal to the IRB; further,

To advocate for the pharmacist's roles in ethical clinical research, including but not limited to serving as a principal investigator, developing protocols, executing research, determining rational-use decisions for the off-label use of drug products, and publishing research findings, and for adequately resourced, sustainable models for filling those roles; further,

To advocate that IRBs include pharmacists as voting members; further,

To advocate that IRBs inform pharmacy of all approved clinical research involving drugs within the hospital or health system; further,

To advocate that pharmacists act as liaisons between IRBs and pharmacy and therapeutics committees in the management and conduct of clinical drug research studies; further,

To support pharmacists' management of drug products used in clinical research.

This policy supersedes ASHP policy 0711.

Rationale
The Food and Drug Administration (FDA), under its regulations, defines an institutional review board (IRB) as a group of people that have been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. Human subjects research is codified in 45 CFR Section 46, and 45 CFR Section 46.102(e)(1) states that a human subject is:

a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Evidence-based healthcare decisions are highly dependent on sound principles of research and investigation. ASHP believes the healthcare workforce needs to be competent in understanding the research process and the protection of human subjects involved in research trials. In addition, hospitals and health systems are home to investigational drug services that support the conduct of clinical trials involving medication use. Pharmacists are critical to the successful management of these trials and therefore need to be engaged in decisions related to developing, conducting, and evaluating research within their institutions.

2208
Pharmacist's Role in Team-Based Care
Source: Council on Pharmacy Practice
To recognize that pharmacists, as core members and medication-use experts on interprofessional healthcare teams, increase the capacity and efficiency of teams for delivering evidence-based, safe, high-quality, and cost-effective patient-centered care; further,

To advocate to policymakers, payers, and other stakeholders for the inclusion of pharmacists as care providers within team-based care and as the provider of comprehensive medication management services; further,

To assert that all members of the interprofessional care team have a shared responsibility in coordinating the care they provide and are accountable to the patient and each other for the outcomes of that care; further,

To urge pharmacists on healthcare teams to collaborate with other team members in establishing and implementing quality and outcome measures for care provided by those teams.

This policy supersedes ASHP policy 1215.

Rationale
There is a growing consensus among healthcare providers and payers that patient-centered care by a collaborative team is the optimal model of care. A collaborative care model provides pharmacists with an opportunity to contribute their expertise in medication use to improving patient outcomes.

The pharmacy profession appears to be struggling, however, with implementation of this care model. Not unexpectedly, there is a wide variation in the way "team-based care" is interpreted

and applied. Therefore, states currently in the process of rewriting practice acts have been challenged to find guidance on the fundamental roles and responsibilities of pharmacists in various care settings. This policy recommendation builds on concepts in ASHP policy 1114, Pharmacist Accountability for Patient Outcomes; sets the expectation for other providers that teams with pharmacists will improve the quality, safety, and efficiency of care; and supports advocacy to the broader healthcare community on the value of care delivery by teams that include pharmacists.

2209
Drug Testing as Part of Diversion Prevention Programs
Source: Council on Public Policy
To advocate for 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- or government-sponsored drug diversion prevention 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 1717.

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 and promotes worker well-being. 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.

2210
Drug Samples
Source: Council on Public Policy
To oppose drug sampling or similar drug marketing programs that circumvent appropriate

pharmacy oversight or control.

This policy supersedes ASHP policy 9702.

Rationale

Drug marketing or sampling programs that involve physical samples can create a number of drug supply and patient risks if they are not subject to strict pharmacy control. However, "virtual" programs that allow pharmacy management of the supply (e.g., situations where a limited amount of drug is dispensed from the pharmacy's supply) are not problematic if proper controls are in place. Specifically, workable drug sampling programs must (1) provide the elements of pharmaceutical care, (2) result in careful drug control, ensuring patients receive only properly labeled and packaged, unexpired, and recorded drugs, (3) provide access to prescription drugs only through authorized, trained personnel, (4) discourage inappropriate prescribing habits, or (5) do not increase the cost of treatment for all patients.

2211

Naloxone Availability

Source: Council on Therapeutics

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

To support efforts to safely expand patient and public access to naloxone through independent pharmacist prescribing authority, encouraging pharmacies to stock naloxone, supporting availability of affordable formulations of naloxone (including zero-cost options), and other appropriate means; further,

To advocate for statewide naloxone standing orders to serve as a prescription for individuals who may require opioid reversal or those in a position to aid a person requiring opioid reversal; further,

To support and foster standardized education and training on the role of naloxone in opioid reversal and its proper administration, safe use, and appropriate follow-up care, and dispelling common misconceptions to the pharmacy workforce and other healthcare professionals; further,

To support the use of objective clinical data, including leveraging state prescription drug monitoring programs and clinical decision-making tools, to facilitate pharmacist-initiated screenings to identify patients who may most benefit from naloxone prescribing; further,

To encourage the co-prescribing of naloxone with all opioid prescriptions; further,

To support legislation that provides protections for those seeking or providing medical help for overdose victims.

This policy supersedes ASHP policy 2014.

Rationale

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

Naloxone is a competitive opioid antagonist that rapidly rescues patients from opioid overdose by displacing mu2 opioid receptors in the central nervous system. Naloxone has an excellent safety profile. The World Health Organization includes naloxone on its model list of essential medicines.

Evidence has demonstrated a clear public health benefit from expanding access to naloxone. Naloxone is currently distributed without a prescription via standing orders, collaborative practice agreements, or pharmacist prescribing authority in all 50 states to ensure liberal access to this lifesaving drug. Several states have also started to permit pharmacy technicians to dispense naloxone under these provisions as well.

Currently there are several formulations of naloxone on the market, which vary in strength and route of administration, including subcutaneous injection (which caregivers or peers may have difficulty administering properly) and intranasal formulations. Studies have shown that intranasal naloxone is as effective as injectable routes in rapid opioid reversal. However, its cost ($130-300 per kit) presents a barrier to widespread use. ASHP encourages the Food and Drug Administration to explore ways to get more user-friendly and less-costly formulations to the market for patients and caregivers. Recognizing that naloxone should not be cost-prohibitive, efforts should be made to fully subsidize the cost of this lifesaving medication.

Despite expanded access to naloxone, there are still significant barriers to its widespread use, including hesitancy among pharmacists to dispense naloxone. Uniform education for those administering the drug, training on safe administration, and recommendations on follow-up care with abuse treatment programs for treated individuals is needed.

Furthermore, although great strides have been made in many areas to improve naloxone access, it is necessary to recognize areas of practice where such efforts are inadequate as a one-size-fits-all model. While pharmacists in all 50 U.S. states now have the ability to participate in naloxone prescribing in some form, barriers to access may still exist, such as in rural communities with no physician willing to participate in a collaborative practice agreement, or indeed, perhaps no physician whatsoever. To that end, pharmacists' naloxone prescribing authority should be independent (i.e., not requiring a protocol or collaborative practice agreement to be in place). Where there are barriers to such independent authority, ASHP should advocate for legislation that promotes standing orders for naloxone as a part of patient care, much as ASHP advocates for pharmacists' independent prescribing authority for medication-assisted treatment (ASHP policy 1909).

Pharmacists should make every effort to intervene on behalf of their patients' safety;therefore, pharmacist education regarding use of naloxone should begin in the didactic curriculum in schools of pharmacy and be part of an ongoing effort for pharmacists as lifelong

learners. Current literature suggests that one key barrier to expanded pharmacist involvement in naloxone prescribing is a lack of confidence — which may be addressed by increased education — and also by persistent misconceptions, such as the notion that increased naloxone availability will promote opioid misuse. Because the pernicious nature of this idea is so harmful, it should be highlighted for targeted educational efforts.

Significant access and racial prescribing disparities have been noted in clinical literature regarding naloxone (Dayton L et al. Racial Disparities in Overdose Prevention among People Who Inject Drugs. *J Urban Health* 2020; 97:823–30). Encouraging pharmacists to be proactive in making clinical interventions is important, but safeguarding patients to protect them from the harms of bias is essential in ensuring equitable access to this medication. Whenever possible, pharmacists should use objective measures (e.g., history of overdose, polypharmacy including multiple CNS-depressing agents, high morphine milligram equivalents per day) to identify high-risk patients and make proactive interventions to provide naloxone to them.

Finally, encouraging co-prescribing of naloxone with every opioid prescription aligns ASHP with the American Medical Association, CDC guidelines, and other organizations that recommend prescribing or co-prescribing naloxone to reduce the risk of overdose deaths. Laws, including medical amnesty and those that provide protection against legal liability for persons administering naloxone (i.e., Good Samaritan laws), are needed as well as laws protecting individuals who call for help for someone who has overdosed from prosecution from minor drug possession or drug paraphernalia.

2212

Safe and Effective Therapeutic Use of Invertebrates

Source: Council on Therapeutics

To recognize use of medical invertebrates (e.g., maggots and leeches) as an alternative treatment in limited clinical circumstances; further,

To educate pharmacists, other providers, 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, use, and disposal; further,

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

This policy supersedes ASHP policy 1724.

Rationale

Medical invertebrates, including leeches and maggots, are used as a therapeutic intervention for various indications, 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. In addition, leeches may present a biohazard. Application or manipulation may require expulsion of blood to encourage reattachment, and there have been cases in which engorged leeches have fallen off patients, potentially exposing caregivers and other patients to blood.

To promote safe use of medical invertebrates, pharmacy departments, in cooperation with other health-system departments, should assure appropriate formulary consideration and safe procurement, storage, use (e.g., control, prescribing, preparation, dispensing, administration, application, manipulation, documentation, consideration for antimicrobial prophylaxis, clinical and regulatory monitoring), and disposal.

2213

Criteria for Medication Use in Geriatric Patients

Source: Council on Therapeutics

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

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

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

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

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

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

This policy supersedes ASHP policy 1221.

Rationale

Criteria have been developed to identify high-risk drugs that should be avoided in geriatric patients (i.e., those 65 years of age or older) based on the potential for these therapies to cause adverse drug events that can result in falls, hospitalizations, and other incidents that lead to significant morbidity and mortality in this patient population. Those criteria include the 2019 iteration of the Beers criteria and the Screening Tool of Older Persons' Potentially Inappropriate Prescriptions, or STOPP (version 2 of the STOPP/START criteria was published in 2015). Although ASHP supports the intent of these criteria to prevent patient harm, safe and effective use of medications in geriatric patients requires the more thorough assessment associated with pharmacist-provided comprehensive medication management. ASHP opposes adoption of the Beers criteria by the Centers for Medicare & Medicaid Services (CMS) and other accreditation and quality improvement organizations as a tool to assess prescribing in long-term care and other settings, noting concerns about the development and validation of that tool. More importantly, studies evaluating the clinical application of the 2003 iteration of the Beers criteria have not demonstrated a reduction in adverse events when that tool is used. The American Geriatric Society publishes an update every three years, with the most recent update occurring in 2019. Although the update addressed some concerns (e.g., removal of drugs no longer available, drug-drug interactions), some of the criteria's shortcomings (e.g., lack of validation) remain unresolved. In that regard, STOPP, which is based on organ systems and accounts for patients' concomitant disease, is considered more useful. Studies evaluating STOPP, though small in number and consisting of heterogeneous study populations and implementation plans, project a favorable impact on patient outcomes. ASHP encourages additional work to develop, refine, and validate this and similar evidence-based criteria.

Quality indicators for appropriate medication use in older adults were identified as part of the Assessing Care of Vulnerable Elders (ACOVE) project. The indicators provide suggestions for improving prescribing practices and identify medications that require monitoring or should be avoided in vulnerable elders. Practical indicators that can be reviewed from patient encounters and transitions of care include maintenance of a medication list, periodic drug therapy review, assessing response to therapy, drug monitoring, and patient education. Review of these indicators may facilitate benchmarking and consideration of discontinuing unnecessary medications, dose reduction, and consideration of nonpharmacologic alternative strategies.

Further, there is a need for practice-based research to evaluate the application of such criteria and inclusion of validated criteria in clinical decision support systems and other information technologies is necessary to facilitate the use of these criteria in clinical practice. Finally, these tools are intended to serve as a guide or screening tool and should not replace the clinical judgment of pharmacists and other clinicians.

2214

Medication Adherence

Source: Council on Therapeutics

To recognize that medication adherence improves the quality and safety of patient care when the following elements are included: (1) assessment of the appropriateness of therapy, (2) provision of patient education, and (3) confirmation of patient comprehension of information necessary to support safe and appropriate use of prescribed therapies; further,

To advocate that the pharmacy workforce take a leadership role in interdisciplinary efforts to improve medication adherence; further,

To recognize that clinicians, patients, and caregivers share accountability for the outcomes of medication therapies, and that the central role patients and their caregivers have in disease management includes responsibility for following instructions for safe and effective medication use; further,

To encourage development, evaluation, and dissemination of models and tools that improve adherence, including those that combine existing strategies that have demonstrated effectiveness; further,

To oppose misinformation or disinformation that leads patients to decline education and clinical information regarding their medication therapy; further,

To support the development of mechanisms to document medication adherence interventions, including information technology solutions; further,

To advocate for payment models that facilitate an expanded role for the pharmacy workforce in and provide reimbursement for medication adherence efforts.

This policy supersedes ASHP policy 1222.

Rationale

The need to improve medication adherence as a cornerstone of efforts to improve patient care outcomes is widely recognized. A 2010 *New England Journal of Medicine* editorial issued a call to action to improve adherence based on estimates that 50% of all patients are non-adherent, resulting in an estimated $100 billion spent annually on avoidable hospitalizations. ASHP supports programs to improve adherence, but such efforts are not useful, and are perhaps harmful, if they fail to (1) assess the appropriateness of therapy, (2) provide patient education, and (3) ensure patient comprehension of information necessary to support safe and appropriate use of prescribed therapies. Because of their distinct knowledge, skills, and abilities, pharmacists are the ideal clinician to lead interdisciplinary efforts to develop, implement, monitor, and maintain effective strategies for improving medication adherence, and other members of the pharmacy workforce can have important roles in those efforts. Other members of the interdisciplinary team could include physicians, nurses, health psychologists, and social workers. Patients and their caregivers must share accountability with clinicians for medication therapy outcomes, including the responsibility for following instructions for safe and effective medication use. Otherwise, the results from efforts of pharmacists and other clinicians would be negligible. Some interventions to improve medication adherence have shown favorable results, but the greatest success is achieved by models that incorporate multiple strategies reinforced over time. Therefore, the development, evaluation, and dissemination of models that use multimodal approaches are encouraged. The development of

information technology solutions and other mechanisms (e.g., digiceuticals) to document interventions intended to improve medication adherence is also recommended. Further, payment models that support an expanded role for the pharmacy workforce in medication adherence efforts should be pursued.

2215
ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics
Source: Section of Pharmacy Informatics and Technology
To approve the ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics.

This statement supersedes the ASHP Statement on the Pharmacy Technician's Role in Pharmacy Informatics dated June 3, 2013.

2216
Career Counseling
Source: Council on Education and Workforce Development
To advocate that structured student-centered career counseling begin early and continue throughout college of pharmacy curricula; further,

To urge pharmacists to partner with colleges of pharmacy for participation in structured and unstructured student-centered career counseling; further,

To encourage colleges of pharmacy to provide professional development opportunities for faculty and other pharmacy professionals to promote equitable and inclusive student-centered career counseling approaches; further,

To urge colleges of pharmacy to develop an assessment process to evaluate the equity and inclusivity of their career counseling.

This policy supersedes ASHP policy 8507.

Rationale
To ensure students are exposed to the increasing diversity of postgraduate opportunities and ensure their success in obtaining those opportunities, a structured student-centered career counseling approach must be taken. ACPE Standards 14.4 (Advising) and 19.5 (Faculty/Staff Development) address career counseling but fail to address current concerns about equity and inclusivity in career counseling. Promoting a more equitable and inclusive student-centered career counseling approach will ideally result in a more diverse pharmacy workforce that is nimble and able to provide patient care services in more underserved communities and nontraditional care settings.

2217
Workforce Diversity
Source: Council on Education and Workforce Development
To affirm that a diverse and inclusive workforce contributes to improved health equity and health outcomes; further,

To advocate for the development and retention of a workforce whose background, perspectives, and experiences reflect the diverse patients for whom care is provided; further,

To advocate that institutions incorporate diversity, equity, and inclusion initiatives into daily practices and strategic plans.

This policy supersedes ASHP policy 1705.

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 care is provided. 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 (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). Diversity in the pharmacy workforce includes, but is not limited to, the categories of sexual identity and gender expression, age, national origin, socioeconomic origin, ethnicity, culture, gender, race, religion, and physical, sensory, or mental disability. A diverse pharmacy workforce will provide the best care for all patients. Recognizing the positive impact of diversity, equity, and inclusion (DEI) on patient outcomes, it is important for the pharmacy workforce to incorporate DEI initiatives in strategic plans, communications, and hiring and retention practices across the pharmacy enterprise.

2218
Pharmacy Executive Oversight of Areas Outside Pharmacy
Source: Council on Pharmacy Management
To advocate for opportunities for pharmacy leaders to assume healthcare executive leadership roles outside the pharmacy department; further,

To urge pharmacy leaders to seek out formal and informal opportunities to provide such leadership; further,

To encourage pharmacy leaders to use tools, resources, and credentialing identified by national pharmacy and professional healthcare organizations to demonstrate competence and readiness for healthcare executive leadership; further,

To encourage pharmacy leaders to support development of leaders with a broader scope of executive responsibilities by balancing generalization and service-line specialization in their career development and the career development of rising pharmacy leaders; further,

To advocate for healthcare organization structures that provide pharmacy leaders with opportunities to assume leadership responsibilities outside the pharmacy department; further,

To promote continuing professional development opportunities in executive leadership to provide pharmacy leaders with evidence of a commitment to lifelong learning and leadership excellence.

Rationale

In health systems, pharmacy operations often span multiple practice settings, and pharmacists contribute to many different interdisciplinary teams. ASHP's Statement on the Roles and Responsibilities of the Pharmacy Executive notes there is need for a "strategic and innovative pharmacy executive who plans and oversees the design and operation of the entire and complex medication-use process throughout the system." As each health system is unique in the size and range of services offered to patients, there is significant variability of the scope for the pharmacy executive's position. The role of the pharmacy executive, as it originated, was to provide cohesive oversight of the entirety of the medication-use process, including medication-use policy considerations. However, as practice has evolved, medication use and pharmaceutical management has as well. Recent areas of expansion related to medication management in health systems include drug shortages, medication safety and quality, 340B Drug Pricing Program oversight, investigational drugs, and patient assistance support. Some areas for which health systems have sought pharmacy executive oversight that are less directly related to medication management include compliance and regulatory assurance, transitions of care, supply chain, laboratory operations, and dietary services. Pharmacy executives also manage relationships with stakeholders, evaluate quality and outcome metrics, support medication access, and provide leadership in optimizing reimbursement.

Health-system pharmacy leaders possess skills that have often made them candidates for positions outside pharmacy. As senior leadership teams become smaller to reduce labor costs, pharmacy leaders may be asked to take on additional responsibilities. Over 70% of the 2020 ASHP Foundation Pharmacy Forecast panelists indicated this will be a likely occurrence in many organizations within five years. Adding to a pharmacy leader's portfolio of responsibility creates opportunities for sharing experience and resources across multiple departments. Placing multiple departments under the leadership of one executive also makes it easier to reduce silo budgeting by identifying and implementing interventions that may increase cost in one department while reducing cost to a greater degree in another. Pharmacy leaders who accept responsibility for other service lines must exploit the strengths of their other departments, drive collaboration across all areas they lead, and avoid undermining authority entrusted to subordinate service-line leaders.

Pharmacy executive leaders should strive to demonstrate a commitment to achieving and maintaining excellence in pharmacy and healthcare leadership to communicate value to

colleagues, healthcare administrators, and the public. This goal could be achieved by seeking national recognition of core competencies (e.g., leading people and processes, professionalism, financials) identified by national pharmacy and professional healthcare organizations (e.g., American College of Healthcare Executives fellowship program, 360 evaluations, career coaching, professional leadership certificates, ASHP Certified Pharmacy Executive Leader credential). Pharmacy executive leaders should continually seek opportunities for professional development to demonstrate their competence, leadership, and commitment to the profession and to enhance their essential executive knowledge, skills, and abilities in order to facilitate team success.

A key driver enabling a pharmacy executive leader the ability to devote the time and energy for expanded roles includes striking a balance with service-line personnel breadth and depth. This balance is of particular importance when establishing a talent pipeline of capable leaders that will keep the service lines running with little to no interruption. In some health systems, pharmacists hold roles such as chief executive officer, chief operating officer, and senior vice president. Some institutions include oversight of additional service lines within the purview of their highest-ranking pharmacist administrator, such as combining "Pharmaceutical and Nutrition Care," or appointing a pharmacist to manage all "intravenous admixture services."

To achieve maximum performance in an expanded leadership role, the conditions for success must exist. Organizational structure (e.g., hierarchal, matrix, divisional) aligns and defines the relationships of parts of an organization, and the structure chosen affects an organization's success in carrying out its strategy, goals, and objectives. Leadership should understand the characteristics, benefits, and limitations of various structures in aligning organizational structure with the enterprise's business strategy.

2219

Hospital-at-Home Care

Source: Council on Pharmacy Practice

To affirm that patients treated in the hospital-at-home (HAH) setting are entitled to the same level of care as those treated in an inpatient hospital setting; further,

To support HAH care models that provide high-quality, patient-centered pharmacist care, including but not limited to: (1) clinical pharmacy services that are fully integrated with the care team; (2) a medication distribution model that is fully integrated with the providing organization's distribution model and in which the organization's pharmacy leader retains authority over the medication-use process; (3) information technology (IT) systems that are integrated or interoperable with the organization's IT systems and that allow patient access to pharmacy services, optimize medication management, and promote patient safety; and (4) ensuring the safety of the pharmacy workforce throughout the HAH care delivery process; further,

To advocate that pharmacists be included in the planning, implementation, and maintenance of HAH programs; further,

To advocate for legislation and regulations that would promote safe and effective medication use in the HAH care setting, and for adequate reimbursement for pharmacy services, including clinical pharmacy services, provided in the HAH care setting; further,

To provide education, training, and resources to empower the pharmacy workforce to care for patients in HAH care settings and to support the organizations providing that care; further,

To encourage research on HAH care models.

Rationale

Hospital-at-home (HAH) care is a patient care model that provides acute-level care to patients in their own homes. The first described HAH program was originally developed by the Johns Hopkins Schools of Medicine and Public Health over 25 years ago, and the HAH care model has seen broader adoption by other hospitals and health systems in recent years. HAH care models have been shown to improve clinical outcomes, reduce length of stay, provide higher patient satisfaction, and reduce costs and medical complications.

The COVID-19 pandemic forced hospitals and health systems to explore new and innovative care models, with a heightened focus on remote care. In March 2020, the Centers for Medicare & Medicaid Services (CMS) announced its Hospitals Without Walls program, which resulted in broader regulatory flexibility in providing services beyond hospital walls. This program was expanded in November 2020 to include the Acute Hospital Care at Home program, which allows eligible patients to be treated for acute illnesses in the comfort of their homes. CMS has outlined more than 60 acute conditions such as heart failure, asthma, pneumonia, and chronic obstructive pulmonary disease (COPD) that can be safely managed from a patient's home with proper monitoring and treatment protocols. As of June 4, 2021, there were 59 health systems and 133 hospitals in 32 different states participating in the Acute Hospital Care at Home program.

Medication management is a mainstay for most, if not all, of the conditions treated under HAH programs. Pharmacy practice leadership and expertise is therefore needed to ensure patient safety and quality outcomes. Patients treated in HAH programs are entitled to the same level of high-quality, patient-centered pharmacist care as those treated in an inpatient hospital setting. ASHP supports HAH care models that provide high-quality, patient-centered pharmacist care. Patients receiving HAH care should have access to clinical pharmacy services that are fully integrated with the services provided by rest of the patient's care team. To ensure optimal medication use, the HAH program should use a medication distribution model that is fully integrated with the providing organization's distribution model, and the organization's pharmacy leader should retain authority over the entire HAH medication-use process to promote integration with the organization's pharmacy enterprise. The HAH program should use information technology (IT) systems that are integrated or interoperable with the organization's IT systems to allow patients to access pharmacy services, the pharmacy

workforce to optimize medication management, and the organization to promote patient safety. Finally, HAH programs should ensure the safety of the healthcare workers delivering care, including members of the pharmacy workforce.

The pharmacy workforce needs to be included in the planning, implementation, and maintenance of HAH programs. Early in the planning process, pharmacy departments can evaluate and determine (1) the in-person, virtual, and electronic patient assessment role for pharmacists in the HAH program to determine staffing requirements; (2) how medications will be provided and stored for patients, especially controlled substances and medications with strict storage requirements (e.g., temperature-sensitive medications); (3) formulary considerations and payer design; (4) state and federal regulations and licensure interpretations to support the practice and supply chain model requirements necessary for HAH programs; (5) how medication administration will be documented (e.g., through bar-code-enabled medication administration), including waste management; (6) electronic healthcare record platform capabilities required to support the HAH program, including an assessment of ancillary information systems or platforms that will need to be integrated with the organizations IT systems to support medication-use documentation and pharmacist consultations; and (8) differences between HAH and home infusion models, and when to deploy the appropriate model.

Pharmacy departments should proactively assess the pharmacy clinical services needed to care for patients in the HAH program and determine the competencies and training to meet expected demands. Examples would include determining how drug information questions will be channeled and how care transitions will be managed (e.g., follow-up appointments for chronic care management, transitions to palliative care). The pharmacy department will need to develop processes to integrate telehealth services for patients to receive pharmacist care (e.g., education). Other considerations include patient choice and healthcare disparities, which may impact the ability to meet the criteria to receive HAH care.

Changes in law, regulations, and standards will be required to support HAH care models, particularly because some elements of the HAH care model were supported by temporary regulatory flexibilities granted to address the COVID-19 public health emergency. Specifically, the continued adoption and expansion of the HAH model will require the creation of sustainable reimbursement models for pharmacist-provided HAH services. Additionally, regulatory changes, particularly from CMS may be needed to ensure that pharmacists can administer medications in the home setting.

To prepare the pharmacy workforce to meet the needs of patients in HAH programs and the organizations managing them, ASHP will need to provide education, training, and resources to prepare the pharmacy workforce for these new and evolving roles, including the development of best practices, residency standards, and workforce competencies. To achieve these goals, ASHP will need to collaborate with interprofessional organizations such as the Hospital at Home Users Group (HAHUsersgroup.org), a collaborative of HAH programs around the U.S. and Canada that fosters the development and dissemination of resources and best practices to expand the reach of HAH programs, drive practice advancement, and inform regulatory and reimbursement policies to spread the HAH model of care. To provide a basis for these efforts, ASHP will also need to encourage research on the HAH model of care.

2220

Promoting Telehealth Pharmacy Services

Source: Council on Pharmacy Practice

To advocate for innovative telehealth pharmacy practice models that (1) enable the pharmacy workforce to promote clinical patient care delivery, patient counseling and education, and efficient pharmacy operations; (2) improve access to pharmacist comprehensive medication management services; (3) advance patient-centric care and the patient care experience; and (4) facilitate pharmacist-led population and public health services and outreach; further,

To advocate for removal of barriers to access to telehealth services; further,

To advocate for laws, regulations, and payment models for telehealth services that are equitable to similar services provided in person by health systems, with appropriate accountability and oversight; further,

To encourage comparative effectiveness and outcomes research on telehealth pharmacy services.

Rationale

The definitions and terminology used to describe telehealth vary. Many refer to virtual health, telehealth, telemedicine, and/or telepharmacy interchangeably. The Centers for Medicare & Medicaid Services (CMS) describes telemedicine as a means for improving a patient's health by permitting two-way, real-time, interactive communication between a patient and a healthcare provider who are geographically separated. ASHP defines telepharmacy as a method used in pharmacy practice in which a pharmacist utilizes telecommunications technology to oversee aspects of pharmacy operations or provide patient care services.

Telehealth is part of a larger digital transformation in healthcare. Patients are increasingly making decisions about who delivers their care and engaging in the delivery of that care digitally. As a result, hospitals and health systems need a strategy for their own digital transformation and to meet patient demands. In general, telehealth includes a broader scope of remote healthcare services than telemedicine and telepharmacy; therefore, ASHP considers telehealth to be the overarching term for the remote delivery of patient care services.

The availability of telehealth services in rural areas facilitates greater access to care by eliminating the need to travel long distances to see a qualified healthcare provider. It promises to save patients time and money, reduces patient transfers, emergency department and urgent care center visits, and delivers savings to payers (American Hospital Association [AHA]. Fact Sheet: Telehealth; AHA. Optimizing Pharmacy Services: Managing your hospital pharmacy during the COVID-19 pandemic and beyond). Pharmacists' role in telehealth is instrumental, as telehealth serves are a valuable tool for the profession of pharmacy to extend its reach to patients for the provision of medication management and complex patient care (AHA. Optimizing Pharmacy Services: Managing your hospital pharmacy during the COVID-19 pandemic and beyond; ASHP Statement on Telepharmacy). Telehealth services have grown significantly over recent years, especially during the COVID-19 pandemic. Telehealth services have the potential to improve patient access to care, cost efficiencies, and quality while

meeting consumer demand. They also offer patients the convenience of remote drug therapy monitoring, authorization for prescriptions, patient counseling, and monitoring patients' compliance with prescriptions, and they can be offered remotely to patients with diabetes, congestive heart failure, and other chronic diseases. Pharmacists may also use telehealth when suitable to remotely verify sterile compounding, offer pre- and postoperative medication order review, provide interactive postoperative patient medication counseling, or deliver drug information to a facility that is geographically isolated (ASHP Statement on Telepharmacy). To ensure the best patient care outcomes and most efficient use of healthcare resources, additional research will be needed to compare telehealth pharmacy services with those offered in person.

2221
Tamper-Evident Packaging on Multidose Products
Source: Council on Pharmacy Practice
To support the standardization and requirement of tamper-evident packaging on all multidose prescription and nonprescription products; further,

To encourage proper safety controls be in place to prevent harm and ensure proper disposal of multidose products.

This policy supersedes ASHP policy 9211.

Rationale
Multidose products provide more than one dose of a medication. Medications available in multidose forms include but are not limited to topical creams, gels, and ointments, inhalers, and solutions. Tamper-evident packaging is needed to ensure the viability and safety of medications in multidose containers. The Food and Drug Administration defines a tamper-evident package as "one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering occurred." In addition, when multidose products are disposed of, best practices in medication waste disposal need to be employed to prevent harm or diversion.

2222
Pharmacist's Role in Medication Procurement, Distribution, Surveillance, and Control
Source: Council on Pharmacy Practice
To affirm the pharmacist's expertise, responsibility, and oversight in the procurement, distribution, surveillance, and control of all medications used within health systems and affiliated services; further,

To assert that the pharmacy leader retains the authority to determine the safe and reliable sourcing of medications; further,

To assert that the pharmacy workforce is responsible for the coordination of medication-related care, including optimizing access, ensuring judicious stewardship of resources, and providing intended high-quality clinical care; further,

To encourage payers, manufacturers, wholesalers, accreditation bodies, and governmental entities to enhance patient safety by supporting the health-system pharmacy workforce's role in medication procurement, distribution, surveillance, and control.

This policy supersedes ASHP policy 0232.

Rationale

Pharmacists are accountable for ensuring that medications will be optimally used in the care setting in which they work. (For the purposes of this policy, "medications" include those used by inpatients and outpatients, large- and small-volume injectables, radiopharmaceuticals, diagnostic agents including radiopaque contrast media, anesthetic gases, blood-fraction drugs, dialysis fluids, respiratory therapy drugs, biotechnologically produced drugs, investigational drugs, drug samples, drugs brought to the setting by patients or family, and other chemicals and biological substances administered to patients to evoke or enhance pharmacologic responses.) The pharmacist and pharmacy workforce, as part of their leadership over all aspects of the medication-use process, are responsible for medication procurement, distribution, surveillance and control. One of the central roles of the pharmacist and pharmacy workforce in hospitals, health systems, and affiliated services is to oversee and assume accountability for these responsibilities while also supporting patient access to medications and engaging in clinical services to optimize medication use. While recognizing the stakeholders that influence medication procurement, distribution, surveillance, and control such as payers, manufacturers, wholesalers, accreditation bodies, and governmental entities, pharmacists require the autonomy to make decisions related to these aspects for their institutions and affiliated service provision.

2223

ASHP Statement on the Role of the Pharmacy Workforce in Emergency Preparedness

Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Role of the Pharmacy Workforce in Emergency Preparedness.

This statement supersedes the ASHP Statement on the Role of Health-System Pharmacists in Emergency Preparedness dated June 2, 2002.

2224

Drug Desensitization

Source: Council on Therapeutics

To encourage an allergy reconciliation process to ensure allergy documentation is accurate and complete for drug desensitization; further,

To advocate for pharmacist involvement in the interdisciplinary development of institutional drug desensitization policies and procedures; further,

To support the creation and implementation of drug desensitization order sets and safeguards in the electronic health record to minimize potential error risk; further,

To recommend appropriate allocation of resources needed for the drug desensitization process, including adequate availability of allergic reaction management resources near the desensitization location; further,

To support the education and training of pharmacists regarding allergy reconciliation, drug desensitization processes, and allergic reaction prevention and management; further,

To recommend patient education and appropriate documentation in the electronic health record of the outcomes of the drug desensitization process.

Rationale

Only about 5-10% of all drug-related adverse events are allergic in nature. Patients are often labeled with an allergy on the basis of a side effect or intolerances such as headache or gastrointestinal disturbance. Allergen misidentification and documentation can be detrimental to patient care by preventing the use of optimal drugs or by causing re-exposure to a true allergen. However, when a patient has a true allergy, and the drug is required for treatment, drug desensitization is often the next step in patient care.

Drug desensitization is a procedure that transiently alters a patient's immune response to a drug to permit an allergic patient to receive the sensitizing drug safely. Approaches to desensitization are often drug- and protocol-specific and vary widely (e.g., in the length of sensitization based on patient-specific factors such as immune response, body composition, height, and weight). This approach to patient care is not without risk or controversy, as the mechanism of drug desensitization is not completely understood but the procedure is often deemed essential to patient care when a specific drug is the only appropriate therapy for a patient. Drug concentrations and dilutions are often not standardized, and depending on the drug, can be a source of significant error, particularly with high-risk medications such as chemotherapeutic agents. Sources of error that have been cited in the literature include compounding errors, order entry into the electronic health record, lack of standardized order sets, variability in concentrations of sensitizing doses, allergic reaction prevention, and documentation of desensitization outcomes.

2225

ASHP Statement on Pharmacist Prescribing of Statins

Source: Council on Therapeutics

To approve the ASHP Statement on Pharmacist Prescribing of Statins.

This statement supersedes the ASHP Statement on Over-the-Counter Availability of Statins dated June 14, 2005.

2226
ASHP Statement on the Role of Pharmacists in Primary Care
Source: Section of Ambulatory Care Practitioners
To approve the ASHP Statement on the Role of Pharmacists in Primary Care.

This statement supersedes the ASHP Statement on the Pharmacist's Role in Primary Care dated June 7, 1999.

2227
ASHP Statement on Telehealth Pharmacy Practice
Source: Section of Pharmacy Informatics and Technology
To approve the ASHP Statement on Telehealth Pharmacy Practice.

This statement supersedes the ASHP Statement on Telepharmacy dated November 18, 2016.

2228
Role of the Pharmacist in Service-Line Development and Management
Source: Council on Pharmacy Management
To recognize pharmacists bring unique clinical, operational, and financial expertise to help organizations develop and manage high-value health-system service lines; further,

To support the role of pharmacy leadership in the development and management of high-value health-system service lines.

Rationale
To drive success in the current market, health systems, especially those within integrated delivery networks, must optimize growth by applying strong tactics to acquire and retain patients. Service-line development is structuring patient-centered care in clinically specific areas across the healthcare system. Service-line design groups patients into specific areas of need, improving care coordination and accountability and allowing for a nimble response to changes (e.g., in the allocation of resources).

Pharmacists bring clinical, operational, and financial expertise to help organizations (1) optimize resources, (2) ensure safe medication use and patient-centric system design, (3) drive patient and provider satisfaction, (4) improve patient outcomes, and (5) achieve financial growth when part of critical decision-making for setting an organization's overall service-line growth and management strategy. For example, pharmacists working as part of a specialty pharmacy can leverage their expertise to assess a certain population within a service line, with the goal of improving care and patient safety while promoting use of cost-effective treatments. Most specialty pharmacies allow pharmacists to oversee financial, operational, and clinical services, which has led to growth in patient access and revenue for health systems. Health systems can reap many benefits from expanding service lines, including increased patient volumes, improved health outcomes, boosted market share, and improved patient and provider satisfaction. By focusing on developing high-value service lines, health systems have

the opportunity to achieve financial growth and significant return on investment. Growing high-value service lines is one of the most effective ways in which hospitals and health systems can add value to the healthcare system. Growing service lines requires careful strategic planning, and success hinges on an organization's proficiency in (1) understanding and predicting patient needs; (2) acquiring commercial health plans; (3) using an omni-channel approach; (4) focusing on provider referrals; (5) safe medication use and patient-centric system design (e.g., medication stewardship, formulary alignment, medication-use policies); and (6) ensuring the C-suite is fully committed to the service-line development strategy. High-value service lines exemplify exceptional performance in many ways, including attracting the most patients and providers, driving the most revenue, achieving the highest care success rates, and presenting the greatest growth potential. Healthcare organizations identify their high-value service lines by analyzing financial data, external market factors (e.g., value-based contracts), and other relevant economic conditions. Data analytics and effective patient communication are important when healthcare organizations are working to grow service lines. High-value service lines may differ among hospitals, depending on the patients and markets they serve. During times of scarce capital and growing demand for services, service-line analysis becomes a high-priority task for hospital and health-system decision-makers. Leaders must face hard questions when it comes to identifying the areas of operations critical to an institution's long-term financial viability and should ensure those service lines get the investment and management attention they need. Service-line analysis may also mean eliminating low-volume and/or unprofitable service lines that drain resources. Before hospital leaders decide to discontinue a given service line, they should consider whether the line has been properly managed. Many hospitals may have inadvertently harmed service-line management by not investing sufficiently in the resources needed for success.

In today's environment, successful service-line development efforts need input from pharmacy leaders from the outset of discussions through implementation and management. Engagement in every step of service-line development and management assures long-term success as strategic direction is set. Success as a pharmacy leader is predicated on building and maintaining relationships with diverse groups of people in order to be part of setting the overall strategy for an organization. This relationship-building may include partnering with nontraditional healthcare participants to develop new strategies for care. As healthcare markets continue to shift away from volume and toward value, appealing to patients by building high-value service lines designed to meet patients' unique needs will become increasingly important.

2229

Pharmacist's Role in Respiratory Pathogen Testing and Treatment

Source: Council on Therapeutics

To advocate that state board of pharmacy regulations include respiratory pathogen testing and associated prescribing or dispensing under pharmacists' scope of practice; further,

To support the development of specific and structured criteria for pharmacist prescribing, dosing, and dispensing of antimicrobials for treatment of respiratory infections; further,

To advocate for laws and regulations that would allow pharmacists to dispense antimicrobials when clinically indicated or refer patients, as appropriate, based on point-of-care testing; further,

To support the diagnosis and tracking of reportable diseases through pharmacist-driven testing and reporting to appropriate public health agencies prior to dispensing of antimicrobials; further,

To advocate for reimbursement for pharmacists' patient care services involved in respiratory pathogen testing and treatment; further,

To promote training and education of the pharmacy workforce to competently engage in respiratory pathogen testing and treatment when clinically indicated.

Rationale

There is currently a patchwork of state legislation that permits pharmacists in collaborative practice agreements to perform rapid testing to diagnose group A streptococcal pharyngitis and prescribe antimicrobial therapy when a test is positive. This practice model has been shown to decrease the cost of diagnosis and treatment for children and adults and has demonstrated increased patient satisfaction. The availability of rapid influenza tests allows pharmacists to quickly diagnose and recommend treatment for influenza A and B, which has been found to reduce the time to first dose of antiviral drugs among individuals with influenza-like illness, compared to those referred to prescribers. ASHP advocates development of specific and structured criteria for pharmacist prescribing, dosing, and dispensing of antimicrobials for this purpose, under a variety of models (e.g., autonomous prescribing authority for pharmacists, delegation protocols, or collaborative practice agreements).

Furthermore, a 2018 study found that 69% of pharmacists are willing to perform point of care testing (POCT) in a community pharmacy setting, and 86% either strongly agreed or agreed to be willing to recommend appropriate treatment for influenza and group A streptococcal pharyngitis. With collaborative practice agreements in place, patients can bypass visiting a primary care provider, empowering pharmacists to assume an active role not only in treating patients but also in promoting public health by reporting positive cases to local health departments, should rapid testing and reporting be a requirement of dispensing.

Finally, a Washington State University study demonstrated that after a POCT training module, student pharmacists were not only able to proficiently perform POCT for group A streptococcal pharyngitis, influenza, and human immunodeficiency virus, but also showed an increased willingness to perform and recommend the tests, which could expand access.

2230

Advancing Diversity, Equity, and Inclusion in Education and Training

Source: Council on Education and Workforce Development

To advocate that health systems and organizations cultivate training and education partnerships that advance diversity, equity, and inclusion; further,

To advocate that all members of the pharmacy workforce actively participate in the equitable training and education of people from marginalized populations.

Rationale

People from marginalized populations, including Black, Indigenous, and People of Color (BIPOC) and others, can experience disparities when receiving or accessing healthcare. Implicit biases exist against underrepresented minorities among many healthcare providers, which can perpetuate medication nonadherence, decrease trust in healthcare, and ultimately increase morbidity and mortality (Hall WJ, Chapman MV, Lee KM, et al. Implicit racial/ethnic bias among health care professionals and its influence on health care outcomes: a systematic review. *Am J Public Health.* 2015; 105:e60-e76).

ASHP created the Task Force on Racial Diversity, Equity, and Inclusion in June 2020. One of its three focus areas was education and training, which resulted in two key recommendations (13 and 16). The first of these recommendations encourages hospitals and health systems to include statements and/or integrate expectations into their departments' planning and operations for the equitable training of underrepresented minorities. Further, the Task Force recommended hospitals and health systems partner with knowledgeable organizations to help educate and train the pharmacy workforce on how to support future underrepresented minority pharmacy workforce members (e.g., training on implicit bias, cultural competency, and fostering an inclusive climate)(Report of the ASHP Task Force on Racial Diversity, Equity, and Inclusion. *Am J Health-Syst Pharm.* 2021; 78:903–906). Organizations are encouraged to partner with their respective offices of diversity, equity, and inclusion (DEI) as well as local or national organizations to support these education and training efforts (e.g., National Association for Equity, Diversity, and Inclusion [NAEDI] and Government Alliance on Race and Equity [GARE]). By advancing DEI in the education and training of the pharmacy workforce, all members of the pharmacy workforce can positively impact patient care.

2231

Cultural Competency

Source: Council on Education and Workforce Development

To foster the ongoing development of cultural humility and competency within the pharmacy workforce; further,

To educate the pharmacy workforce to interact with patients and caregivers in a manner that demonstrates respect for and responsiveness to personal and social identities; further,

To educate healthcare providers on the importance of providing culturally congruent care to achieve quality care and patient engagement.

This policy supersedes ASHP policy 1613.

Rationale

The United States is rapidly becoming a more diverse nation. Culture influences a patient's belief and behavior toward health and illness. Cultural humility and competence can significantly affect clinical outcomes. Research has shown that overlooking cultural beliefs may

lead to negative health consequences. According to the National Center for Cultural Competency, there are numerous examples of benefits derived from the impact of cultural competence on quality and effectiveness of care in relation to health outcomes and well-being. Further, pharmacists can contribute to providing "culturally congruent care," which can be described as "a process of effective interaction between the provider and client levels" of healthcare that encourages provider cultural competence while recognizing that "[p]atients and families bring their own values, perceptions, and expectations to healthcare encounters which also influence the creation or destruction of cultural congruence." The Report of the ASHP Ad Hoc Committee on Ethnic Diversity and Cultural Competence and the ASHP Statement on Racial and Ethnic Disparities in Health Care support ways to raise awareness of the importance of cultural competence in the provision of patient care so that optimal therapeutic outcomes are achieved in diverse populations.

When considering holistic approaches to patient care, clinicians should recognize and respond effectively to all personal and social identities, including but not limited to the categories of sexual identity and gender expression, age, national origin, socioeconomic origin, ethnicity, culture, gender, race, religion or spirituality, and physical, sensory, or mental disability. Spiritually congruent care may be expressed in prayer requests, in clinician-chaplain collaborations, and through health care organizations' religious accommodations for patients and staff. Numerous publications have outlined the role of spirituality in overall health, longevity, and quality of life, especially for patients with severe illness. The pharmacy workforce should be educated on the importance of individual patient spirituality and its impact on health and on ways to facilitate patient access to spiritual care services.

2232

Revenue Cycle Management and Reimbursement and Pharmacist Compensation for Drug Product Dispensing

Source: Council on Pharmacy Management

To encourage the pharmacy workforce 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, transparent billing and reimbursement policies and practices by both government and private payers; further,

To collaborate with payers in developing optimal methods of reimbursing pharmacies and pharmacists for the costs of drug products dispensed, pharmacy and pharmacist services, and associated overhead; further,

To educate the pharmacy workforce and stakeholders about those methods; 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 policies 1710 and 1807.

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, and the pharmacy department 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, or in some cases a contracted third-party vendor, handle all billing issues with various degrees of pharmacy department involvement. Accurate billing requires integration of the organization's clinical services, pharmacy, billing, and chargemaster 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.

In well-intentioned efforts to reduce healthcare costs, public and private payers often seek to minimize the reimbursement to pharmacies for drug products. Historically, those reimbursements have sometimes exceeded the simple cost of the drug product to reimburse pharmacies for associated costs (e.g., storage, compounding, preparation, dispensing). 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. Because cost-management efforts are likely to continue to reduce pharmacy reimbursement, other means of compensating pharmacies for those expenses will need to be found, and pharmacists and other stakeholders will require education about those reimbursement methods. In addition, pharmacists and pharmacies need to be reimbursed for professional services associated with management of medications and related patient care. 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 Leaders are committed to developing and sharing best practices and providing education to support pharmacists in optimizing reimbursement and pharmacist compensation for drug product dispensing and pharmacy's role in revenue cycle compliance.

2233

Value-Based Purchasing

Source: Council on Pharmacy Management

To support value-based purchasing reimbursement models when they are appropriately structured to improve healthcare quality, patient satisfaction, and clinical outcomes, and encourage medication error reporting and quality improvement; further,

To affirm the role of pharmacists in actively leading the design and interdisciplinary implementation of medication-related value-based purchasing initiatives; further,

To support pharmacy workforce efforts to ensure safe and appropriate medication use by using data and technology for continuous quality improvement in pharmacy-designed, medication-related value-based purchasing initiatives; further,

To advocate that the Centers for Medicare & Medicaid Services and others guide the development of a common portfolio of measures for potential alignment across regulated programs, federal programs and agencies, and the private sector.

This policy supersedes ASHP policy 1209.

Rationale

Value-based purchasing is one aspect of a portfolio of healthcare reform incentives based on pay-for-performance principles. The Hospital VBP Program adjusts payments to hospitals under the Inpatient Prospective Payment System (IPPS) based on the quality of care they deliver. In April 2021, the Centers for Medicare & Medicaid Services (CMS) announced efforts to (1) readdress 2020 policies during the duration of COVID-19 public health emergency (PHE) and (2) close healthcare equity gaps and provide greater accessibility to care, requesting comments regarding the modernization of the quality measurement enterprise to digital quality measurement. In response to the pandemic, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) for eligible discharges during the PHE. To enhance the medical workforce in rural and underserved communities, CMS is proposing to distribute 1,000 additional physician residency slots to qualifying hospitals, phasing in 200 slots per year over five years. To address the future of digital quality measurement, CMS is currently reviewing proposals and holding discussions through 2022.

CMS was seeking comment on plans to modernize its quality measurement enterprise by:

- clarifying the definition of digital quality measures;
- using the Fast Healthcare Interoperability Resources (FHIR) Standard for electronic clinical quality measures that are currently in the various quality programs;
- standardizing data required for quality measures for collection via FHIR-based application programming interfaces;
- leveraging technological opportunities to facilitate digital quality measurement;
- better supporting data aggregation; and
- developing a common portfolio of measures for potential alignment across CMS regulated programs, federal programs and agencies, and the private sector.

ASHP recognizes the pharmacist's leadership role while explicitly acknowledging the interdisciplinary nature of initiatives designed to achieve value-based purchasing measures. Often, however, active membership on the design team does not include pharmacy. Because there needs to be thoughtful consideration of what pharmacy can reasonably control within an organization in terms of achievable tactics to improve a specific goal, pharmacy leaders need to engage their entire departments in these efforts to ensure that there is a concerted approach toward improving patient care. Finally, as value-based purchasing program proliferate, CMS and other stakeholder organizations need to guide the development of a common portfolio of measures for potential alignment across regulated programs, federal programs and agencies, and the private sector.

2234

Financial Management Skills

Source: Council on Pharmacy Management

To foster the systematic and ongoing development of management skills for the pharmacy workforce in the areas of (1) health-system economics, (2) business plan development, (3) financial analysis, (4) metrics for clinical and distributive services, (5) pharmacoeconomic analysis, (6) diversified pharmacy services, (7) compensation for pharmacists' patient-care services, and (8) revenue cycle compliance and management; further,

To encourage colleges of pharmacy to incorporate these management areas in course work, electives (e.g., financial and managerial accounting), and experiential education; further,

To promote the growth of dual PharmD/MBA degree programs, postgraduate training, and other degree programs focused on financial management, and similar certificates or concentrations; further,

To encourage financial management skills development in pharmacy residency training programs; further,

To provide education for new practitioners and student pharmacists on foundational skills for business administration and personal financial management; further,

To promote education on financial management for other members of the pharmacy workforce (e.g., pharmacy technicians, data scientists, inventory specialists, department business managers).

This policy supersedes ASHP policy 1207.

Rationale

Revenue cycle compliance and management represent an increasingly important aspect of the business operations of hospitals and health systems. Pharmacy leaders must exert leadership in managing medication-related revenue cycle compliance in order to ensure financial success of the healthcare enterprise. The development of foundational skills in financial literacy and business management is critical for many members of the pharmacy workforce (e.g., residents, new practitioners, student pharmacists, pharmacy technicians, and support staff such as data scientists, inventory specialists, or department business managers) to gain perspectives on contemporary management techniques and fiscal solvency. Some ways to achieve this are through (1) college of pharmacy curriculum (e.g., dual Pharm.D./M.B.A. degree or similar programs) or experiential program requirements; (2) degree programs with a concentration in financial management; (3) during residency training as incorporated projects; or (4) as a certificate program for student pharmacists, residents, and new practitioners. Pharmacy leaders must also develop and maintain knowledge in this area to sharpen skills in planning, forecasting, decision-making, and implementation.

2235

Use of Inclusive Verbal and Written Language

Source: Council on Pharmacy Practice

To recognize that stigmatizing and derogatory language can be a barrier to safe and optimal patient care as well as compromise effective communication among healthcare team members; further,

To promote the use of inclusive verbal and written language in patient care delivery and healthcare communication; further,

To urge healthcare leadership to promote use of inclusive language; further,

To provide education, resources, and competencies for the pharmacy workforce to champion the use of inclusive verbal and written language.

Rationale

Inclusive verbal and written language (i.e., language that is free of stigma, bias, and oppression) is essential for the provision of equitable patient care. The use of derogatory and stigmatizing language in the healthcare environment is a risk to patient safety and a threat to optimal health. In addition, when used among care team members, it introduces a culturally insensitive and noninclusive work environment. Stigmatizing language may fuel and trigger implicit or explicit bias in a healthcare clinician or team member and harm patients, worsen health outcomes, and compromise team dynamics. Derogatory and stigmatizing language may occur between patients and the care team, among care team members, and in medical documentation. Commitment to the use of conscious language—the intentional use of words and terms to create empathetic, inclusive, and non-stigmatizing content—is suggested as an alternative to ensure language and communication does not lead to poorer health outcomes, health inequities, and stigma.

The use of stigmatizing and derogatory language in medical chart documentation becomes even more damaging as patients have increased access to their own health records (Davis B. Derogatory language in charting: the domino effect. *Patient Safety*. 2021; 3:74-8.). Patients may not be empowered to take ownership of their care if stigmatizing and derogatory language is used. The same can apply for verbal communications. The use of argot or slang to disguise the meaning to bystanders may be useful to build bonds between colleagues but is unprofessional and creates judgments about patients not based in facts (Goldman B. Derogatory slang in the hospital setting. *AMA J Ethics*. 2015; 17:167-71).

There are multiple strategies for eliminating the use of stigmatizing language in the course of caring for a patient, such as using person-first and technical language and avoiding the use of sensational or fear-based language. Eliminating derogatory and stigmatizing language from healthcare settings requires leadership commitment across the spectrum of care delivery and an educated and empowered healthcare workforce. Pharmacists, student pharmacists, and pharmacy technicians have a professional duty to provide culturally competent and compassionate patient care and can serve as champions in eliminating the use of stigmatizing language in healthcare.

2236

Pharmacist Prescribing in Interprofessional Patient Care

Source: Council on Pharmacy Practice

To advocate that healthcare delivery organizations establish credentialing and privileging processes for pharmacists that delineate scope of practice, support pharmacist prescribing, and ensure that pharmacists who prescribe are accountable, competent, and qualified to do so; further,

To advocate for comprehensive medication management that includes autonomous prescribing authority for pharmacists as part of optimal interprofessional care; further,

To advocate that all pharmacists on the interprofessional team have a National Provider Identifier (NPI); further,

To advocate that payers recognize pharmacist NPIs.

This policy supersedes ASHP policy 1213.

Rationale

Pharmacists are highly trained medication experts skilled in providing comprehensive medication management (CMM) services across the continuum of care. Nearly all states include pharmacist prescribing authority within their state practice acts, although those acts differ in how pharmacist prescribing authority is described, terminology used, and the degree of prescribing autonomy (i.e., autonomous or collaborative). Regulations at the state level are critical to ensuring that pharmacists can seamlessly provide CMM services within the interprofessional team and to the top of their skills and abilities. Pharmacists are a core healthcare team member, well-positioned to provide high-quality, cost-effective care that increases patient access and reduces the burden on other healthcare providers. Hundreds of studies published in peer-reviewed literature, conducted throughout a variety of organizations and health systems, have consistently demonstrated the benefits of pharmacist-directed patient care across a variety of clinical practice settings. A 2010 comprehensive systematic review of 298 studies of U.S. pharmacists' effect as a member of the patient care team found positive results on therapeutic and safety metrics (Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. *Med Care.* 2010; 48:923-33).

Autonomous prescribing allows pharmacists to be fully optimized as a part of the interprofessional healthcare team and ensures that their skills are used to the fullest potential to allow them to be responsible and accountable and fully execute CMM treatment plans. Pharmacist prescribing is implicit to interprofessional care delivery, but the form and manner of pharmacist prescribing varies among health systems and organizations. Independent and autonomous drug therapy decision-making by pharmacists is already common and accepted by other licensed practitioners (e.g., physicians, physician assistants, and nurse practitioners). Practitioners participating in interprofessional teams that include pharmacists rely on the

knowledge, demonstrated competency, and expertise of those pharmacists for CMM. Pharmacists in specialty practice areas such as anticoagulation management, solid organ transplant, and nutrition support have long functioned in roles in which autonomous prescribing authority has improved clinical outcomes in the management and monitoring of medication therapy. In settings such as the Indian Health Service and Veterans Health Administration systems, prescribing authority for pharmacists providing CMM services has been in place for over 40 years and has demonstrated positive clinical impact and increased patient access across the continuum of care.

Many health systems authorize pharmacists to manage drug therapy by enacting pharmacy and therapeutics committee policies that require use of medical staff protocols and physician oversight for pharmacist-initiated orders. While this model works effectively for specific scenarios (e.g., management of population-specific patients), it does not allow the pharmacist to fully function and fulfill the CMM needs of their patients. Depending on the patient, medication, and degree of trust with the pharmacist, physicians often delegate therapeutic decision-making and medication treatment planning to pharmacists, based on the trust relationship developed through the interprofessional team and shared experiences in successfully dealing with challenging clinical situations, rather than through formal collaborative practice agreements. Common examples of pharmacist prescribing include independently managing symptoms and adverse events in oncology patients, identifying and resolving drug-induced disease or problems, managing anticoagulant therapy for patients whose clinical status falls outside specified parameters, and responding to general directives to simply "fix the problem" when medication therapy is indicated. Further, there are settings of care and pharmacy practice models that allow for autonomous and accountable prescribing authority by pharmacist practitioners as core component of CMM, without the need for collaborative practice authority for specific patients or populations. Pharmacist autonomous prescribing authority should be the gold standard for practice, especially when appropriate credentialing and privileging is in place and there is a separation of duties to ensure that a prescribing pharmacist is not responsible for the processing and dispensing of that medication order.

Pharmacists who prescribe must be recognized by payers and reimbursed for performing these advanced practice services. All pharmacist prescribers on the interprofessional team must possess a National Provider Identifier (NPI) number to monitor the care provided as well as reimburse for services rendered. Credentialing and privileging of individual healthcare providers is essential for determining who is authorized to prescribe and should ensure the appropriate evaluation of the quality of care provided. The credentialing procedures used to establish pharmacists' competency to prescribe must ensure that patients receive treatment from highly qualified caregivers. In addition to verifying appropriate education, licensure, and certification, the process should include

- the same transparency and rigor applied to other prescribers,
- criteria used to measure patient care quality, and
- peer review by similar or higher-level peers (i.e., pharmacist prescribers or other licensed practitioners who are authorized to prescribe).

Healthcare organizations should use privileging methods that establish the scope of practice and clinical services that pharmacists are authorized to provide commensurate with their

demonstrated competency within an area or areas of clinical expertise. The practice of credentialing and privileging should be consistent between hospitals health systems, accountable care organizations, and other organizations where the pharmacists function as a part of the interprofessional team. Finally, interdisciplinary health professional training programs should incorporate the concept of pharmacist prescribing in a standard way to ensure consistency amongst pharmacists practicing in similar practice settings and with similar levels of responsibilities.

2237

Universal Vaccination for Vaccine-Preventable Diseases in the Healthcare Workforce

Source: Council on Pharmacy Practice

To support policies and mandates that promote universal vaccination for preventable infectious diseases among healthcare workers, including all members of the pharmacy workforce, as a safeguard to patient and public health; further,

To encourage the use of evidence-based risk assessments to determine inclusions in and exemptions from mandatory vaccine requirements; further,

To support employers in establishing and implementing mandatory vaccine requirements for healthcare workers if evidence-based risk assessments determine they are safe and promote patient and public health; further,

To urge healthcare organizations to have policies that address additional infection prevention practices required for exempted healthcare workers; further,

To develop tools, education, and other resources to promote vaccine confidence, increase vaccination rates, and minimize vaccine-preventable diseases among healthcare workers.

This policy supersedes ASHP policies 2138 and 2140.

Rationale

Vaccine-preventable diseases (VPDs) pose a threat to vulnerable patients, the healthcare workforce, and public health. Vaccines are effective in protecting the healthcare workforce and the patients they care for and with whom they interact.

Voluntary vaccination of healthcare workers (HCWs), supported by employer-offered strategies, increases vaccination rates to some extent. For example, the Centers for Disease Control and Prevention (CDC) estimates that in the 2019-2020 season, approximately 80% of healthcare workers were vaccinated against influenza, with rates over 90% among hospital employees, despite the fact that only approximately 70% of hospitals require an annual influenza vaccination and the CDC has recommended influenza vaccinations for HCWs since 1981.

Mandatory vaccination requirements, in contrast, carry heavier weight and can result in near-universal vaccination rates (Schumacher S et al. Increasing influenza vaccination coverage in healthcare workers: a review on campaign strategies and their effect. *Infection.* 2021; 49:

387–99. https://doi.org/10.1007/s15010-020-01555-9). The effectiveness of the mandatory approach has led to HCW vaccination requirements from the Occupational Safety and Health Administration, recommendations from the Centers for Disease Control and Prevention (CDC), policy endorsements from numerous professional organizations, and quality measures for federal and commercial payer reporting programs. For example, the CDC Advisory Committee on Immunization Practices proposes recommendations for the immunization of healthcare workforce based on (1) those diseases for which routine vaccination or documentation of immunity is recommended for healthcare personnel because of risks to them in their work settings and, should healthcare personnel become infected, to the patients they serve; and (2) those diseases for which vaccination of healthcare personnel might be indicated in certain circumstances. The current list of VPDs in which healthcare personnel are considered to be at substantial risk for acquiring or transmitting and in which vaccination is recommended includes hepatitis B, influenza, measles, mumps, rubella, pertussis, and varicella. In the future, this list may include vaccination against SARS-CoV-2.

In its recommendations, the CDC considers HCWs to include (but not be limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCWs and patients.

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

2238

Patient Disability Accommodations

Source: Council on Public Policy

To promote safe, inclusive, and accessible care for patients with disabilities; further,

To advocate for research to enhance capabilities in meeting the needs of patients with disabilities; further,

To advocate for inclusion of caring for patients with disabilities in college of pharmacy and pharmacy technician program curricula and in postgraduate residencies; further,

To support pharmacy workforce training to improve awareness of the barriers patients with disabilities face and ensure equitable care.

Rationale

Current statistics indicate that 20–30% of Americans have some type of disability Many of these patients, regardless of whether their disability is physical or mental, would benefit from the creation and adoption of technology and communication tools that improve how pharmacists and other providers interact with them. Because there is such a broad spectrum of potential patient needs, additional research on appropriate and safe implementation of technology and the creation of new solutions, including solutions to improve health equity, is needed and should be supported by federal, state, and private funding. Further, pharmacy schools and other pharmacy workforce training programs should integrate education on serving patients with disability into their established curricula.

2239

Drug Pricing Proposals

Source: Council on Public Policy

To advocate for drug pricing and transparency mechanisms that ensure patient access to affordable medications, preserve existing clinical services and patient safety standards, and do not increase the complexity of the medication-use system.

Rationale

As drug prices have continued to climb, policymakers have proposed numerous solutions. While each proposal will need to be evaluated on its merits, it is critical that, at a minimum, policy solutions promote transparency, protect patient access to medications. and limit or reduce patient out-of-pocket costs. However, drug pricing solutions should not threaten programs that support expanded patient services (e.g., the 340B Drug Pricing Program), create patient safety risks (e.g., certain drug importation proposals), or add to the administrative or practice burden of healthcare providers.

2240

Post-Intensive Care Syndrome

Source: Council on Therapeutics

To recognize that multidimensional rehabilitation is essential for recovery after intensive care; further,

To support research on and dissemination of best practices in the prevention, identification, and treatment of post-intensive care syndrome (PICS) in patients of all ages; further,

To advocate that health systems support the development and implementation of interdisciplinary clinics, inclusive of pharmacists, to treat patients with PICS, including provisions for telehealth and innovative practice models to meet the needs of patients with PICS; further,

To advocate for the integration of post-ICU patient and ICU caregiver support groups; further,

To provide education on the role of the pharmacist in caring for patients with PICS.

Rationale

Post-intensive care unit (post-ICU) rehabilitation is essential for recovery after critical illness. Post-intensive care syndrome (PICS) is a conglomerate of new or worsening multidimensional impairments in physical, psychological, cognitive, and social status arising from critical illness that continue after hospital discharge. PICS is associated with high morbidity among patients discharged from ICUs, with 30-80% of patients having issues with remembering, paying attention, solving problems, or organizing and working on complex tasks.

The burden of PICS continues to grow. With only up to 50% of patients with PICS able to return to work within the first year, some are unable to return to the jobs they had before their illness and need help with activities after leaving the hospital. While PICS is widely discussed across medical disciplines, it not well defined, nor are ways to prevent and treat this disorder well researched. It is recognized that patients with PICS require a multidimentional, interdisciplinary treatment effort, including cognitive rehabilitation, mental health treatment, and intensive transitions of care interventions, as patients may be discharged on medications that should not be continued and they may need support to resume daily activities. The rapid COVID-19-related increase in patients requiring the use of ICUs has exacerbated the demand for high-quality PICS care, but the simultaneous expansion of telemedicine and other innovative patient care models has shown that rapid changes in team-based care can be achieved with the proper incentives and flexibilities.

2241

Human Use of Veterinary Pharmaceuticals

Source: Council on Therapeutics

To oppose human use of pharmaceuticals approved only for veterinary use; further,

To support use of veterinary pharmaceuticals only under the supervision of a licensed veterinarian in compliance with the Animal Medicinal Drug Use Clarification Act of 1994; further,

To encourage state and federal regulatory bodies as well as other stakeholders to monitor the misuse of veterinary pharmaceuticals and, when appropriate, limit the public availability of those pharmaceuticals; further,

To educate healthcare professionals and the public about the adverse effects of human consumption of veterinary pharmaceuticals; further,

To encourage research, monitoring, and reporting on the adverse effects of human consumption of veterinary pharmaceuticals to define the public health impact of and to quantify the strain these agents place on the healthcare system.

Rationale

Medications that are formulated for veterinary use are often supplied at higher concentrations, contain compounds not safe for human use, and require specialized knowledge to administer.

The prevalence of drug misuse in the veterinary setting is not well documented, but surveys of veterinarians by the Idaho Board of Veterinary Medicine, Colorado Veterinarians, and Veterinary Hospitals in Pennsylvania found that they suspect 23% of animal owners misuse veterinary medicines on themselves, their children, or friends, and that the most-documented misused drugs are opioids, benzodiazepines, and ketamine. These findings are concerning because animals often require a more potent dose of controlled substances, which can be appealing for individuals with substance use disorders, and medications are often dispensed directly to the animal owner, bypassing pharmacists, who are critical players in prescription drug misuse risk mitigation.

In the in United States, licensed veterinarians can prescribe, administer, carry, stock, and dispense medications, including veterinary-only drugs, drug compounds, and FDA-approved over-the-counter veterinary drugs. These drugs are typically veterinary formulations that are not tested for human safety or approved for human use, and the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) permits veterinarians to prescribe those drugs in an "extralabel" manner. Under AMDUCA regulations, "extralabel use" means the actual or intended use of a drug, by or on the order of a veterinarian, in a manner that is not in accordance with approved labeling (similar to off-label use in human medicine). Any deviation from labeled use, by veterinarians or lay persons, is an illegal use unless it meets all the requirements of FDA's extralabel drug-use rules. Deviations from the label include use in a species or production class not on the label and use of a different route of administration.

More recently, the COVID-19 pandemic has exacerbated human consumption of veterinary compounds, as some medications being studied for efficacy against the virus produce promising or equivocal preliminary results that are seized upon by the public and some prescribers, leading to inappropriate prescribing. For example, ASHP, APhA, and AMA have called for an immediate end to the prescribing, dispensing, and use of ivermectin for treatment of COVID-19 outside of a clinical trial. Due to the response of the medical community, many physicians and pharmacies are not writing or filling prescriptions for this medication, driving patients to purchase the animal formulation of ivermectin for human consumption. Earlier in the pandemic, a patient in Arizona consumed chloroquine phosphate meant for fish as a treatment for COVID-19 and died. The FDA, aware of the misuse of chloroquine products, issued a cautionary letter to stakeholders and worked with online marketplaces to remove the products from the market.

Finally, some veterinary compounds produce mild to life-threatening human adverse effects upon accidental or intentional exposure or ingestion. Patients exposed to or ingesting these products present to the emergency department with symptoms that range from bronchospasm, central nervous system stimulation, and miscarriage to sudden death, which demonstrates the need for timely reporting of abuses, misuses, or accidental exposures of these agents.

2242

Use of Intravenous Drug Products for Inhalation

Source: Council on Therapeutics

To encourage healthcare organizations to develop an interdisciplinary team that includes pharmacists and respiratory therapists to provide institutional guidance; safety

recommendations regarding preparation, dispensing, delivery, and exposure; and electronic health record support for prescribing and administration of intravenous drug products for inhalational use; further,

To advocate for further research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for inhalational administration, devices for administration, and the effects of excipients; further,

To foster the development of educational resources on the safety and efficacy of inhalational administration of drug products not approved for that route and devices for administration; further,

To encourage manufacturers to develop ready-to-use inhalational formulations when evidence supports such use.

Rationale

Practitioners have been increasingly seeking out novel delivery mechanisms for drugs to patients who require a more localized application. This approach has more frequently seen through the nebulization of antibiotics and antifungals that are formulated for intravenous (IV) use as a part of an effort to treat an invasive pulmonary infection in critically ill patients. Nebulization of IV morphine has also been used to provide relief in chronic obstructive pulmonary disease exacerbations, dyspnea in cancer patients, and pain management in trauma patients. Data for these treatment efforts is limited to small patient populations, and the information on the pharmacokinetics, safety, and efficacy of drugs administered by this method remain insufficient. Furthermore, the number of drug products that are formulated exclusively for the purpose of aerosolization is limited, and the degree of pulmonary penetration depends on the properties of antimicrobial formulations, including size, viscosity, surface tension, osmolality, tonicity, and pH. Drug stability, safety for both the patient receiving and the person administering the drug, and the methods of preparation and delivery also bear consideration. The mechanism of nebulization also introduces uncertainty. Because pneumatic nebulizers and ultrasonic nebulizers have different particle size tolerance and deliverability capabilities, susceptibility for contamination may vary, depending on the device used.

Nebulized drugs also present a potential risk to healthcare providers, who may be exposed to drug particles that are expelled through the device when administering the drug. Therefore, an interdisciplinary team that includes representatives from pharmacy and respiratory therapy (as it is often a respiratory therapist who administers the drug in an inpatient setting) is needed to ensure that occupational exposure is minimized, that patients are placed in rooms with proper ventilation, and that, if necessary, caregivers are provided with appropriate masks during administration.

There is evidence that certain drugs delivered by nebulization have a beneficial role in management of patient disease. It important to recognize that nebulized drugs that are not commercially available may be compounded with both sterile and nonsterile ingredients and that, when possible, should be compounded with preservative- and additive-free formulations in order to improve patient tolerability. Due to this variability and potential source for sterile

compounding and potential administration errors, where there is evidence that supports the use of compounded nebulized drugs, manufacturers should be encouraged to create a commercially available formulation for delivery via nebulizer.

2243
Enrollment of Underrepresented Populations in Clinical Trials
Source: Council on Therapeutics
To support the enrollment of underrepresented populations in clinical trials; further,

To advocate that drug product manufacturers and researchers conduct and report outcomes of pharmacokinetic, pharmacodynamic, and pharmacogenomic research in underrepresented populations to facilitate safe and effective dosing of medications in these patient populations; further,

To advocate that if such research considers age, sex, gender, ethnicity, or race, the reason for such consideration be based on validated ethical or scientific reasons and be specified in the research protocol; further,

To foster the use and development of postmarketing research strategies to support the safe and effective use of drug products for approved and off-label indications in underrepresented populations; further,

To advocate that pharmacists should be involved in the design of clinical trials to provide guidance on drug dosing, administration, and monitoring in all patient populations.

This policy supersedes ASHP policy 1723.

Rationale
Pregnant patients, fetuses, neonates, children, members of racial or ethnic minority groups, the elderly, and transgender individuals are populations in which the pharmacokinetic, pharmacodynamic, and pharmacogenomic properties of medications may differ from those of people typically enrolled in clinical trials. 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 incentives 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 dosing for these patients, which varies based on medication- and patient-specific characteristics. There is a paucity of research in these patient populations, which is similar to the lack of preapproval studies in obese patients. ASHP also encourages independent clinical and practice-based research in which pharmacists are involved in the study design to further define clinical use of medications in the treatment of these patients, as well as clinician reporting of patient experience via published articles and clinical registries.

2244

Pediatric Dosage Forms

Source: Council on Therapeutics

To support research on and development of pediatric-specific drug formulations; further,

To encourage manufacturers to develop formulations suitable for pediatric administration during research that includes pediatric patients; further,

To encourage manufacturers of off-patent medications that are used in pediatric patients to develop formulations suitable for pediatric administration; further,

To advocate that manufacturers comparably price a newly developed pediatric-specific commercial product to that of its extemporaneously prepared formulation; further,

To educate prescribers and caregivers regarding the nuances of pediatric drug administration to ensure the availability of an appropriate dosage form is considered when selecting and administering safe and effective therapies for a pediatric patient.

This policy supersedes ASHP policy 9707.

Rationale

Pediatric patients are at high risk for medication errors because so few formulations are created for them. Challenges to pediatric dosage development include insufficient background information on the drug molecule in the target population, issues with safety and tolerability of excipients, taste-masking issues, technology requirements, the risks involved in clinical trials, small market size and low profitability, and lack of regulatory clarity.

To ensure that the proper dose is administered, different routes of administration, dosage forms, and strengths may be required. Because many existing formulations are not suitable for children, many hospitals and health systems will use components to extemporaneously prepare a formulation that provides a measurable, stable, and consistent delivery of a needed medication. The concentration and availability of these formulations, most often in the form of suspensions and solutions, may also vary in storage requirements, bioavailability, and palatability, all which can affect patient tolerability and adherence.

Furthermore, since many medications are needed for a relatively small patient population, often only a few commercial products are manufactured, resulting in the need for compounding. As a result, research is often stymied in the pediatric patient population as well, since compounding a medication may introduce variables that may affect results in unpredictable ways.

Boards of pharmacy have also recognized the safety issues surrounding variability in stability and concentrations of the same drug, and many have laws in place that prohibit the extemporaneous compounding of drugs in concentrations that are commercially available.

As pediatric patients have different tolerability to excipients, organ development, taste preferences, and swallowing abilities as they age, it is essential that pharmacists are a part of

the team that determines a medication regimen. It is also important that caregivers are taught to properly measure, store, and administer pediatric formulations as a part of patient care.

2245
Substance Use Disorder
Source: Council on Therapeutics
To affirm that a patient with a substance use disorder (SUD) has a chronic condition with associated neurodevelopmental, physiologic, and psychosocial changes; further,

To recognize that dehumanizing language and stigmatization regarding SUD and persons who use drugs (PWUD) create barriers to healthcare access and result in poor clinical outcomes; further,

To recognize the disproportionately harmful health impact that criminalization and policing practices related to SUD and PWUD have had on communities, particularly those of color; further,

To advocate for destigmatization efforts and elimination of barriers to care for SUD and PWUD; further,

To support risk mitigation and harm reduction strategies, including syringe services programs, recognizing the roles they have in public health efforts to reduce infectious disease burden, improve access to healthcare, improve patient trust, and reduce expenditures; further,

To advocate for expansion of comprehensive medication management services provided by pharmacists for prevention, treatment, and recovery services within the interprofessional care team and throughout the continuum of care; further,

To support pharmacists leading community-based comprehensive preventive health and treatment programs; further,

To encourage the inclusion of longitudinal SUD training in didactic pharmacy curricula, starting with an early initiation of education; use of evidence-based practices, including risk mitigation, harm reduction, and destigmatizing communication strategies; and increasing experiential education pertaining to SUD; further,

To support and foster standardized education and training on SUD, including dispelling common misconceptions to the pharmacy workforce and other healthcare professionals.

This policy supersedes ASHP policy 9711.

Rationale
Substance use disorder (SUD) is a public health crisis that has grown to epidemic levels in the United States over the past 30 years. The Department of Health and Human Services recognized

it as a public health emergency in 2017. In 2019, over 70,000 people died from drug overdoses, and between June 2019 and June 2020, overdoses of synthetic opioids caused over 48,000 deaths. Additionally, the Centers for Disease Control and Prevention (CDC) estimates that the economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement. The National Academy of Medicine and the Department of Health and Human Services identify several populations that are at risk for SUD, including justice-involved populations; those living in rural areas; people who inject drugs; pregnant patients; children born to SUD; and those with lower incomes, insecure housing, and lacking access to health insurance. Additionally, researchers have demonstrated links between the increase in opioid overdoses and the rate of opioid prescriptions, particularly in populations in which overdoses had not been seen before. Age-adjusted rates of opioid overdose deaths from 1990 to 2017 have increased sixfold among Whites, climbed from 3.5 to 6.8 overdoses per 100,000 people among Hispanics, and among Blacks has increased from 3.5 to 12.9 per 100,000 people in the U.S. The age-adjusted rate of overdose deaths increased by 31% from 2019 (21.6 per 100,000) to 2020 (28.3 per 100,000). When considering infectious diseases, SUD had also been cited as a cause for a tripling of hepatitis C cases from 2010 to 2017 as well as increases in hepatitis B, human immunodeficiency virus, bacterial, and fungal bloodstream infections, as well as sexually transmitted infections and endocarditis.

SUD is a chronic condition with associated neurological and physiological changes, not a personal choice. Dehumanizing language and stigmatization regarding SUD and people who use drugs (PWUD) create barriers to healthcare access and result in poor clinical outcomes. In addition, criminalization and policing practices related to SUD and PWUD have disproportionately harmful health impact on communities of color.

The best approach to managing SUD is a multifaceted one that requires involvement at the community, hospital and health system, legislative, government, and provider levels. Programs must also include stakeholders from these levels at the planning, implementation, and enduring service stages to optimize uptake, adoption, and sustainability. Pharmacists are an essential team member as part of interprofessional teams and providing comprehensive medication management (CMM) for patients with SUD. Pharmacists are integrated as key team members across the continuum of care from community pharmacies, health systems, and ambulatory care settings. Clear communication and coordination are also crucial so that successes and failures can be assessed, modified, or discontinued to suit the goals of prevention, treatment, harm reduction, and recovery.

Harm reduction strategies including syringe service programs have proven effective, not only in preventing deaths from injectable drug overdoses and infections but also as a site of care for providing such additional services as vaccinations, testing, referral to infectious disease care and substance use treatment, and access to and disposal of needles, syringes, and other injection equipment. Elimination of barriers to sterile syringe access, including discouraging prescription or logbook requirements and providing methods of syringe disposal, promotes access to healthcare.

Education and tools for the pharmacy workforce that assist in supporting the needs of PWUD and patients with SUD should also incorporate specifics about destigmatization, person-first language, harm reduction strategies, evidence-based practices, social determinants of

health, and ways to provide trauma-informed and culturally sensitive care to patients. Education should include efforts to recognize bias and misinformation, as these contribute to the stigma that serves as a major barrier in treating SUD.

2246
Autoverification of Medication Orders
Source: Council on Pharmacy Practice
To recognize the importance of pharmacist verification of medication orders, and the important role pharmacists have in developing and implementing systems for autoverification of select medication orders; further,

To recognize that autoverification of select medication orders under institution-guided criteria can help expand access to pharmacist patient care; further,

To discourage implementation of autoverification as a means to reduce pharmacist hours; further,

To promote and disseminate research, standards, and best practices on the safety and appropriateness of autoverification of medication orders; further,

To encourage healthcare organizations to develop policies, procedures, and guidelines to determine which care settings, medications, and patient populations are appropriate candidates for autoverification of select medication orders in order to support the implementation of autoverification models for those circumstances; further,

To advocate for regulations and accreditation standards that permit autoverification of select medication orders in circumstances in which it has proven safe.

Rationale
The purpose of autoverification of medication orders is to improve medication-use safety and quality and more efficiently and effectively utilize pharmacy personnel. When autoverification functionality is used, medications ordered via computerized provider order entry (CPOE) are evaluated against predetermined parameters in electronic health records (EHRs). Orders that fall within set parameters are autoverified and available to be administered; those that fall outside the parameters require review by a pharmacist. Critical values, patient history, and clinical decision support tools are used to create the algorithm that determines whether a medication order is reviewed. The healthcare community has long recognized the importance of pharmacist verification of medication orders, and that role is no less important when developing and implementing systems for autoverification of select medication orders. Recent experience has shown that autoverification of medication orders, when done safely and efficiently, can allow more effective use of pharmacist resources by expanding access to pharmacist patient care.

In the 2016 ASHP survey of health systems, 51.6% of hospitals utilized the autoverification functionality in the CPOE system; this rose to 62.2% utilization by the 2019

survey. Of the health systems surveyed in 2019 that utilized autoverification, 52.9% autoverified in selected areas (e.g., all emergency department orders, perioperative orders); 50.2% identified selected medications for autoverification in specific areas (e.g., pain medications in the emergency department); and 17.1% of hospitals had autoverification for select medications (e.g., flushes, influenza vaccine) throughout the hospital. Between 2016 and 2019, overall use of autoverification and autoverification of select medications throughout the hospital and for select medications in certain areas increased. In contrast, the use of autoverification for all medications in a select area of the hospital decreased from 2016 to 2019.

According to the ASHP survey, the most commonly cited reasons for not implementing autoverification were patient safety concerns (40.4%); "our hospital has not discussed this" (23.2%); and requirements by law, regulation, or accreditors (22.9%). Less common reasons were that EHR software does not have the functionality (6.9%) and EHR limitations on criteria used for autoverification (4.6%). Healthcare professionals have also expressed a concern about medication optimization: medication appropriateness may not be the same as medication optimization. Pharmacy directors have also stated that staffing determinations based on pharmacist workload and other measurable metrics must be carefully considered; autoverification should not be a mechanism for reducing pharmacist hours, which would negate the potential to expand patient care services.

2247

Pharmacy Workforce's Role in Vaccination

Source: Council on Pharmacy Practice

To affirm that the pharmacy workforce has a role in improving public health and increasing patient access to vaccinations by promoting and administering appropriate vaccinations to patients and employees in all settings; further,

To collaborate with key stakeholders to support the public health role of the pharmacy workforce in the administration of adult and pediatric vaccinations; further,

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

To advocate that states grant appropriately supervised pharmacy technicians the authority to prepare and administer all adult and pediatric vaccinations; further,

To advocate for the inclusion of pharmacist-provided vaccination training in college of pharmacy curricula and pharmacy technician-provided vaccination training in technician training programs; further,

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

To advocate that state and federal health authorities establish centralized databases for timely documentation of vaccine administrations that are interoperable and accessible to all healthcare providers; further,

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

To encourage the pharmacy workforce to educate all patients, their caregivers, parents, guardians, and healthcare providers to promote vaccine confidence and convey the importance of vaccinations for disease prevention; further,

To encourage the pharmacy workforce to seek opportunities for involvement in disease prevention through community vaccination programs; further,

To foster education, training, and the development of resources to assist the pharmacy workforce and other healthcare professionals in building vaccine confidence; further,

To advocate for adequate staffing, resources, and equipment for the pharmacy workforce to support vaccination efforts to ensure patient safety; further,

To advocate for appropriate reimbursement for vaccination services rendered; further,

To work with federal, state, and local governments and others to improve the vaccine development and supply system in order to ensure an adequate and equitably distributed supply of vaccines.

This policy supersedes ASHP policies 1309 and 2122.

Rationale

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

Although all states permit pharmacist administration of some vaccines, state laws differ in the range of vaccines pharmacists may administer and the patient populations they are permitted to vaccinate. During the COVID-19 public health emergency, new regulatory flexibility under the Public Readiness and Emergency Preparedness (PREP) Act allowed pharmacy technicians and pharmacy students, under the supervision of a licensed pharmacist, to administer COVID-19 and pediatric vaccinations. Permanently allowing trained and certified

pharmacists, including student pharmacists, to order and administer all adult and pediatric vaccines (e.g., by eliminating the requirement that some pharmacist-provided vaccinations be conducted within a collaborative drug therapy management agreement) would encourage standardization of pharmacy vaccination practice within and among states, as would permitting appropriately supervised pharmacy technicians to prepare and administer vaccinations. ASHP also advocates for appropriate reimbursement for all vaccination services.

Only pharmacists, student pharmacists, and pharmacy technicians who undergo appropriate training and certification should be authorized by state boards to provide vaccinations. To ensure their consistency and quality, those training and certification programs should meet Centers for Disease Control and Prevention standards.

To aid in sharing important patient vaccination information, centralized and interoperable databases of patient vaccinations should be established, and all authorized vaccination providers, including pharmacists, student pharmacists, and pharmacy technicians, should be required by law or regulation to document their vaccinations in those databases in a timely manner when they become available.

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

The pharmacy workforce has an integral role in promoting disease prevention and health equity by promoting vaccine confidence. The CDC defines vaccine confidence as "the trust that patients, their families, and providers have in recommended vaccines, the providers who administer vaccines, and the processes and policies that lead to vaccine development, licensure or authorization, manufacturing, and recommendations for use." Building vaccine confidence can involve helping patients, caregivers, healthcare providers, and members of the public overcome vaccine hesitancy, which is a delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines, and is influenced by factors such as complacency, convenience, and confidence. Vaccine-hesitant patients, healthcare providers, and caregivers have been found to be responsive to vaccine information, consider vaccination, and are not opposed to all vaccines, and therefore would benefit from counseling.

The pharmacy workforce, and in particular its leaders, also has an important role in working with federal, state, and local government, the pharmaceutical industry, and other stakeholders to improve the vaccine development and supply system to ensure a consistent and adequate supply of vaccines, and to ensure that vaccines supplies are equitably distributed to promote public health by reducing disparities in vaccine access.

2248

Health-System Use of Drug Products Provided by Outside Sources

Source: Council on Pharmacy Management

To support care models in which drug products are procured and/or prepared for administration by the pharmacy and are obtained from a licensed, verified source to ensure drug product and patient safety and continuity of care; further,

To encourage hospitals and health systems not to permit administration of drug products supplied to the hospital, clinic, or other healthcare setting by the patient, caregiver, or pharmacy contracted by a healthcare insurance payer or pharmacy benefit manager; further,

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of drug products; further,

To advocate that insurers and pharmacy benefit managers be prohibited from mandating drug-distribution models that introduce patient safety and supply chain risks or limit patient choice.

This policy supersedes ASHP policy 2032.

Rationale

Hospitals and health systems have a responsibility to confirm drug product integrity and pedigree to ensure safe and appropriate administration of drug products. Drug products supplied to a hospital or health system without an institution's direct oversight raise questions about the product's proper storage and pedigree. These drug products include patient home drug products, including clinician-administered pharmaceuticals (i.e., brown bagging) brought in by the patient or caregiver, and clinician-administered pharmaceuticals shipped from an external pharmacy directly to the location where they are being administered (i.e., white bagging). ASHP supports care models in which drug products are procured and/or prepared for administration by the pharmacy and are obtained from a licensed, verified source and encourages hospitals and health systems not to permit administration of drug products supplied by the patient, caregiver, or a pharmacy contracted by a healthcare insurance payer or pharmacy benefit manager.

Healthcare insurance and pharmacy benefit management (PBM) models should ensure fair reimbursement and payment for drug product preparation and administration and in the provision of direct patient care services for drug products supplied to patients. Due to patient safety and supply chain risks, hospitals and health systems should advocate for action from boards of pharmacy to directly address payer-mandated drug-distribution models and encourage state policymakers to prohibit insurers and PBMs from mandating white and brown bagging, including prohibiting insurers and PBMs from steering patients away from hospitals and health systems that refuse to accept potentially dangerous white-bagged or brown-bagged drug products.

2249

Screening for Social Determinants of Health

Source: Council on Pharmacy Management

To encourage social determinants of health (SDoH) screening and data collection using standardized codes during the provision of pharmacy patient care services; further,

To promote the integration of SDoH data into the design and delivery of clinical pharmacy services, including the creation of targeted interventions and leveraging the use of clinical decision support to improve patient outcomes; further,

To encourage the use of SDoH data in reporting and evaluating the effectiveness of pharmacist patient care; further,

To encourage the use of SDoH data to identify opportunities to reduce healthcare disparities and improve healthcare access and equity; further,

To educate the pharmacy workforce and learners about SDoH principles, including their impact on patient care delivery and health outcomes; further,

To advocate for the funding of community resources related to improving patient access to medications, and the integration of these resources into health-system care delivery models; further,

To encourage research to identify methods, use, and evaluation of SDoH data to positively influence key quality measures and patient outcomes.

Rationale

Social determinants of health (SDoH) are defined by the Centers for Disease Control and Prevention (CDC) as the "conditions in the environments where people are born, live, learn, work, play, worship and age." These conditions can have a significant impact on healthcare outcomes, health equity, and the quality of life for individuals and communities. SDoH have been found to account for 80-90% of modifiable contributors to health outcomes. The CDC recognizes five distinct SDoH domains: Economic Stability, Education Access and Quality, Healthcare Access and Quality, Neighborhood and Built Environment, and Social and Community Context. From a third-party payer perspective, the recent shift of many organizations from fee-for-service to value-based reimbursement models places more emphasis on SDoH, screening, and evidence-based decision making to prioritize long-term health outcomes. Healthy People 2030, a national program developed by the Office of Disease Prevention and Health Promotion within the U.S. Department of Health and Human Services, includes 355 measurable, data-driven, national objectives to improve the health and well-being of the American public by the year 2030. Efforts to address SDoH through pharmacy practice have varied. A 2018 survey of postgraduate pharmacy residents and their program directors found that only 1% of residents and 4% of residency program directors stated they had received training on Healthy People 2020. (Chandra RN. Pharmacists' knowledge of social determinants of health in post-graduate pharmacy residency programs. Wright State University; Dayton, OH; 2018.)

The pharmacy workforce has opportunities to advance the use of SDoH in clinical practice (e.g., consults, medication reconciliation, patient assistance programs) to improve health outcomes. Patient screenings and data collection to ascertain SDoH should use standardized codes (e.g., ICD-10-CM Z codes, SNOMED-CT value sets) that are consistent, discrete data elements that are reportable and can be shared with other technologies, leading to actionable intelligence to enhance quality improvement initiatives. To support this goal, there is a need for broader implementation of SDoH health information technology (IT) tools into general practice and development of policies for how to appropriately use SDoH in clinical decision-making. The Office of the National Coordinator for Health Information Technology has

identified four priority areas for advancing interoperability and use of SDoH data: standards and data, infrastructure, policy, and implementation. The 2020-2025 Federal Health IT Strategic plan includes strategies such as increasing standardization of SDoH data, integrating all captured SDoH data into electronic health records, strengthening health IT infrastructure through secure exchange of data and interprofessional collaboration, and leveraging data to improve related health outcomes. Many health IT and electronic health record (EHR) vendors have invested significant resources in development of SDoH tools and products. Among these products are screening tools, population health metrics, referral and care transition tools, and analytic and reporting tools. Most vendors use the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) framework, which is a standardized patient risk assessment tool as well as a repository of resources to act on SDoH data. Vendors develop screening tools that are largely customizable to the needs of each customer organization or health system. In many situations, there is a need for patients to be referred to community-based organizations or external programs to address SDoH during transitions of care. Health systems must have access to appropriate technology-based platforms to exchange SDoH data and make referrals for patients at discharge or transfer to another institution. Lack of standardization of data and reporting across health systems makes sharing of best practices and metric goal-setting difficult. Additional tools available within some EHR platforms include those measuring quality of life, suicidal ideation rating, community service referral capabilities, and use of secondary survey data in conjunction with the CDC social vulnerability index to further evaluate population health at a community level. SDoH tools can be categorized as either single domain, such as the Hunger Vital Sign tool to evaluate food insecurity, or multiple domain, such as the WE CARE survey to evaluate education, employment/income, food insecurity, and housing/utility domains. The validity of each tool should be considered before implementing into practice. The Pharmacy Quality Alliance (PQA) has developed a Medication Access Framework for Quality Measurement and is evaluating a pharmacy measure concept to address the social determinants of health that hinder patient medication access and contribute to poor health outcomes.

2250

Access to Reproductive Health Services

Source: House of Delegates

To recognize that reproductive healthcare includes access to and safe use of medications; further,

To recognize that reproductive health services include pre-conception, conception, post-conception, and termination of pregnancies; further,

To advocate for access to safe, comprehensive reproductive healthcare for all patients, including historically underserved patient groups such as patients of color, those with limited means, and those living in rural areas; further,

To affirm that healthcare workers should be able to provide reproductive healthcare per their clinical judgment and their conscience without fear of legal consequence, workplace sanctions, social stigmatization, harassment, or harm.

Rationale

Reproductive health has been defined as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes," and reproductive healthcare has been defined as "the constellation of methods, techniques and services that contribute to reproductive health and well-being by preventing and solving reproductive health problems." (International Conference on Population and Development Programme of Action, Twentieth Anniversary Edition, United Nations Population Fund, Sep 2014). In the U.S., the term "reproductive health services" is defined in 18 USC § 248(e)(5) as "medical, surgical, counselling or referral services relating to the human reproductive system, including services relating to pregnancy or the termination of a pregnancy." Reproductive health services include pre-conception, conception, post-conception care, including termination of pregnancies, and reproductive healthcare includes access to and safe use of medications.

ASHP advocates for access to safe, comprehensive reproductive healthcare for all patients, including historically underserved patient groups. Studies show that there have been longstanding disparities in access to and outcomes from reproductive health services in the U.S., especially for racial and ethnic minorities. For example, black women have the highest maternal morbidity and mortality rates in the country. These disparities include contraceptive use, reproductive cancers, preterm deliveries, and maternal morbidity and mortality. (Sutton MY, Anachebe NF, Lee R et al. Racial and ethnic disparities in reproductive health services and outcomes, 2020. *Obstet Gynecol.* 2021; 137:225–33.)

On June 24, 2022, the Supreme Court of the United States overturned *Roe v. Wade*, freeing states to restrict or outlaw abortion. Thirteen states had implemented trigger laws that would outlaw abortion almost immediately, and 26 states were expected to ban or severely restrict access to abortion. These state laws are likely to impact patient access to necessary treatments, including medications, and the practice of pharmacy, in the following ways:

- *Access to necessary treatments:* Pharmacists are involved in treating patients with ectopic pregnancy or pregnant patients with cancer diagnoses. These laws could limit patient access to lifesaving treatments because of the risk of legal liability for providers. Pharmacists have a role in providing medications for these treatments as well as supporting patients' mental health and well-being related to reproductive health.
- *Access to medications:* A number of companies have formed that provide telehealth access to medications used to induce abortion. There are likely to be challenges to interstate mail order of these medications. In addition, some overseas companies also provide these medications, which raises questions about foreign importation of medications. ASHP opposes wholesale importation of medications from other countries due to supply chain security concerns but does not object to patients ordering from legitimate foreign pharmacies for their personal needs. Further, medications (e.g., misoprostol) that are used off-label as abortifacients but have other clinical uses may become harder for patients to access because providers fear the legal liability for

prescribing or dispensing these medications. Finally, access to medications is a national security issue. For examples, the Department of Defense is required by law to make contraceptive services available to all female active-duty servicemembers.

- *Clinician judgment:* Restrictions on medication abortion function as limitations on clinicians' professional judgment. As noted above, because some medications can be used off-label as abortifacients, it is possible that there will be increased scrutiny of the prescribing and dispensing of certain medications. Further, some states are pursuing laws that would allow citizens a private right of action against a clinician who assists in an abortion (i.e., "bounty laws"). These laws could create civil and/or criminal liability against clinicians who prescribe or dispense abortion medications.

In addition to these concerns, other procedures that are not abortion but might result in destruction of an embryo (e.g., in vitro fertilization therapy) could fall into an uncertain legal zone. Medications used to induce labor to protect a pregnant patient could be restricted. Because the decision in *Roe v. Wade* was based on a constitutional right to privacy, other privacy-related rulings are now in question, including *Griswold v. Connecticut*, which allowed access to contraception.

The decision to terminate a pregnancy is a complicated, difficult, and often extremely emotional choice for patients and healthcare providers, and it often involves weighing the risks to the pregnant patient. Under some state laws, pregnant patients could be prosecuted for seeking lifesaving treatment, and healthcare providers involved in these difficult decisions and providing necessary treatments could be subject to unjust criminal prosecution. ASHP believes that healthcare workers should be able to provide reproductive healthcare per their clinical judgment and their conscience without fear of legal consequence, workplace sanctions, social stigmatization, harassment, or harm.