

House of Delegates

Policies Approved by the 2021 ASHP House of Delegates

2101

DIRECT-TO-CONSUMER CLINICAL GENETIC TESTS

Source: Council on Therapeutics

To support research to validate and standardize genetic markers used in direct-to-consumer clinical genetic tests and guide the application of test results to clinical practice; further,

To encourage the Food and Drug Administration (FDA) to continue to regulate direct-to-consumer clinical genetic tests as medical devices and work with the National Institutes of Health to evaluate and approve direct-to-consumer clinical genetic tests; further,

To advocate that direct-to-consumer clinical genetic tests be provided to consumers through the services of appropriate healthcare professionals who order tests from laboratories certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA); further,

To support FDA policies and procedures regarding advertising of direct-to-consumer clinical genetic tests, including the following requirements: (1) the relationship between the genetic marker and the disease or condition being assessed is clearly presented, (2) the benefits and risks of testing are discussed, and (3) such advertising is provided in an understandable format, at a level of health literacy that allows the intended audience to make informed decisions, and includes a description of the established patient-healthcare provider relationship as a critical source for information about the test and interpretation of test results; further,

To encourage health systems to create policies and procedures addressing direct-to-consumer genetic testing results as it relates to confirmatory testing, integration of genomic information into the healthcare record, genetic counseling, and clinical decision-making; further,

To encourage pharmacists to educate consumers and clinicians on the potential risks and benefits of direct-to-consumer clinical genetic tests for disease diagnosis and decisions involving drug therapy management.

This policy supersedes ASHP policy 1103.

Rationale

Since 2018, the FDA has implemented multiple processes, procedures, and guidance documents surrounding in vitro diagnostics (IVDs), also referred to as direct-to-consumer (DTC) testing. The FDA now reviews DTC tests for moderate- to high-risk medical purposes, to determine the validity of the test claims. The FDA review consists of assessing for analytical validity, clinical validity, and claims made by the company marketing the test about how well it works. Additionally, the FDA reviews descriptive information about the test for accuracy and for an appropriate level of health literacy.

The FDA now regulates DTC tests as medical devices. The specific regulatory requirements depend on the risk classification of the individual IVD. The FDA has been proactive about streamlining the regulation of DTC tests, as well as determining appropriate for use by a consumer without the involvement of a healthcare provider.

In October 2018 and April 2019, the FDA issued a safety communication to alert the public to concerns regarding pharmacogenetic tests with unapproved claims to predict an individual's response to a specific therapeutic drug, where these claims may not be supported by clinical evidence. Warning letters were sent by the FDA to select companies. Patients and providers were advised the FDA has not evaluated genetic tests, which make claims regarding the effects of a specific medication.

As consumer use of DTC testing continues to be prevalent, it is critical healthcare systems develop policies and best practices related to the utilization of data patients may present to their healthcare teams. Providers should be aware for most medications the relationship between genetic variations and a medication's effects has not been established. If a patient provides a test report from a genetic DTC test claiming to predict a person's response to a specific medication, the healthcare team should seek information in the FDA-approved drug label regarding whether genetic information should be used for determining therapeutic treatment. Confirmatory testing should be ordered by the healthcare team from a CLIA-certified laboratory.

2102

USE OF ANTIMICROBIALS IN SURGICAL WOUNDS AND PROCEDURES

Source: Council on Therapeutics

To oppose the use of antimicrobial agents in surgical wounds and procedures not based on evidence; further,

To encourage further research to assess the efficacy, safety, and risks of resistance development of antimicrobials used in surgical wounds and procedures; further,

To foster evidence-based recommendations on the use of antimicrobial agents in surgical wounds and procedures and on how to prepare those agents according to appropriate sterile practices; further,

To advocate that antimicrobial stewardship programs review and monitor the use of antimicrobial agents in surgical wounds and procedures; further,

To encourage pharmacists to educate prescribers on adverse outcomes and reactions

associated with the use of antimicrobials in surgical wounds and procedures; further,

To support clear and consistent documentation of antimicrobial agents used for surgical wounds and procedures in the electronic health record.

Rationale

The addition of antimicrobials to irrigation solutions during surgical procedures in an effort to prevent surgical site infections has been a long-standing surgical practice. Antibiotics are the most common additives to surgical irrigation fluids, but recent data has shown no clinical benefit compared with saline irrigation, likely due to the mechanism of antibiotics needing a longer exposure time than is allowed during irrigation. Further, the use of topical antibiotics in the open surgical wound is often not monitored and has not been subject to any evidence-based standardization of care. When mixing practices were surveyed across hospitals and health systems, most respondents from facilities in which the solutions were mixed in the operating room (OR) were unaware of who was doing the mixing; of those who were aware, surgical scrub technicians or OR nurses were the individuals most often reported to be doing the mixing.

The results of numerous surveys of surgeons has indicated that the practice of using topical antibiotics intraoperatively, in both irrigation fluids and powders, is widespread. This practice stemmed from the belief that applying antibiotics locally would minimize toxicity and resistance. However, newer data suggest that there is a potential for toxicities and systemic exposure leading to resistance associated with these practices. Because of this, the Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, Surgical Infection Society, American Society of Health-System Pharmacists, World Health Organization, American College of Surgeons, and the International Consensus on Orthopedic Infections all recommend against the use of topical antimicrobial irrigation. Despite these recommendations, this practice is still prevalent throughout hospitals and health systems. Complicating the picture is that neither the Joint Commission nor the Centers for Medicare and Medicaid Services have addressed the use of topical antibiotics.

Due to the risks of topical use and the lack of evidence supporting it, this practice should be an essential part of antimicrobial stewardship programs. All antibiotics sent from pharmacy to the OR, including those intended for topical use, should be documented clearly in the electronic health record, including type and amount used, and should be part of comprehensive surveillance for patient outcomes for surgical site infections, allergic reactions, resistance trends, management of shortages, and toxicity adverse events related to topical surgical administration of antibiotics.

2103

PROFESSIONAL DEVELOPMENT AS A RETENTION TOOL

Source: Council on Education and Workforce Development

To recognize that pharmacy workforce development is an essential component of staff recruitment, retention, and well-being; further,

To recognize that pharmacy workforce development encompasses more than formal

education programs and includes informal learning among colleagues, mentoring, participation in activities of professional organizations, and other types of learning; further,

To encourage healthcare executives to support pharmacy workforce development programs, including leadership succession planning, as an important benefit that aids in recruiting and retaining qualified staff; further,

To support healthcare executives with pharmacy workforce development by providing educational programs, services, and resources.

This policy supersedes ASHP policy 0112.

Rationale

Workforce development can take many forms, including formal education, informal mentoring, participation in certification programs, career ladder implementation, and expanded experiences. The need for job growth and career advancement is an important motivator for job satisfaction among those entering the workforce, such as student pharmacists and residents. Evidence suggests that staff development programs are associated with increased pharmacist retention. There is also a growing need to provide education on topics, such as clinical management, that are not taught in education and training programs and nurture the workforce to provide continuous succession planning.

2104

FOSTERING LEADERSHIP DEVELOPMENT

Source: Council on Education and Workforce Development

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

To encourage leaders to seek out and mentor members of the pharmacy workforce in developing administrative, managerial, and leadership skills; further,

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

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

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

To foster leadership skills for members of the pharmacy workforce, including skills for pharmacists to use on a daily basis in their roles as leaders in patient care.

This policy supersedes ASHP policy 1611.

Rationale

In their 2013 report, *Is there still a pharmacy leadership crisis?* A seven-year follow-up assessment (*Am J Health-Syst Pharm.* 2013; 70:443–7), White and Enright anticipated a high rate in turnover of pharmacy directors and middle managers over the coming decade. Healthcare organizations must address this ongoing challenge if there are to be a sufficient number of new directors and managers to fill those positions. Factors that may contribute to a shortage of potential new leaders and managers include:

- New graduates frequently accept clinical positions or positions in drug distribution. After a few years, they may have a desire to assume managerial positions in health-system pharmacies, but training programs may not be convenient for them, and they may not have the resources to obtain training.
- Health-system pharmacy management positions do not turnover often. Prospective managers view those positions as unavailable for the near future, so there is little incentive to obtain training to be ready to move into those positions.
- Job satisfaction among pharmacy managers appears low to prospective managers.
- Frequent turnover in organizational administrative positions (above pharmacy) is frustrating to pharmacy directors, because they continually need to inform new administrators about the organization's medication-use strengths and weaknesses and the pharmacy department's roles, strategic plans, and priorities for sustaining quality and making improvements. In those turnover circumstances, diligently achieved pharmacy service improvements can sometimes be eroded and reversed. The ensuing frustration can induce pharmacy directors to depart voluntarily from management positions and make those positions unattractive to others.
- Flattening of organizational structures in healthcare organizations has eliminated numerous managerial positions in pharmacies, leaving fewer pharmacists to serve as mentors for prospective managers. Without positive role models, it is difficult for pharmacists to gain good management experience.
- Pharmacy management positions that combine clinical and management responsibilities sometimes allow little time for clinical work.
- Many pharmacists, even those in managerial positions, have no training in personnel administration. Skills such as conflict resolution and negotiation are rarely taught in pharmacy curricula but are very important in leadership positions.
- In some healthcare organizations, managers receive raises predicated on overall organizational or departmental performance. However, the compensation of some staff may be based on individual performance. These differing bases can lead to instances in which the compensation of those supervised is higher than that of their managers. When that occurs, it can be a disincentive to individuals considering management positions.

Leadership and managerial potential in today's student pharmacists, pharmacy technicians, and new graduates is as high as it has ever been, but more effort is needed to nurture that potential

and develop leadership and management skills in practice. Colleges of pharmacy, state associations, residency programs, pharmacy technician training programs, and practitioners themselves need to foster the development of leadership and management skills. ASHP can help foster leadership competencies at all levels of practice through actions such as providing education about leadership and management roles, developing web-based resources, and facilitating networking among leaders, managers, and those aspiring to such roles.

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

2105

INTERPROFESSIONAL EDUCATION AND TRAINING

Source: Council on Education and Workforce Development

To advocate for interprofessional education as a component of didactic and experiential education in pharmacy workforce education and training programs; further,

To support interprofessional education, mentorship, and professional development for healthcare professionals and learners; further,

To urge collaboration with other healthcare professionals and executives in the development of education and training models for interprofessional, team-based, patient-centered care; further,

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

This policy supersedes ASHP policy 1612.

Rationale

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

The Hospital Care Collaborative (HCC) has described common principles for team-based care. The HCC principles recognize the knowledge, talent, and professionalism of all team members and support role delineation, collaboration, communication, and the accountability of

individual team members and the entire team. The HCC principles note that collaboration of the healthcare team can lead to improved systems and processes that provide care more efficiently and result in better patient outcomes. The HCC states that current undergraduate and postgraduate professional education of team members is inadequate to promote true team functions.

ASHP believes that interprofessional education is important not only for student pharmacists but also throughout one's professional career. Similarly, it is important for other professionals on the team so that collaboration and synergistic relationships can develop. Failure to establish these collaborative working relationships early in one's career can result in poor interactions in years to come. A positive working relationship, including interprofessional mentorship, with physicians and nurses is productive, while a bad working relationship can be counterproductive and devastating to all parties, including patients.

2106

PHARMACY EDUCATION AND TRAINING MODELS

Source: Council on Education and Workforce Development

To promote pharmacy education and training models that: (1) provide experiential and residency training in interprofessional patient care; (2) use the knowledge, skills, and abilities of students and residents in providing direct patient care; and (3) promote use of innovative and contemporary learning models; further,

To encourage the collaboration between colleges of pharmacy and residency programs with accreditation agencies on innovative education and training models; further,

To support the assessment and dissemination of the impact of these pharmacy education and training models on the quality of learner experiences and patient care outcomes.

This policy supersedes ASHP policy 1829.

Rationale

Pharmacy training models are continuously evolving. The ideal training model includes characteristics such as flexibility to be useful in all patient care settings, providing patient care through an interprofessional team, and allowing team members to practice at the top of their licenses. Many healthcare organizations are successfully employing innovative and contemporary training models. One such model is the layered learning approach to residency and student pharmacist training, in which a pharmacist oversees multiple residents, student pharmacists, and sometimes generalist pharmacists. Each member of this pharmacy team is integrated into a patient care team, with specific roles and responsibilities, but each also has accountability to the supervising pharmacist. The layered learning model may be more practical in larger institutions, however, because they have more staff, residents, and student pharmacists than smaller hospitals. ASHP recognizes that it is important to individualize the training program to the practice site and its corresponding practice model, and supports the assessment of the impact of these pharmacy training models on the quality of learner experiences and patient care outcomes.

2107**PHARMACY INTERNSHIPS**

Source: Council on Education and Workforce Development

To encourage state boards of pharmacy to adopt the standardized pharmacy internship hour requirements recommended in the National Association of Board of Pharmacy Model Rules for Pharmacy Interns; further,

To support structured requirements, goals, and objectives for pharmacy internship experiences, in alignment with requirements for introductory and advanced pharmacy practice experiences; further,

To promote new staffing models that offer expanded roles for pharmacy interns, providing work experiences that build upon their knowledge and help them develop as future pharmacists.

This policy supersedes ASHP policy 1110.

Rationale

State boards of pharmacy vary with respect to the pharmacy internship requirement. Some state boards of pharmacy allow internship hour requirements to be completed as part of the pharmacy curriculum. Other state boards of pharmacy require students to complete internship hours outside of the pharmacy curriculum.

Inconsistencies in internship requirements among states have had significant implications for pharmacy residents. Pharmacy graduates from a state with minimal internship requirements may relocate to a state post-graduation for employment with stringent internship requirements, sometimes delaying their eligibility for licensure until they can complete internship requirements. Greater standardization would prevent these issues as new graduates relocate to other states.

The National Association of Boards of Pharmacy Model Rules for Pharmacy Interns requirements coincide with the ACPE Accreditation Standards and Guidelines. In the rule, boards of pharmacy are strongly encouraged to utilize these Accreditation Standards and Guidelines as a basis for the establishment and revision of board standards for pharmacy practice experiences.

2108**PATIENT EXPERIENCE**

Source: Council on Pharmacy Management

To encourage the pharmacy workforce to evaluate their practice settings for opportunities to improve the experience patients have with healthcare services and with the outcomes of their drug therapy; further,

To educate the pharmacy workforce about the relationship between patient experience and outcomes; further,

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

To promote use of interactive patient technology (e.g., self-learning teaching resources) to augment patient experience and help prioritize and improve the effectiveness of pharmacy services; further,

To facilitate a dialogue with and encourage education of patient experience database vendors to include the value of pharmacy services in the patient experience.

This policy supersedes ASHP policy 1616.

Rationale

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

A study detailed in a white paper by The Beryl Institute found that hospitals using interactive technology to communicate with patients saw improvement in patient satisfaction scores. Interactive patient technology gives patients faster access to hospital staff and services, including access to health education information about the care they receive and the steps they need to take after discharge. Hospitals using interactive technology realize tangible benefits, which translate into significant, measureable improvements in patient outcomes, the hospital’s financial performance, and greater patient engagement, making for an exceptional patient experience.

2109

PHARMACY SERVICES FOR UNINSURED AND UNDERINSURED PATIENTS

Source: Council on Pharmacy Management

To support the principle that all patients have the right to receive care from pharmacists; further,

To declare that pharmacists should play a leadership role in ensuring access to pharmacists' services for indigent or low-income patients who lack insurance coverage or are underinsured; further,

To encourage the pharmacy workforce to work with organizational patient assistance,

case management, and care coordination teams to ensure seamless patient care transitions for all patients, including uninsured and underinsured patients; further,

To advocate better collaboration among health systems, community health centers, state and county health departments, and the federal Health Resources and Services Administration in identifying and addressing the needs of indigent and low-income patients who lack insurance coverage or are underinsured.

This policy supersedes ASHP policy 0101.

Rationale

Consistent with ASHP Practice Advancement Initiative 2030 themes for change, patients must have access to: 1) a pharmacist in all settings of care; 2) a collaborative, interprofessional care team that coordinates seamless, convenient, and cost-effective care transitions; and 3) a collaborative, interprofessional care team that identifies, assesses, and resolves barriers to medication access, adherence, and health literacy. These principles apply even for patients who lack insurance coverage or are underinsured. Pharmacists and pharmacy technicians should take leadership roles in ensuring access to pharmacists' services for these patients, working with organizational patient assistance, case management, and care coordination teams to ensure seamless patient care transitions for this vulnerable population. Further, community health centers, state and county health departments, and the federal Health Resources and Services Administration should collaborate in identifying and addressing the needs of these patients.

2110

PATIENT ACCESS TO PHARMACY SERVICES IN SMALL AND RURAL HOSPITALS

Source: Council on Pharmacy Practice

To advocate that critical-access hospitals (CAHs) and small and rural hospitals meet national medication management and patient safety standards, regardless of size or location; further,

To provide resources and tools to assist pharmacists who provide services to CAHs and small and rural hospitals in meeting standards related to safe medication use; further,

To promote allocation policies that address the unique challenges faced by CAHs and small and rural hospital pharmacies in procuring medications and supplies.

This policy supersedes ASHP policy 1022.

Rationale

State legislation has sometimes exempted small or rural hospitals from requirements applied to others. For example, Texas has exempted hospitals with fifty or fewer beds in remote locations from requiring prospective medication order review by a pharmacist. Pharmacist prospective order review is a well-supported safety practice that is required by the Centers for Medicare &

Medicaid Services Conditions of Participation, Joint Commission accreditation standards for hospitals, and in state practice acts. ASHP policy supports pharmacist prospective order review as a minimum standard for pharmacies in hospitals and a consistent standard of care for all patients regardless of where that care is provided. Furthermore, ASHP encourages under-resourced facilities, including rural settings, to employ alternative strategies, such as expanded use of telehealth and pharmacy technicians, to meet the challenges they face. In addition, ASHP recognizes that one of the challenges faced by these hospital is industry allocation practices (e.g, allocations based on previous purchases) and restrictive distribution criteria (e.g., requiring specific facilities, equipment, or staff) that reduce access to medications and other resources in times of critical need. ASHP advocates that those allocation practices be made more flexible to meet patient needs, especially in times of crisis.

2111

PHARMACIST INVOLVEMENT IN THE STRATEGIC NATIONAL STOCKPILE

Source: Council on Public Policy

To advocate for the inclusion of pharmacist expertise in the development and maintenance of the Strategic National Stockpile (SNS); further,

To advocate for transparency and improvement of SNS processes, including standardization of the request process and enhanced periodic review of SNS contents; further,

To advocate that pharmacists lead distribution of medications and related supplies requested from the SNS.

Rationale

The depletion of the Strategic National Stockpile (SNS) during the COVID-19 pandemic presents an opportunity to significantly improve SNS operations. Pharmacists should be engaged in determining which medications and supplies are included in the SNS, as well as how to maintain quality and ensure the stock remains up to date.

At the outset of the pandemic, hospitals and health systems struggled to make requests to the SNS for both medications and supplies. Because there was not a clear mechanism for making requests, with the process varying among states, even sharing tips and best practices between providers was not always helpful. The SNS should increase transparency regarding stock and should implement a single consistent process for making requests. Providers should not have to devote huge amounts of time to making SNS requests in the midst of an emergency – and there should be a mechanism for quickly checking on the status of SNS requests to avoid additional wasted time.

Finally, to streamline processes, the SNS should have a standard distribution logistics process for medications and related supplies centered on pharmacists. Ensuring that pharmacists receive distributions of medications and related supplies will allow them time to prepare storage space (e.g., freezer space for remdesivir) and ensure proper storage and handling of products.

2112**MEDICATION PRICE-GOUGING LAWS**

Source: Council on Public Policy

To advocate for price-gouging laws that include medications.

This policy supersedes ASHP policy 1622.

Rationale

Price gouging, whether due to shortages or other causes, can result in trafficking in counterfeit and diverted products through gray-market distributors, which can ultimately result in adverse patient outcomes and increased healthcare costs. Strategies, including specific legislation with stiff penalties for price gouging on medications, are needed to deter these activities. Thirty-one states currently have price-gouging laws that prohibit price markups on life-sustaining products (e.g., food, water, fuel), usually during a time of disaster, natural or otherwise. ASHP advocates for laws that specifically address price gouging on medications at any time, rather than predating action on a triggering event, such as a disaster or shortage.

2113**PHARMACOGENOMICS**

Source: Council on Therapeutics

To advocate that pharmacists take a leadership role in pharmacogenomics-related patient testing, based on current or anticipated medication therapy; further,

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage health systems to support an interprofessional effort to implement appropriate pharmacogenomics services and to determine appropriate dissemination of actionable genetic information to appropriate healthcare providers for review; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To advocate that all health insurance policies provide coverage for pharmacogenomic testing to optimize patient care; further,

To encourage pharmacy workforce education on the use of pharmacogenomics and its application to therapeutic decision-making.

This policy supersedes ASHP policy 1104.

Rationale

Clinical pharmacogenomics is the practice of using genetic information to guide optimal drug selection and drug dosing for patients to maximize therapeutic effects, improve outcomes, and minimize toxicity. Currently, pharmacogenomic testing is used for specific drug-gene pairs in patients currently taking a medication associated with gene or prior to initiating therapy. Pharmacists are especially prepared to take a leadership role in selecting appropriate tests as they have an understanding of pharmacokinetic and pharmacodynamics properties of drugs in specific diseases and patient populations.

Over the past 10 years, the Clinical Pharmacogenetics Implementation Consortium (CPIC) has published over 23 guidelines that cover 19 genes and 46 drugs across several therapeutic areas as well as resources to facilitate the implementation of pharmacogenomics into routine clinical practice and the electronic health record. These guidelines include indications for which drugs and genes are most likely to be clinically useful based on current evidence. However, barriers such as prioritizing testing, interpretation for actionable results, incorporation of genomic data into the electronic health record, and reimbursement remain. Furthermore, there is also the challenge of how to ensure that the results of pharmacogenomic tests stay with the patient throughout their health journey. Implementation of pharmacogenomic testing has the potential to improve patient care by decreasing failed treatment attempts due to medication ineffectiveness or adverse effects and by increasing effectiveness of improperly dosed medications.

With the advent of widely available pharmacogenomic tests, many are also marketed to the public, which introduces another layer of complexity. The Food and Drug Administration (FDA) has alerted patients and healthcare providers that claims for many genetic tests to predict a patient's response to specific medications have not been reviewed by the FDA and may not have the scientific or clinical evidence to support their use. Changing drug treatment based on the results from such a test could lead to inappropriate treatment decisions and potentially serious health consequences for the patient.

Another barrier that many providers and patients encounter is insurance coverage of pharmacogenomic testing. A 2019 *JAPhA* article found that coverage and payments of pharmacogenomics varied by the company and gene-drug pairs and remain suboptimal. The article found that, of gene-drug indication group (GDIG), 50% were mentioned in policies but were covered less than 20% of the time. When mentioned in a policy, 7 GDIGs were uniformly covered, and 11 GDIGs were uniformly not covered. Overall, insurance companies covered approximately 40% of GDIGs mentioned in their policies.

Furthermore, the [ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics](#) states that pharmacogenomics has an essential place in pharmacy education because pharmacists should be educated to be able to recommend pharmacogenomic testing for drug and dosage selection; design patient-specific drug and dose regimens based on the patient's pharmacogenomic profile and other pertinent information; educate patients, pharmacists, and other healthcare professionals about pharmacogenomic principles and appropriate indications for clinical pharmacogenomic testing; and communicate pharmacogenomic-specific drug therapy recommendations to the healthcare team.

2114**FDA REQUIREMENT FOR DOSE-RESPONSE INFORMATION**

Source: Council on Therapeutics

To advocate that the Food and Drug Administration require drug product manufacturers to (1) identify average dose-response curves for desirable and undesirable effects, and make this information available to healthcare providers; and (2) publish dose-response information, to the extent possible, on factors that lead to differences in pharmacokinetics and pharmacodynamics among individuals; further,

To encourage drug product manufacturers to conduct studies on and publicly report minimum effective dose data.

This policy supersedes ASHP policy 0602.

Rationale

Knowledge of the relationships among dose, drug concentration in blood, and clinical response (effectiveness and undesirable effects) is important for the safe and effective use of drugs. This information can help identify an appropriate starting dose, titration of dosing, and identification of doses that would produce unacceptable side effects or be unlikely to provide added benefit. Important to this understanding is the analysis of the dose-response relationship, particularly with drug levels above the ED50, the dose that provides approximately 50% of the maximum possible drug effect, as efficacy increases only slightly, while adverse effects increase.

Manufacturer dose-finding studies sometimes provide a dose estimate and the range of a drug's population ED50, but this information appears to have little bearing on prescribing. Many are either not aware of this measurement or do not consult the information after the drug is marketed with recommended dosage guidelines. Often overlooked is the variation in individual ED50 depending on body size, pharmacokinetics, and pharmacodynamics. This variation in ED50 may cause the effective dose to be lower in many patients compared with participants in clinical trials. It is important to note that the ED50 also can alert a clinician to the likely useful and safe dose range and should be more widely available. ED50 should be an important variable in drug approval, marketing, and, most importantly, prescribing. Furthermore, numerous observational studies have shown that providers often prescribe increasingly higher levels of treatment, often without clear clinical indication for such high doses. As such, the FDA recommends that dose-response assessment should be an integral part of drug development, including minimum effective doses.

2115**MEDICAL CANNABIS**

Source: Council on Therapeutics

To recognize that there is limited evidence to support safe and effective use of medical cannabis; further,

To encourage research that quantifies the therapeutically active components and defines the effectiveness, safety, and clinical uses of medical cannabis; further,

To recognize that there is not a standardized product subject to the same regulations as a prescription drug product, and to advocate for the development of processes that would ensure standardized formulations that would ensure consistent potency and quality of medical cannabis; further,

To advocate for the alignment of federal and state laws to eliminate barriers to research on and therapeutic use of medical cannabis, including review of medical cannabis's status as a Schedule I controlled substance, and its potential for reclassification; further,

To encourage healthcare organizations to develop policies and procedures regarding the handling of medical cannabis consistent with applicable laws, regulations, and accreditation standards; further,

To promote the documentation of medical cannabis use and indication in the electronic health record; further,

To encourage education that prepares pharmacists as part of an interprofessional team to educate patients, caregivers, healthcare providers, and healthcare administrators about therapeutic and legal aspects of medical cannabis use.

This policy supersedes ASHP policy 1101.

Rationale

To date, 33 states and the District of Columbia, Guam, and Puerto Rico have enacted workable medical cannabis laws that provide, or will provide, meaningful access to medical cannabis for qualifying patients. Healthcare providers in those jurisdictions, including pharmacists, are grappling with the challenges presented by medical use of medical cannabis (defined for purposes of this policy as whole or parts of the natural marijuana plant and therapeutic products derived therefrom). ASHP recognizes that there is some evidence supporting the effectiveness of medical cannabis to treat or ameliorate symptoms of disease. The extent and quality of this evidence is limited, however, and even less is known about the safety of medical cannabis, especially related to its long-term use. Well-designed research is necessary to further define the therapeutic uses of medical cannabis, including determination of its therapeutically active components; clinical indications and contraindications; precautions; dosing; routes of administration; adverse effects; drug-drug, drug-disease, and drug-laboratory interactions; and effectiveness compared to existing therapies.

Current inconsistencies in product formulation, potency, and quality are also a hindrance to developing a strong evidence base. Standardizing these factors, to the extent possible, will help ensure the quality and reliability of research results. ASHP encourages efforts by the United States Pharmacopeia to develop quality standards for medical cannabis. Federal legislation and regulation, including marijuana's classification as a Schedule I substance under

the Controlled Substances Act, remains a barrier to the necessary research, and ASHP advocates that federal and state laws and regulations be aligned to remove or minimize these barriers.

Conflicting federal and state laws also create confusion about research on and use of medical cannabis, as federal law precludes procurement, storage, preparation, or distribution of medical cannabis by pharmacies or healthcare facilities registered with the Drug Enforcement Administration. Given the complexity of the issues involved, ASHP encourages healthcare organizations to develop policies and procedures regarding medical cannabis to conduct research and provide patient care that is consistent with applicable laws, regulations, and accreditation standards. Recreational or medical use of cannabis should be documented in the patient medical record. ASHP recognizes the need for pharmacists and other healthcare providers to provide education about the unique therapeutic and legal issues created by research on and use of medical cannabis

2116

NONPRESCRIPTION AVAILABILITY OF OSELTAMIVIR

Source: Council on Therapeutics

To support expanded access to oseltamivir through a proposed intermediate category of drug products, as described by ASHP policy, that would be available from all pharmacists and licensed healthcare professionals (including pharmacists) who are authorized to prescribe medications, rather than nonprescription designation; further,

To support diagnosis and tracking of influenza through pharmacist-driven influenza point-of-care testing and reporting to the appropriate public health agencies prior to oseltamivir dispensing; further,

To support interoperable documentation of oseltamivir dispensing and associated testing accessible by all members of the healthcare team in outpatient and inpatient settings; further,

To advocate that specific and structured criteria be established for prescribing, dosing, and dispensing of oseltamivir for treatment and prophylaxis by pharmacists; further,

To advocate that pharmacist-provided counseling for oseltamivir and patient education on influenza be required for dispensing; further,

To continue to promote influenza vaccination by pharmacists, despite oseltamivir availability; further,

To advocate that the proposed reclassification of oseltamivir be accompanied by coverage changes by third-party payers to ensure that patient access is not compromised and that pharmacists are reimbursed for the clinical services provided.

Rationale

Oseltamivir (Tamiflu) is a neuraminidase inhibitor used for the treatment and chemoprophylaxis of influenza. In July 2019, manufacturer Sanofi signed a deal with Roche Pharmaceuticals to obtain exclusive nonprescription rights to Tamiflu. ASHP would support the availability of oseltamivir as an intermediate category of drug products, as described in the ASHP Statement on Criteria for an Intermediate Category of Drug Products. This designation would facilitate appropriate use of oseltamivir after patient assessment and professional consultation by a pharmacist or other licensed healthcare professional who is authorized to prescribe medications.

There are several perceived advantages and disadvantages of the nonprescription designation for oseltamivir. Potential benefits include quicker and improved oseltamivir access for patients, public health value by reducing exposure of sick individuals at provider visits, unlikely development of oseltamivir resistance based on currently available data, and experience with oseltamivir as a nonprescription medication in New Zealand since 2007. Potential concerns include stockpiling, shortages, questionable efficacy (an approximate reduction in symptom duration of one day), adverse effects (e.g., nausea, vomiting, headache, neuropsychiatric effects), reduction of influenza vaccination rates because of oseltamivir availability, dosing considerations (e.g., renal function, pediatric weight-based dosing), costs, reimbursement for clinical services provided by pharmacists (e.g., point-of-care influenza testing, questionnaire screening tool for oseltamivir dispensing), blunting of other more severe underlying conditions without a provider visit, and overextension of pharmacist responsibilities and duties. Furthermore, public health considerations must also be a part of this expanded access. With availability over or behind the counter, patients may bypass visiting their primary care providers to obtain oseltamivir, and pharmacists will therefore need to assume an active role in promoting public health by reporting positive cases to local health departments, should rapid testing and reporting be a requirement of dispensing.

Given the intent to expand patient access to oseltamivir, ASHP advocates that the proposed reclassification should not result in increased costs to patients and pharmacies. Modifications to national, regional, and local drug coverage decisions are needed to ensure that payer policies do not unintentionally restrict or prevent access. In addition, the reclassification will likely result in an increased workload and potential liability associated with pharmacist provision of this care, which includes patient screening (and point-of-care testing, if applicable), patient education, oseltamivir dosing, counseling, and documentation of the care provided in the pharmacy and medical record. Pharmacists should be compensated for these clinical and patient care services.

2117

EDUCATION AND TRAINING IN TELEHEALTH

Source: Council on Education and Workforce Development

To acknowledge that telehealth is a growing modality that supports the pharmacy workforce in providing direct patient care; further,

To support training and education for the pharmacy workforce in innovative models that support telehealth services; further,

To promote the incorporation of students and residents into virtual modalities of care and interdisciplinary collaboration; further,

To foster documentation and dissemination of best practices and outcomes achieved by the pharmacy workforce as a result of telehealth services.

Rationale

Continuous development of information technology is rapidly redefining the provision of healthcare. The expansion of telehealth services creates opportunity to improve access to telepharmacy and telemedicine for patients unable to access health services in traditional modalities. Lack of access to healthcare remains critical for many individuals for a variety of reasons including geographic issues (i.e. rural communities), lack of transportation, physical or fiscal challenges. The provision of medical care using telehealth allows patients to have access when they need it at the time they need it.

To ensure that telepharmacy becomes a strong component of telehealth, training and education must be developed that supports the pharmacy workforce in their delivery of optimal patient care. Expanded access for the pharmacy workforce as well as interoperability and information integrity between organizations where patients may receive care is crucial. Additionally, student learners must have appropriate access levels with oversight to the electronic health record to ensure development of the skills needed for this type of care. Research supporting improved outcomes while maintaining security for patients' health information is needed to foster continued development.

2118

SUPPLY CHAIN RESILIENCE DURING DISASTERS AND PUBLIC HEALTH EMERGENCIES

Source: Council on Pharmacy Management

To support building an enhanced and resilient hospital and health-system supply chain that is lean and economical during normal operations yet nimble enough to support patient care needs during large surges in demand for pharmaceuticals and medical supplies; further,

To advocate for ongoing federal evaluation of a national hazard vulnerability assessment to determine how pandemics and disasters present risks to healthcare and public health critical infrastructure; further,

To advocate for the development of critical pharmaceutical and medical supply requirement listings based on a national hazard vulnerability assessment to guide the composition of government and distributor-managed emergency stockpiles; further,

To urge Congress and state legislatures to direct medical supply and pharmaceutical distributors to manage both "private sector-owned" medical materiel (just-in-time for normal operations) and government-owned/distributor-managed emergency stockpiles (just-in-case for emergencies) that can flow into the private sector supply chain when release of government-owned materiel during public health emergencies, disasters, or contingencies is authorized.

Rationale

Hospitals and health systems experience supply chain challenges for patient care during routine operations, and these challenges can be exacerbated by public health emergencies and disasters. Aspects of the novel coronavirus disease 2019 (COVID-19) pandemic that have required nimbleness in thinking and action are the transformation of organizational governance and the need for speed in decision-making. The COVID-19 pandemic has dramatically changed inventory management and supply chain practices.

Many pre-existing factors contributed to the supply chain crises triggered by COVID-19, including but not limited to overextended supply lines, lean manufacturing, and outsourcing, which have been especially unfavorable for hospitals and health systems running just-in-time (JIT) inventory replenishment. Designed to use capital more efficiently, JIT replenishment relies on highly accurate demand forecasting and tight coordination with suppliers. When there is a sudden increase in demand, from a larger number of buyers trying to purchase the same products at the same time or from the typical number of buyers trying to make larger purchases, the thin supply chains that support JIT inventories can't respond quickly enough, creating long-term backorders at the local, regional, and national levels. An alternative just-in-case (JIC) inventory strategy would maintain extensive inventories to reduce backorder risks in the face of supply and demand uncertainties, but at the cost of forcing organizations to tie up capital in inventory.

During the COVID-19 pandemic, hospital and health-system governance structures had to quickly pivot to accommodate shifts in unexpected operational, clinical, and financial challenges. Organizations quickly embraced the “new normal” of supply chain management conundrums (e.g., shortages of personal protective equipment and critical drug, minimizing drug waste), controversial drug therapy considerations for pharmacy and therapeutics committees, and provisioning planning for alternate care sites (e.g., field hospitals). To prepare the healthcare system to endure the stresses on critical infrastructure caused by future public health emergencies or disasters, a shift toward a hybrid supply chain model needs serious consideration, to reap the benefits of both models and build resiliency into supply chains. Such a system would use information from a national hazard vulnerability assessment to guide the composition of emergency stockpiles of critical pharmaceuticals and medical supplies and require private-sector distributors of those products to manage the supply chains for those stockpiles when they are released during public health emergencies or disasters in addition to their normal operations.

2119**ASHP STATEMENT ON THE PHARMACIST'S ROLE IN PUBLIC HEALTH**

Source: Council on Pharmacy Practice

To approve the ASHP Statement on the Pharmacist's Role in Public Health.

2120**ASHP STATEMENT ON THE PHARMACIST'S ROLE IN CLINICAL PHARMACOGENOMICS**

Source: Section of Clinical Specialists and Scientists

To approve the ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics.

2121**UNIVERSAL INFLUENZA VACCINATION**

Source: Council on Therapeutics

To advocate for universal annual administration of influenza vaccinations to the United States population; further,

To advocate that annual influenza vaccination be a national public health priority; further,

To support the development of safe, effective, and affordable universal influenza vaccination, with the goal of long-term immunity.

This policy supersedes ASHP policy 0601.

Rationale

Influenza places a significant health burden on the United States, with estimates of 9–35 million illnesses, 4–16 million outpatient medical visits, and 139,000–708,000 hospitalizations each season. The influenza virus evolves and changes each year, with changes in its genome that require adjustments to vaccine viruses each season. Furthermore, the timing of the onset, peak, and end of each flu season varies annually, typically falling in the fall and winter. Evidence from several observational studies demonstrate that higher influenza vaccination is associated with a lower risk of influenza outbreaks, but Healthy People 2030 estimates that only 49.2% of persons 6 months or older were vaccinated for the 2017-18 season. Influenza vaccination in low-risk individuals has also shown to be effective and can prevent many illnesses, deaths, and losses in productivity.

The *Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza* emphasize that annual vaccination is the best method for preventing or mitigating the impact of influenza, and the 2030 Infectious Disease Goals for Healthy People 2030 have a goal of minimum vaccination rates of 70%. In 2019, an Executive Order created the National Influenza Vaccine Task Force, which identified that collaborative efforts across the federal government, academia, the private sector, and international stakeholders over the past decade have advanced influenza vaccine technologies. The Task Force also noted that influenza is a public health and national security challenge, with significant gaps remaining in vaccine effectiveness, pace of vaccine production, sustainable manufacturing, and vaccine access and coverage across all populations.

2122**VACCINE CONFIDENCE**

Source: Council on Therapeutics

To recognize the importance of vaccination to public health in the United States; further,

To affirm that members of the pharmacy workforce are integral members of the interprofessional team to promote disease prevention and health equity through vaccine confidence and access; further,

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

To promote pharmacy workforce engagement with patients, healthcare providers, and caregivers, and to educate patients on the risks of vaccine hesitancy and the importance of timely vaccination.

Rationale

Immunizations have led to a significant decrease in rates of vaccine-preventable diseases and have had a significant impact on the health of adults and children. Despite the availability of vaccines, in recent years the U.S. has seen outbreaks of whooping cough, measles, mumps, meningococcal disease, influenza, and hepatitis A. Studies have associated vaccine refusal with such outbreaks (Phadke VK et al. JAMA. 2016; 315:1149-58). The pharmacy workforce has an integral role in promoting disease prevention and health equity by boosting vaccine confidence. The Centers for Disease Control and Prevention (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.

2123

THERAPEUTIC INDICATION IN CLINICAL DECISION SUPPORT

Source: Council on Therapeutics

To encourage healthcare organizations to optimize the use of clinical decision support systems with indications-based prescribing; further,

To advocate to the Food and Drug Administration, the National Council for Prescription Drug Programs, and other organizations to select and implement a single standard coding system for labeled therapeutic indications that can be integrated throughout the medication-use process, enabling optimum clinical workflows and decision support functionality; further,

To advocate for federal and state laws and regulations to include diagnosis-based indication(s) on medication order(s) and prescription(s), and to allow the withholding of indication on medication prescription labels when patient privacy risks outweigh benefits.

This policy supersedes ASHP policy 1608.

Rationale

Several well-known studies have demonstrated reductions in wrong-patient errors and adverse events with the inclusion of indication on the prescription order. In 2010, Equale (*Drug Saf.* 2010; 33: 559-67) described the accuracy of indication information in electronic health records (EHRs). Galanter (*J Am Med Inform Assoc.* 2013;20:477–81) focused on preventing wrong-patient medication errors with the use of indication-based prescribing. Indication-based alerts resulted in an interception rate of 0.25 interceptions per 1000 alerts. One team of investigators conducted a trial of inpatient indication-based prescribing using computerized provider order entry (CPOE) with drugs commonly used off-label (*Appl Clin Inf.* 2011;2:94–103). Off-label prescription drug use without strong scientific evidence has also been associated with increased rates of adverse drug events (*JAMA Internal Medicine* 2016; 176:55-63). The authors suggested that use of and proper documentation of therapeutic indication can help improve surveillance and safety and decrease risk. This additional safety check is critical in limiting errors due to wrong and/or look-alike/sound-alike medications. In addition to error prevention, indication-based prescribing can improve patient engagement, patient education, and provide pharmacists with information that may be necessary for prior authorizations or claim processing. To foster successful implementation of indication-based prescribing in EHRs, several authors have documented the success of starting electronic prescriptions with a problem or indication list first before medications can be selected to reduce time and medication errors while maintaining clinician satisfaction.

In several countries, including Canada and Spain, the EHR includes indication as part of comprehensive documentation. ASHP first developed official policy on the importance of pharmacists' access to indications in 1993. In 1996, the National Coordinating Council for Medication Error Reporting and Prevention recommended including the purpose of medication orders because of concerns about safety, unless considered inappropriate by the prescribers. In 1999, the Institute for Safe Medication Practices recommended including the purpose of prescribing on all written orders. In 2004, the National Association of Boards of Pharmacy (NABP) approved a resolution encouraging national and state medical associations to support legislative and regulatory efforts to require prescribers to include indications for all oral, written, and electronically transmitted prescriptions. In 2012, the United States Pharmacopeia made amendments to the standards for prescription container labeling to include "purpose-for-use" language. In 2015, the National Council of Prescription Drug Plans drafted language to recommend diagnosis and SNOMED indication be sent with any prescription. Despite these recommendations, few states have adopted any laws requiring inclusion of indication on all medication orders or prescriptions.

More recently, the Institute for Safe Medication Practices recommended updating the five "rights" of patient, drug, dose, time, and route to include a sixth "right": the right indication. They cite benefits of indication-based prescribing as (1) helping to prevent errors by

narrowing medication choices; (2) empowering and educating patients, which helps increase patient adherence; (3) improving communications among the healthcare team, patients, and families; (4) facilitating medication reconciliation; (5) helping prescribers select the best medications for their patients; and (6) aiding in measuring drug effectiveness and learning from off-label use.

ASHP also has policy on off-label use that encourages the use of the three authoritative drug compendia, peer-reviewed literature, and consultation with experts in research and clinical practice to make specific coverage decisions. ASHP supports informed decision-making that promotes third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses.

Implementation and use of clinical decision support systems with indications-based prescribing would be eased by agreement on a single standard coding system for labeled therapeutic indications. The Food and Drug Administration, the National Council for Prescription Drug Programs, and other organizations should work collaboratively to select and implement such a system.

Furthermore, ASHP recognizes that there are circumstances in which it would be inappropriate to include diagnosis on a medication order, and encourages such exceptions in federal and state laws and regulations. One clear example of such an exception would be six protected categories of drugs (antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics), as including these may inadvertently result in breaches in patient privacy.

2124

PREVENTING EXPOSURE TO ALLERGENS

Source: Council on Therapeutics

To advocate for pharmacy workforce participation in the collection, assessment, documentation, and reconciliation of a complete list of allergens and intolerances pertinent to medication therapy, including food, excipients, medications, devices, and supplies; further,

To promote the education of the healthcare team and patients on the differences between medication-related allergic reactions and medication intolerances; further,

To encourage vendors of electronic health records to create readily available and distinct data fields with consistent designations for medication allergies and intolerances; further,

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

To encourage the accurate and complete documentation of allergens and intolerances within the electronic medical record, including detailed descriptions of the reactions occurring upon exposure, for the purpose of clinical decision-making; further,

To advocate that pharmacists actively review allergens and intolerances pertinent to medication therapy and minimize patient and healthcare worker exposure to known allergens, as feasible.

This policy supersedes ASHP policy 1619.

Rationale

The common theme of several ASHP policies is that patients may be exposed to potentially life-threatening allergens in items encountered in the medication-use process (e.g., natural rubber latex, drugs, drug product excipients, devices, and supplies). Pharmacy workforce involvement in collection, assessment, and documentation of a complete list of allergens pertinent to the medication-use process, including food, excipients, medications, devices, and supplies, would assist in clinical decision-making. Members of the pharmacy workforce should also minimize patient and healthcare worker exposure to known allergens, for example by limiting or banning the use of latex gloves in pharmacies and striving for latex-safe medication formularies. Although allergy information is becoming more readily accessible through the electronic health record (EHR) and clinical decision support systems, some well-known cross-sensitivities are good candidates to be included in medication-related databases.

Only about 5-10% of all medication-related adverse events are allergic in nature. Patients are often labeled with an allergy to many drugs on the basis of a side effect or intolerances such as headache or GI disturbance. Allergen misidentification and documentation can be detrimental to patient care by preventing the use of optimal drug agents or by causing re-exposure to a true allergen. Pharmacists and pharmacy technicians can help clarify and provide detailed documentation in the EHR regarding patient allergies. Furthermore, there is inconsistent standards on how and where allergies are located in the EHR and as such, there should be a consistent and standardized approach to documentation.

2125

TOBACCO, TOBACCO PRODUCTS, AND ELECTRONIC NICOTINE DELIVERY SYSTEMS

Source: Council on Therapeutics

To discourage the use of tobacco, tobacco products, and electronic nicotine delivery systems due to their long-term adverse health effects; further,

To oppose the distribution and sale of tobacco, tobacco products, and electronic nicotine delivery systems by pharmacies or facilities that contain a pharmacy; further,

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

To promote legislation that supports pharmacist prescriptive authority for tobacco-cessation medications; further,

To promote the pharmacist's interprofessional role in tobacco-cessation counseling and comprehensive medication management; further,

To join with other interested organizations in statements and expressions of opposition to the use of tobacco, tobacco products, and electronic nicotine delivery systems; further,

To educate the public and patients on the risks of nicotine consumption through traditional and electronic delivery systems.

This policy supersedes ASHP policy 1625.

Rationale

Pharmacists, as healthcare providers, have long discouraged the use of tobacco and tobacco products as a threat to public health. Electronic nicotine delivery systems (e.g., vaporizers, vape pens, hookah pens, and electronic cigarettes and pipes) are relatively new and unregulated delivery systems for nicotine. The contents of these systems include flavorings, propylene glycol, glycerin, and other unknown ingredients, and the long-term effects of their use have not been studied. Given these uncertainties, pharmacists should discourage their use as well. In addition, ASHP opposes the distribution or sale of tobacco, tobacco products, and electronic nicotine delivery systems by pharmacies or facilities that contain a pharmacy (e.g., grocery or retail stores) and advocates that hospitals and health systems be tobacco-free environments.

Furthermore, pharmacists have a role in recommending and managing drug therapy to support cessation of nicotine-containing products, including tobacco and electronic nicotine delivery systems, as described in the [ASHP Therapeutic Position Statement on Cessation of Tobacco Use](#). Newer therapies, including varenicline, are associated with more and evolving safety risks when compared to nicotine replacement therapies. Given the complexity of drug therapy, pharmacists should play a central role in ensuring the safe and appropriate use of these therapies.

2126

USE OF RACE CORRECTION IN CLINICAL ALGORITHMS

Source: Council on Therapeutics

To recognize that clinical algorithms that only use race or ethnicity as a variable can contribute to inequities and adverse outcomes; further,

To oppose the use of race or ethnicity correction in clinical algorithms unless there is strong evidence to support its use; further,

To advocate that health systems remove algorithms based on race or ethnicity from all sources of therapy decisions, medication information, and the electronic health record, where strong evidence does not support its use; further,

To support further research on the impact of race or ethnicity on drug therapy and outcomes; further,

To advocate that if research includes considerations based on race or ethnicity, the reason for its use as a variable be specified; further,

To provide education on the limitations and appropriate use of race- or ethnicity-corrected clinical algorithms; further,

To support uniform documentation in the electronic health record of a patient-identified designation of race or ethnicity.

Rationale

As outlined in the ASHP Statement on Racial and Ethnic Disparities in Health Care, race and ethnicity are social constructs with a cultural rather than a scientific basis. Although patient care can and should be informed by a patient's racial or ethnic identity, healthcare providers need to recognize the limited utility of that information

There are currently numerous clinical algorithms and practice guidelines that use a patient's race or ethnicity to determine outcomes. The clinical algorithms are then used by providers to help guide individualized risk assessments and clinical decisions. In return, these algorithms may direct attention and resources away from racial and ethnic minorities. However, the majority of these clinical algorithms do not have data to support a patient's race or ethnicity as a clinical factor. When a rationale is given and traced to its origins, the answer leads to outdated, suspect racial science, or biased data. Additionally, these algorithms do not take into account socioeconomic factors and other social determinants of health that may have a large influence on health outcomes.

Currently, a patient's race or ethnicity plays a role in a clinical algorithms or practice guidelines in almost every therapeutic class, including cardiology, surgery, nephrology, obstetrics, urology, and oncology. For example, the American Heart Association Get with the Guidelines - Heart Failure adds 3 points to the risk score of a patient that is non-Black. The higher scores in this tool predict higher in-hospital mortality. Ultimately, this tool is used to help guide clinical decisions for allocations of healthcare resources and referral to cardiology. The consequences of adding race to this algorithm would mean less direct patient care due to the patient being deemed as lower risk. There are many other clinical algorithms that adds points to their risk score for a patient that is non-Black, such as the STONE Score, Urinary Tract Infection Calculator, and Osteoporosis Risk SCORE. Another example is the estimated glomerular filtration rate (eGFR) MDRD and CKD-EPI equations. Both these equations report higher eGFR for Black patients than for other patients with the same serum creatinine levels. Originally, this disparity was thought to be due to patients that identify as Black having a higher average serum creatinine. However, there have been some concerns that this is not always true, especially when looking at the complexity of patient's racial backgrounds. Overestimating a patient's renal function can delay the time to referral to a kidney specialist or transplantation. In short, the addition of race to the clinical algorithms leads to less patient-specific interventions and ultimately worse patient outcomes.

Healthcare providers using the clinical algorithms and practice guidelines should be educated on how to critically evaluate the addition of race and ethnicity, along with the consequences of adding race when not clinically appropriate. Many providers do not assess the algorithm prior to implementing the results, which can lead to improper treatment of a patient.

Education on the limitations of the clinical algorithms can help providers and patients

overcome the barriers that the addition of race and ethnicity has created. Additionally, the medical community needs to advocate to re-evaluate our current clinical algorithms and evaluate future algorithms to determine if there is an evidence-based reason that race should be included. It is imperative that the medical community, primarily researchers, understand how race and ethnicity affects the outcome before adding it into a clinical algorithm.

Researchers have developed guidelines to follow when trying to rationalize when race and ethnicity should be included or excluded in a study, such as explaining how the category was determined, considering all confounders, and determining whether there is uncertainty in the algorithm. Researchers should then favor the practices that will help close health inequities over practices that might amplify them. Appropriately determining if race should be included in the algorithm will then help decrease the inappropriate clinical implementation of these tools.

Future research is needed to determine the relationship between pharmacogenomics, race, and ethnicity. Most providers and researchers use the standard five races and two ethnicities categories determined by the Office of Management and Budget to categorize people according to race and ethnicity. However, many individuals do not fit into these categories due to their complex racial and ethnic backgrounds, which may ultimately fail to account for genetic differences.

Drug therapy stems from these clinical algorithms and practice guidelines, and pharmacists need to work with other providers to critically evaluate the current tools. Additionally, pharmacists could collaborate with other providers to perform research to help better understand the differences between genomics and race. Therefore, providers could assess when race and ethnicity should be added to future clinical algorithms and practice guidelines.

2127

TESTING AND DOCUMENTATION OF PENICILLIN ALLERGY AS A COMPONENT OF ANTIMICROBIAL STEWARDSHIP

Source: Council on Therapeutics

To advocate that state board of pharmacy regulations include penicillin allergy skin testing under pharmacists' scope of practice; further,

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

To advocate for documentation and de-labeling of penicillin allergies, intolerances, reactions, and severities in the medical record when appropriate to facilitate optimal antimicrobial selection; further,

To recommend the use of penicillin skin testing, graded antibiotic challenges, and oral direct challenges in appropriate candidates when clinically indicated to optimize antimicrobial selection; further,

To support the education and training of pharmacists in the assessment, management, and documentation of penicillin allergies, intolerances, and adverse events; further,

To advocate for reimbursement for pharmacists' patient care services involved in penicillin allergy skin testing; further,

To educate patients, healthcare providers, and the public about the risks of inaccurate penicillin allergy labeling and the role of pharmacists in health-record reconciliation and the value of pharmacist-driven health-record reconciliation, including penicillin skin testing.

This policy supersedes ASHP policy 1921.

Rationale

Approximately 10% of all patients in the United States report having a penicillin allergy; however, only 1 in 10 patients with a labeled penicillin allergy are truly allergic. Furthermore, approximately 80% of patients with an IgE-mediated penicillin allergy lose their sensitivity after 10 years. Specific rates of cross-reactivity between penicillins and cephalosporins vary depending on specific resources, although the likelihood of cross-reactivity is lower than previously described. Historically, it has been estimated that 10% of patients with a true penicillin allergy will experience an allergic reaction if administered a cephalosporin, but this data is from early cross-reactivity studies with potential contamination of early cephalosporin products with penicillin G. More recent data suggest cross-reactivity rates of less than 1%. Cross-reactivity is more closely associated with structurally similar R-1 side chains than with the beta-lactam ring itself.

Penicillin allergies have led to considerable public health risks and unintended consequences, including receipt of more broad-spectrum antibiotics, suboptimal therapy for infectious disease management, more antibiotic-related costs, increased risk of adverse effects, and increased risk of methicillin-resistant *Staphylococcus aureus* and *Clostridioides difficile*. As such, structured and thorough interview assessments with appropriate documentation and de-labeling of penicillin allergies are necessary to combat these potential negative consequences of labeled penicillin allergies. Penicillin skin testing and graded or oral challenges are excellent opportunities to assist in the assessment and de-labeling of penicillin allergies. Although pharmacists are well positioned to be involved in these processes, state boards of pharmacy have different regulations regarding whether penicillin skin testing is within pharmacists' scope of practice. Penicillin allergy assessment, management, and documentation are excellent opportunities to improve pharmacist involvement in patient care and to improve antimicrobial stewardship initiatives for health systems, and offer a potential opportunity for pharmacists to bill for their services.

The American Academy of Allergy, Asthma, and Immunology, as part of the [Choosing Wisely](#) campaign, recommends against the overuse of non-beta-lactam antibiotics in patients with a history of penicillin allergy, without appropriate evaluation. In a research abstract from the Canadian Society of Allergy and Clinical Immunology meeting in 2014, researchers found that only 15% of hospital-discharged patients notified a family physician of a negative penicillin allergy evaluation; at the same time, 30% were still listed as penicillin allergic upon readmission to the hospital. Additionally, the existence of a pharmacist-provided allergy skin test has proven to positively impact patient care by optimizing antibiotic regimens and accelerate discharges for

patients while reducing healthcare costs.

2128

USE OF UNAPPROVED GENE THERAPY PRODUCTS, DRUGS, BIOLOGICS, AND MEDICAL DEVICES (BIOHACKING)

Source: Council on Therapeutics

To advocate for enhanced government oversight and regulation of use of gene therapy, drugs, biologic products, and medical devices created outside of the Food and Drug Administration approval process (i.e., “biohacking”), and aggressive enforcement of those regulations; further,

To oppose the use of biohacking on vulnerable and at-risk populations and those unable to provide consent; further,

To promote education of healthcare professionals regarding use of biohacking and its implications in the medical setting; further,

To encourage the pharmacy workforce to include questions about the use of biohacking when obtaining medication histories; further,

To encourage the pharmacy workforce to ensure that patients using biohacking are educated about the risks and benefits of these treatments, including lack of regulatory oversight; further,

To recommend that health systems use a consistent method for documenting the use of biohacking in the electronic health record.

Rationale

Biohacking has been defined as “do-it-yourself biology or “do-it-yourself citizen science merging body modification with technology” (Yetisen AK. *Trends Biotechnol.* 2018; 36:744-7). Biohacking is performed by biology enthusiasts, citizen scientists, and other like-minded individuals and includes neurohacking (focuses on brain stimulation for change); manufacturing of pharmaceutical products; implantation of modified technology; and the genetic modification of bacteria, yeast, plants, and humans (as a form of self-experimentation) to improve oneself or treat a disease.

Genetic biohacking in particular has proven to be easy and affordable, with individuals using inexpensive, semi-professional and portable labs to carry out their experiments, including Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology, which permits the user to edit the genome by removing, adding, or altering sections of DNA. It is estimated that more than 30,000 people are involved in do-it-yourself biology in the United States alone. Furthermore, many see themselves as serving the greater health interests of the patient community at large with the right to experiment and create treatments such as gene therapy as a form of social justice. However, many of these biohackers have little to no formal training in safety and do not obtain ethical reviews of their work as one would in an institution with an

internal review board. Although most biohackers currently experiment only on themselves, concern about the practice may grow as the cost of traditional therapies, particularly biologics, increases, luring sick and desperate patients to biohackers in hopes of cheaper or more accessible treatments.

The other concern about the biohacking movement is bioterrorism. The Federal Bureau of Investigation continues to form relationships with labs where genetic experimentation occurs to police this threat, but the concern remains.

Currently in the United States, there is no ban on genome editing outside of licensed laboratories. Although the Food and Drug Administration (FDA) does have jurisdiction over regular raw biological products, traditional drug products, and do-it-yourself CRISPR kits, they have not taken public enforcement action against those conducting genome editing. This may be due to practicality, however, as many biohackers are individuals or work within a small community and are hard to track. Additionally, many current laws are outdated and apply only to agricultural genetic modification. The FDA has issued draft guidance for the regulation of intentionally altered genomic DNA in animals and stated that “any use of CRISPR/Cas9 gene editing in humans [is] gene therapy” and therefore subject to regulation.

Another facet of biohacking that must be addressed is its potential impact on manufacturing. For example, due to the high cost of biosimilar insulins, a community of biohackers has created the Open Insulin Project to develop an insulin production method for personal use. This and similar projects may lead to intellectual property, regulatory, patent, and legal issues that could impact manufacturing.

Another aspect of do-it-yourself biology is implantation of devices into one’s body for medical purposes. Many of these devices are used to monitor a medical condition or to optimize drug delivery to manage disease, such as implantation of veterinary chips for monitoring vital signs, use of a wearable artificial kidney that performs dialysis via a coated skin port, and homemade insulin pumps. Pharmacists need to be aware of these devices, as they impact how patients receive medications and how they are treated. At some point in their health journey, patients using these devices are likely to be admitted to a hospital, a mechanism for documentation of this information in the electronic health record is necessary. Furthermore, pharmacists will need to understand the impact these devices have on the pharmacokinetics, pharmacodynamics, and other aspects of drug therapy.

An overall approach that should be considered is that of education of those engaged in the biohacking movement regarding the role of the federal agencies in consumer protection, risks and benefits and establish practice standards and norms that minimize harm.

2129

PROFESSIONAL IDENTITY FORMATION

Source: Council on Education and Workforce Development

To encourage the pharmacy workforce and pharmacy education and training programs to foster professional identity formation, described as the process of developing a commitment to: (1) high professional standards of pharmacy practice, (2) high personal standards of integrity and competence, (3) service to humanity, (4) a just and inclusive healthcare system and society, (5) analytical thinking and ethical reasoning, (6) continuing professional development, (7) acquisition of personal leadership skills, (8) development of effective interpersonal skills, (9)

maintenance of personal well-being and resiliency, and (10) membership and participation in professional organizations.

This policy supersedes ASHP policy 1113.

Rationale

The terms “professionalism” and “professional identity” are sometimes mistakenly used interchangeably. Professionalism is defined by behaviors that are often outwardly visible (e.g., credentialing, continuing education, efforts to advance the profession). In contrast, professional identity formation (PIF) is defined as the process of internalizing a profession’s core values and beliefs. PIF incorporates the three domains of thinking, feeling, and acting. PIF in pharmacy may be described as the process of developing a commitment to the 10 listed characteristics.

Pharmacy professionals and educators have a direct or indirect responsibility to support the growth and success of others in the pharmacy workforce through mentorship and modelling. As pharmacy professionals interact with learners, new practitioners, and even seasoned colleagues, they have the ability to model professional behavior, integrity, ethical standards, and service to the community. Pharmacy professionals who serve in formal or informal leadership roles are in a unique position to mentor others in leadership skills. Pharmacy professionals should mentor others in the various career paths they may pursue as well as encourage them to elevate their practice level and education.

Some of the barriers to PIF include mentors and preceptors being pressured into a role rather than being allowed to decide whether they choose to do so voluntarily, increased pharmacy workload, and staff burnout. Developing student professionalism (sometimes referred to as “professional socialization”) has been part of pharmacy education for decades, but a broader focus on PIF more generally will better serve the profession of pharmacy during a time of practice transformation than the current approach to teaching professionalism. Colleges of pharmacy, other providers of education and training programs, and employers could promote PIF by providing mentorship programs and other resources.

2130

CAREER OPPORTUNITIES FOR PHARMACY TECHNICIANS

Source: Council on Education and Workforce Development

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

To advocate that pharmacy technicians complete an education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE), and maintain Pharmacy Technician Certification Board certification; further,

To advocate that pharmacy technicians complete ACPE-approved certificate programs that provide training for their current or anticipated roles; further,

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

To encourage employers to offer career advancement opportunities (e.g., career ladders) for pharmacy technicians; further,

To urge compensation for pharmacy technicians commensurate with advanced roles and responsibilities.

This policy supersedes ASHP policy 1610.

Rationale

As the responsibilities of pharmacy technicians expand and their role as a vital member of the healthcare team is recognized, it is imperative that pharmacy technicians be well trained and competent to perform those responsibilities. Pharmacists cannot provide quality patient care without the support of competent pharmacy technicians. To support pharmacists and promote retention, it is important that pharmacy technician positions be viewed as a career and not just a job. Pharmacy technicians should be provided opportunities for life-long advancement and compensated appropriately for advanced roles that they assume. There is current ASHP policy 1912 that addresses the *Pharmacy Technician Training and Certification*, which advocates for the education, training, and certification for new pharmacy technicians. This covers a need for the on-going professional development and career advancement for pharmacy technicians.

2131

ZERO TOLERANCE OF HARASSMENT, DISCRIMINATION, AND MALICIOUS BEHAVIORS

Source: Council on Education and Workforce Development

To assert that the pharmacy workforce has a right to expect and responsibility to ensure a profession in which all individuals are treated with respect and civility, with zero tolerance for all forms of harassment, discrimination, and malicious behaviors; further,

To commit to a culture of responsibility and accountability within the profession, and promote anti-retaliation policies and timely follow-up; further,

To foster the development of tools, education, and other resources to ensure such a culture.

Rationale

The [Code of Ethics for Pharmacists](#) states that “A pharmacist acts with honesty and integrity in professional relationships.” The [ASHP Statement on Professionalism](#) includes among the elements of professionalism pride in and service to the profession, conscience and trustworthiness, and ethically sound decision-making. All forms of discrimination (e.g., race, color, sex, national origin, religious, sexual orientation/identity, age, disability), harassment (including sexual harassment), and malicious behaviors such as bullying, intimidation, or exploitation go against the core beliefs of the profession. All members of the pharmacy workforce have a professional responsibility to create and sustain a culture of responsibility and

accountability within the profession in which all individuals are treated with respect and civility, with zero tolerance of harassment and discrimination.

A culture of responsibility and accountability requires that employers and organizations establish mechanisms for retaliation-free reporting of harassment and discrimination, and that such reports receive timely follow-up. For such a culture to thrive, the pharmacy workforce must recognize its professional obligation to not only follow institutional policies regarding prevention, reporting, and consequences for such behaviors but to seek out ways to improve the effectiveness of those policies and procedures. This culture of responsibility and accountability includes the workplace and learning environments but extends even to such personal but quasi-public conduct as interactions on social media. As stated in the [ASHP Statement on the Use of Social Media by Pharmacy Professionals](#), the “higher standards of conduct expected of professionals, even in personal behavior” imply that “[p]ostings on social media should be subject to the same professional standards and ethical considerations as other personal or public interactions.”

As stated in the [ASHP Statement on Professionalism](#), “[o]ne of the fundamental services of a professional is recruiting, nurturing, and securing new practitioners to that profession’s ideals and mission.” Formal and informal mentorship relationships are fundamental to the growth and health of any profession, and abuses of those positions of trust are especially injurious to victims and the profession. These relationships should be subjected to the strictest scrutiny and oversight to ensure they are held to the highest standards of conduct.

To further the goal of creating and sustaining a culture of responsibility and accountability regarding harassment and discrimination, ASHP commits to developing tools, education, and other resources to help members, employers, and other organizations address these important issues.

2132

STANDARDIZING AND MINIMIZING THE USE OF ABBREVIATIONS

Source: Council on Pharmacy Management

To support efforts to standardize and minimize the use of abbreviations in healthcare; further,

To oppose use of abbreviations when communicating with patients to enhance transparency and understanding; further,

To encourage education of healthcare professionals and learners on standardizing and minimizing the use of abbreviations across all patient care settings.

This policy supersedes ASHP policy 0604.

Rationale

Although there are anecdotal examples of medical abbreviations causing harm to patients, there is little good clinical evidence to demonstrate that medical abbreviation use is dangerous or is causing problems in the delivery of care. Nevertheless, minimizing or even eliminating the use of medical abbreviations in healthcare has been encouraged for decades. The Institute of

Safe Medication Practices regularly receives reports of errors, some of which have resulted in adverse events, due to misinterpretation of medical abbreviations. The Joint Commission has regularly issued updates and guidance on the safe use of medical abbreviations and has also published a short list of dangerous medical abbreviations and dose expressions that should never be used. However, despite many key organizations discouraging the use of medical abbreviations, they continue to be used at an alarming rate. Such use can place new practitioners at great risk when they have to interpret the abbreviations, as the new practitioner may have limited knowledge about what the abbreviations mean. Use of abbreviations should be minimized, and when abbreviation use cannot be avoided, they should be standardized to ensure accurate interpretation. In addition, use of abbreviations when communicating with patients should be avoided to enhance transparency and patients' understanding of their treatment.

2133

OPTIMAL PHARMACY STAFFING

Source: Council on Pharmacy Management

To encourage pharmacy leaders to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care and employee engagement; further,

To encourage pharmacy leaders to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, telehealth practices, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings; further,

To encourage pharmacy leaders to develop contingency plans for changes in staffing models to accommodate rapid changes in the healthcare environment and the needs of patients and staff; further,

To encourage pharmacy leaders to develop key performance indicators to support safe staffing models.

This policy supersedes ASHP policy 2034.

Rationale

The advancement of the pharmacy profession over the past decade has prepared and positioned pharmacists to care for complex patients and adapt to the dynamic and rapidly progressive field of medicine. Throughout the years, an increased involvement of pharmacists in specialty areas such as transplant, critical care, oncology, and pain and palliative care has been observed. Therefore, it is imperative that such advancement is considered when developing staffing models, in order to ensure the pharmacy workforce is appropriately allocated for the provision of consistent, safe, and high-quality patient care.

The complexity of patient care will continue to increase, and with that, so will the expected responsibilities, opportunities, and skills of the pharmacy workforce. Consequently,

pharmacists engaged in direct patient care are encouraged to pursue and maintain their training and credentialing in order to continue to enhance their competency, skills, and participation in innovative practice. The expansion and dynamic nature of the pharmacy profession requires new approaches to explore flexible staffing models to avoid a stagnant practice, encourage continual advancement, and accommodate the evolving priorities of the pharmacy workforce.

The development and implementation of flexible staffing models can enable pharmacists to engage in further professional development and career advancement (e.g., training in areas of specialization, degree programs) and enjoy a more stable work-life integration experience. Recently, more attention has been drawn to burnout, resilience, and job satisfaction among the pharmacy workforce. Research has shown that pharmacists are reporting increased job stress over the previous years and that approximately 53% of pharmacists are reporting a high degree of burnout, which can consequently threaten patient safety. Therefore, there is an imperative to develop staffing models to meet staff members' changing priorities and provide additional flexibility in the workplace. Implementation of flexible staffing models could improve performance and promote employee engagement in the workplace. Pharmacy leaders should be committed to maintaining high-quality and consistent patient care services and to also promote models that balance patient care with staff priorities.

Various options to consider when exploring flexible staffing models include telehealth practices, remote order review and verification (i.e., telecommuting), and productivity measures to ensure patient census is well distributed among pharmacists in charge of providing clinical services. Another concept related to flexible staffing models is leveraging pharmacy technicians' roles to support pharmacist engagement in direct patient care activities. Some institutions have explored data-driven, staffing-to-demand models based on real-time patient-volume metrics. The concept is to allocate staff to tasks based on the current workload, which is evaluated daily. Other institutions are also utilizing metrics such as number of doses dispensed at a certain point in time and volume of order verification throughout the day in order to divide patient care units evenly among pharmacists that perform order verification or provide clinical services. Flexible staffing models should support the following principles:

- Sufficient qualified staff must exist to ensure safe and effective patient care.
- During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care.
- Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services.
- Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

The COVID-19 pandemic and the ensuing reduction in elective procedures, routine visits, and admissions amplified the emphasis on flexing staff to volume. To support fiscal solvency during

and in the aftermath of the pandemic, organizations had to quickly pivot and align staff to accommodate shifts in volume, resulting in redesigned staffing models to optimize scheduling. These models have included a mix of onsite and remote offering of services to perform synchronous and asynchronous work in a more efficient manner, as well as staff furloughs. Flexing pharmacy staffing models have been previously described, such as pharmacy staffing-to-demand models; alternative work schedules; and productivity monitoring to guide hiring and staffing decisions.

Other healthcare disciplines (e.g., nursing) have historically utilized flexible staffing models to optimize services, reduce the risk of adverse events, and improve patient outcomes. The different models explored by nursing include patient ratio, key performance indicators, patient acuity, collaborative staffing, and supplemental staffing models. There is limited literature on the use of flexible staffing models, but the concept is being explored by various health-system pharmacy departments.

2134

PATIENT ACCESS TO PHARMACIST CARE WITHIN PROVIDER NETWORKS

Source: Council on Pharmacy Management

To advocate for laws and regulations that require healthcare payer provider networks to include pharmacists providing patient care services within their scope of practice when such services are covered benefits; further,

To advocate for laws and regulations that require healthcare payer provider networks to consider all qualified pharmacists who apply to participate as a provider in the network and to reimburse all participating providers fairly and equitably for services that are a covered benefit; further,

To acknowledge that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality and viability of healthcare services provided; further,

To advocate for laws and regulations that would help ensure the same level of patient care within a payer network by requiring healthcare payers to (1) disclose to participating providers and those applying to participate the criteria used to include, retain, or exclude providers; (2) ensure that those criteria are standardized across all network providers; and (3) collect data on how well providers meet those criteria and report that data to providers; further,

To advocate for comparative, transparent sharing of performance and quality measure data based on those criteria.

This policy supersedes ASHP policy 1808.

Rationale

As hospitals and healthcare organizations have become more engaged in developing

ambulatory care services, pharmacists providing patient care services within those settings increasingly find themselves excluded from healthcare payer networks. Vertical integration of the healthcare value chain has given payers more control over healthcare costs and has better positioned them to link directly with providers and negotiate value-based contracts. ASHP acknowledges that healthcare payers may develop and use criteria to determine provider access to its networks to ensure the quality of services and the financial viability of providers (i.e., ensuring sufficient patient volume to profitably operate), but when creating provider networks, payers should consider including pharmacists providing patient care services, within their scope of practice, when such services are covered benefits. To ensure equal treatment for healthcare providers, payers should be required to disclose to participating providers and those applying to participate in a provider network the criteria used to include, retain, or exclude providers. When pharmacists obtain provider status, the infrastructure required to implement direct, independent patient care and billing for provider-based services needs to be in place and accessible. Although a possible risk of payer transparency is a reduction in market competition, comparative, transparent sharing of performance and quality measure data, based on standardized criteria, reveals the level of patient care provided and demonstrates to payers and providers where their performance and quality fall in comparison to others. Ensuring that pharmacists have the opportunity to engage and have access to payers and payer networks improves coordination of care and patient access to pharmacists' care.

2135**ROLE OF THE PHARMACY WORKFORCE IN PANDEMIC PREPAREDNESS AND RESPONSE**

Source: Council on Pharmacy Practice

To advocate that all healthcare organizations include pandemic preparedness in emergency preparedness planning; further,

To encourage all healthcare organizations to be actively engaged with their regional healthcare coalitions and to promote collaboration and communication among healthcare workers, healthcare organizations, government agencies, industry, and other stakeholders in pandemic preparedness and response; further,

To promote pharmacy workforce involvement in networks at the federal, state, local, and institutional levels for emergency response; further,

To advocate that pharmacy personnel be included as leaders on teams responsible for pandemic preparedness planning and response at the federal, state, local, and institutional levels, and that they integrate such planning into emergency preparedness planning for their workplaces; further,

To encourage all healthcare organizations to establish criteria for evidence-based medication-use decisions, even when such evidence is scarce, incomplete, or conflicting, and recognize the unique role that pharmacy personnel have in ensuring the safe and effective use of medications based on best available evidence and resources; further,

To advocate that healthcare organizations recognize the unique and collective stress a pandemic places on healthcare workers and provide suitable resources to maintain workers' well-being and resilience; further,

To support research on and provide resources and education to aid the pharmacy workforce in preparing for and responding to pandemics.

Rationale

ASHP has long advocated “that hospital and health-system pharmacists must assertively exercise their responsibilities in preparing for and responding to disasters, and the leaders of emergency planning at the federal, regional, state, and local levels must call on pharmacists to participate in the full range of issues related to pharmaceuticals.” (ASHP Statement on Emergency Preparedness)

The Coronavirus Disease 2019 (COVID-19) global pandemic differs from other types of disasters in significant respects, testing the resiliency of the healthcare system and workforce. Treating patients with a novel viral pathogen has driven rapid evolution in therapies, forcing healthcare providers to make patient care decisions based on scarce, incomplete, or conflicting information. These decisions have sometimes been complicated by shortages of crucial drugs, equipment, or staff, creating a crisis standard of care in which difficult patient care decisions must be made. The patient surges that healthcare organizations have had to manage have lasted significantly longer than those of other disasters. Healthcare workers have faced stressful patient care situations and extended shifts for a longer period of time than in other disasters. In addition, the fear of infection and of spreading that infection to family members and others has added additional stress. Infection control procedures have shut down some areas of healthcare operations, forcing healthcare workers into unfamiliar roles and care settings.

ASHP advocates that the lessons learned from the COVID-19 pandemic be shared broadly and incorporated into emergency planning at the federal, state, local, institutional, and pharmacy department levels. All healthcare organizations should be actively engaged with their regional healthcare coalitions, and pharmacy leaders, with their unique understanding of medication-use processes, should be relied upon to provide strategic direction on the full range of issues related to medication use, especially when evidence is scarce, incomplete, or conflicting, and drugs or other critical resources are in shortage. The pharmacy workforce should incorporate the lessons learned in its emergency planning efforts, integrating those efforts into the efforts of emergency response networks at the federal, state, local, and institutional levels. ASHP pledges to promote collaboration and communication among the various stakeholders in pandemic preparedness and response, and to provide resources and education to aid the pharmacy workforce and others in preparing for and responding to pandemics, including resources regarding novel therapies, shortages of drugs and other critical supplies, and healthcare worker well-being and resilience.

2136

ROLE OF THE PHARMACY WORKFORCE IN SUPPORTING PATIENT ACCESS TO MEDICAL SUPPLIES

Source: Council on Pharmacy Practice

To support patient access to medical supplies as part of a comprehensive treatment plan; further,

To advocate for policies that empower pharmacy personnel to facilitate patient access to and effective use of medical supplies, including reimbursement policies; further,

To educate pharmacists, other healthcare professionals, payers, and policymakers about the role of pharmacy personnel in helping patients obtain and use medical supplies; further,

To collaborate with other healthcare professional and patient advocacy organizations to advocate for expanded patient access to medical supplies.

Note: For purposes of this policy, “medical supplies” includes durable medical equipment, Food and Drug Administration-approved medical devices, and other nondurable disposable healthcare materials.

Rationale

Pharmacists and pharmacy technicians have the knowledge and skills to support patient access to medical supplies and equipment, durable medical equipment (DME), and medical devices. These tools, like medications, are essential components to a patient’s personalized care plan. Although many providers combine medical supplies and equipment, DME, and medical devices under the umbrella term “medical supplies,” as is done here for purposes of this policy, there are critical differences between them that determine how these items are accessed and reimbursed. Under Centers for Medicare & Medicaid Services (CMS) rules, “medical supplies and equipment” (e.g., bandages and gauzes) are nondurable disposable healthcare materials used to serve a medical purpose that cannot be used in the absence of illness or injury or repeatedly by different individuals. CMS typically does not consider medical supplies and equipment as a covered benefit. DME (e.g., blood sugar monitors, blood sugar test strips, continuous glucose monitors, and infusion pumps and supplies) are durable healthcare materials used at home that can withstand repeated use, provide a medical purpose, and are not used in the absence of an illness or injury. In contrast to medical supplies and equipment, DME is covered under Medicare Part B. Finally, the Food and Drug Administration (FDA) defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory (FDA. Medical Devices. Available at: <https://www.fda.gov/medical-devices>. Accessed August 20, 2020).

Pharmacists are experts in initiating and managing a patient’s comprehensive medication management (CMM) plan. A CMM is an individualized care plan that helps patients achieve specific goals of therapy. The patient-centered medical home: integrating comprehensive medication management to optimize patient outcomes resource guide, 2nd ed. www.pcpcc.org/sites/default/files/media/medmanagement.pdf). Any intervention that supplements medication goals and improves a patient’s quality of life and patient outcomes should be considered in the CMM process and plan, including use of medical supplies and equipment, DME, and medical devices, and provide an opportunity for a pharmacist or

pharmacy technician to improve patient care.

ASHP has long advocated for the role pharmacists have in helping patients obtain and properly use drug delivery systems and devices. The ASHP Statement on the Pharmacist's Role with Respect to Drug Delivery Systems and Administration Devices states:

Pharmacists bear a substantial responsibility for ensuring optimal clinical outcomes from drug therapy and are suited by education, training, clinical expertise, and practice activities to assume responsibility for the professional supervision of drug delivery systems and administration devices. As a natural extension of efforts to optimize drug use, pharmacists should participate in organizational and clinical decisions with regard to these systems and devices.

Extension of those responsibilities to medication-related medical supplies and equipment, DME, and medical devices is a natural progression in pharmacist patient care. There are many actions that pharmacists can implement to help improve patient outcomes in regards to medical supplies and equipment, DME, and medical devices. To increase patient access, pharmacists can collaborate with patients and physicians to determine which device to use based on patient indication, preferences, and product specifications. Pharmacists could also collaborate with CMS and other insurance plans to ensure that patients have adequate coverage of DME along with advocating to allow pharmacists to submit claims for reimbursement. Furthermore, ASHP could collaborate with patient advocacy organizations and disease specific organizations (e.g., American Diabetes Association) to advocate for increased patient access to specific medical supplies and equipment.

Additionally, pharmacists can advocate for broader pharmacy management of medical supplies and equipment, DME, and medical devices along with medications as a part of the patient's CMM plan. Pharmacists can support patient access through documentation required for coverage, provide education on how to use the device, monitor the device for safety and efficacy, and interpret results if applicable. Collaborative practice agreements and credentialing and privileging are two ways pharmacist can use data provided from the devices to help make necessary changes to the patient's medication plan. Pharmacists' expertise should be leveraged to help patients procure and manage their medical supplies and equipment, DME, and medical devices to provide all-encompassing comprehensive medication management.

2137

DOCUMENTATION OF PHARMACIST PATIENT CARE

Source: Council on Pharmacy Practice

To promote the use of standardized, integrated documentation of pharmacist care provision in a patient's health record; further,

To advocate that documentation by pharmacists in the medical record be used for billing and attribution of value without requiring additional documentation from other clinicians; further,

To advocate for standardized measurement of pharmacist care provision and the attribution of those activities to patient-centered outcomes.

Rationale

ASHP has advocated for the importance of documentation of pharmacist care in patient medical records to ensure accurate and complete documentation of the care and services provided to the patient. However, differences in pharmacy practice within and across health systems make it hard to standardize such documentation in the electronic health record (EHR). The differences are caused by diverse clinical practices, EHR permissions, and documentation elements of the care provided by pharmacists. Documentation by the pharmacist may change depending on care settings, the level of care provided, or in respect to reimbursement. As a result, it is hard to validate and evaluate pharmacists' impact on patient outcomes due to the incomplete measurement and attribution of such care and lack of standardized documentation.

Other healthcare providers have released similar statements on documentation within their fields. The American College of Physicians states that physicians should define professional standards regarding clinical documentation and use macros and templates appropriately (Kuhn T, Basch P, Barr M et al. Clinical documentation in the 21st century: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med.* 2015; 162:301-3). The American Nurses Association (ANA) Principles for Nursing Documentation states that if patient documentation is not timely, accurate, accessible, complete, legible, readable, and standardized, it will interfere with the ability of those who were not involved in and are not familiar with the patient's care to use the documentation (ANA's Principles for Nursing Documentation: Guidance for Registered Nurses. 2010. www.nursingworld.org/~4af4f2/globalassets/docs/ana/ethics/principles-of-nursing-documentation.pdf). The American Speech-Language-Hearing Association (ASHA) states that speech-language pathologists should participate in the development of the templates that they will use for billing and clinical documents so that the information that is necessary is provided (ASHA. Documentation in health care. www.asha.org/PRPSpecificTopic.aspx?folderid=8589935365§ion=References).

Other healthcare providers have recognized the benefits of requiring their documentation to be recorded in a standardized form that allows other healthcare stakeholders to quickly access the information. Employing accessible, standardized documentation improves communication and knowledge sharing between providers. Pharmacists are valuable members of the healthcare team that contribute significantly to patient care. More consistency and standardization of a pharmacist's documentation can provide essential information on a patient's care, such as therapeutic drug monitoring, appropriateness and effectiveness of patient's medications, or pain and antibiotic management, for example. Standardized notes enable healthcare team members to review the pharmacist note and become aware of the medication plan. Implementing standardized and integrated documentation across all healthcare providers, especially pharmacists, will allow for increased interactions and information to be shared between healthcare providers to improve overall patient care. In addition, such standardized and integrated documentation by pharmacists should be used for billing and attribution of value without additional documentation requirements from other clinicians.

Implementing a standardized clinical pharmacy documentation system will also inform and enable a measurement approach for evaluation of the impact of pharmacist services. Many institutions use different tools for operational internal and external benchmarking to meet

these measures; however, the tools are limited in their use for clinical benchmarking (Rough SS, McDaniel M, Rinehart JR. Effective use of workload and productivity monitoring tools in health-system pharmacy, pt 1. *Am J Health Syst Pharm*. 2010; 67:300–11). Institutions have tried to implement their own clinical pharmacy productivity measures tools to help demonstrate the value of de-centralized pharmacists on patient care teams. However, no current measure or measure set accurately identifies the impact pharmacists have on patient care outcomes or allows comparison and benchmarking across institutions. In response to this need, the ASHP Pharmacy Accountability Measures (PAM) Work Group seeks to identify pharmacy-related clinical quality measures that institutions could use for benchmarking (Andrawis MA, Carmichael J. A suite of inpatient and outpatient clinical measures for pharmacy accountability: recommendations from the Pharmacy Accountability Measures Work Group. *Am J Health Syst Pharm*. 2014; 71:669-78).

The PAM Workgroup evaluated quality measures endorsed by the National Quality Forum (NQF) and curated those selected into six therapeutic areas, which include antithrombotic safety, cardiovascular control, glycemic control, pain management, behavioral health, and antimicrobial stewardship (Andrawis M, Ellison C, Riddle S et al. Recommended quality measures for health-system pharmacy: 2019 update from the Pharmacy Accountability Measures Work Group. *Am J Health Syst Pharm*. 2019; 76:874–87). Using the NQF-endorsed measures along with appropriate documentation of the care may allow institutions to more readily benchmark performance.

After determining the most appropriate pharmacy quality measures, the documentation of the care provided should be standardized and efficient. Implementing standardized templates and more retrievable data fields in the documentation process has been shown to improve workflow for pharmacists. One study demonstrated that by implementing EHR note templates that allowed retrievable data to be incorporated, pharmacists increased the amount of time providing value-added services from 47% to 72% and in providing direct patient care from 27% to 53% (Ekstrand MJ, Kobany JM, Pestka DL. Leveraging quality improvement principles in comprehensive medication management pharmacy practice: a case example. *J Am Pharm Assoc*. 2020; 60:509-15.e1.).

Finally, pharmacists must also be properly educated on how to use a standardized pharmacy documentation system. In one study, a health system that implemented an improved pharmacist documentation process found that a focused education initiative increased the number of pharmacist-delivered services by 120% while also improving cost avoidance (Rector KB, Veverka A, Evans SK. *Am J Health-Syst Pharm*. 2014; 71:1303–10). Overall, research has shown that focused education has helped improve the standardized documentation of pharmacist care, leading ultimately to better care for patients and demonstrating the value of pharmacy services.

2138

INFLUENZA VACCINATION REQUIREMENTS TO ADVANCE PATIENT SAFETY AND PUBLIC HEALTH

Source: Council on Pharmacy Practice

To advocate that hospitals and health systems require healthcare workers to receive an annual influenza vaccination in accordance with U.S. Centers for Disease Control and Prevention Advisory Committee on Immunization Practices recommendations; further,

To encourage the hospital and health-system pharmacy workforce to take a lead role in developing and implementing policies and procedures for vaccinating healthcare workers and in providing education on the patient safety benefits of annual influenza vaccination; further,

To work with the federal government and others to improve the vaccine development and supply system in order to ensure a consistent and adequate supply of influenza virus vaccine.

This policy supersedes ASHP policy 0615.

Rationale

The Centers for Disease Control and Prevention (CDC) estimates that the 2019-2020 influenza season was associated with 38 million illnesses, 18 million medical visits, 405,000 hospitalizations, and 22,000 deaths. The economic burden of influenza-attributable illness is estimated at over \$83 billion, encompassing direct costs such as hospitalizations and outpatient visits and indirect costs such as lost productivity from missed days at work.

Influenza immunization of healthcare workers can improve patient safety and decrease morbidity and mortality by protecting vulnerable patients such as young children and elderly, immunocompromised, and critically ill patients. The CDC has recommended vaccination of healthcare workers since 1981. In its recommendation, the CDC considers healthcare workers as including (but are not 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 healthcare workers and patients. In the 2019-2020 season, approximately 80% of healthcare workers were immunized against influenza, with rates over 90% among hospital employees, despite the fact that only approximately 70% of hospitals currently require an annual influenza vaccination, according to the CDC. Members of the pharmacy workforce have a responsibility, as knowledgeable purveyors of evidence-based medication information, to not only lead by example in receiving annual influenza vaccinations but also to take a lead role in developing and implementing policies and procedures for vaccinating healthcare workers and in providing education to healthcare workers and patients about the importance of influenza vaccination.

2139

SAFE AND EFFECTIVE EXTEMPORANEOUS COMPOUNDING

Source: Council on Pharmacy Practice

To affirm that extemporaneous compounding of medications, when done to meet immediate or anticipatory patient needs, is part of the practice of pharmacy and is not manufacturing; further,

To support the principle that medications should not be extemporaneously compounded when drug products are commercially and readily available in the form necessary to meet patient needs; further,

To encourage the pharmacy workforce members who compound medications to use only drug substances that have been manufactured in Food and Drug Administration-registered facilities and that meet official United States Pharmacopeia (USP) compendial requirements, where those exist; further,

To advocate that all compounding activities meet applicable USP standards and federal and state regulations; further,

To support the principle that the pharmacy workforce be adequately trained and have sufficient facilities and equipment that meet technical and professional standards to ensure the quality of compounded medications; further,

To encourage USP to develop drug monographs for commonly compounded preparations; further,

To educate prescribers and other healthcare professionals about the potential risks associated with the use of extemporaneously compounded preparations.

This policy supersedes ASHP policy 0616.

Rationale

The practice of compounding has evolved along with the profession of pharmacy and it remains an essential component of patient care and pharmacy practice. With advances in pharmaceutical manufacturing, the need for preparation of individualized medications based on a prescription or medication order has decreased but not disappeared. Extemporaneous compounding of medications, when done to meet immediate or anticipatory patient needs, will likely always be an essential part of the practice of pharmacy, and cannot be replaced by any manufacturing model currently envisioned. Commercially and readily available drug products in the form necessary to meet patient needs should always be preferred to extemporaneously compounded alternatives. When extemporaneous compounding is required, it should meet strict requirements to protect patients from receiving substandard or poor-quality medications that pose a safety risk to their health and well-being. In particular, extemporaneously compounded sterile preparations must ensure highest quality. Extemporaneous compounding should be performed only using drug substances that have been manufactured in Food and Drug Administration-registered facilities and that meet official United States Pharmacopeia (USP) compendial requirements. Such compounding should only be performed by adequately

trained pharmacists and pharmacy technicians, in facilities and with equipment that meet technical and professional standards to ensure the quality and integrity of the compounded medication, and in accordance with USP standards and other applicable federal and state regulations. To facilitate such a high level of compounding, USP should develop drug monographs for commonly compounded preparations. ASHP and its members have always devoted a great deal of effort to promoting safe extemporaneous compounding, through education of pharmacists and pharmacy technicians, publication of best practices, and advocacy, recognizing the inherent risks of any such endeavor. Pharmacists and pharmacy technicians have a responsibility to safely prepare and distribute compounded medications to meet the unique and customized therapeutic needs of their patients, and ASHP and pharmacists therefore have a responsibility to educate prescribers and other healthcare professionals about the potential risks associated with the use of extemporaneously compounded preparations.

2140**UNIVERSAL IMMUNIZATION FOR VACCINE-PREVENTABLE DISEASES IN THE HEALTHCARE WORKFORCE**

Source: Council on Pharmacy Practice

To support policies 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 vaccines approved by the Food and Drug Administration (FDA) and encouraging the use of vaccines that have received FDA emergency use authorization, if risk assessments determine it would 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 prevent vaccine-preventable diseases among healthcare workers.

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. Although voluntary vaccination of healthcare workers (HCWs), supported by employer-offered strategies, increases vaccination rates to some extent, mandatory vaccination requirements carry heavier weight and can result in near-universal vaccination rates. The effectiveness of this 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.

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; 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.

2141

PHARMACIST ENGAGEMENT IN AND PAYMENT FOR TELEHEALTH

Source: Council on Public Policy

To advocate for pharmacists' provision of telehealth services in all sites of care; further,

To advocate that reimbursement for pharmacists' provision of telehealth services be commensurate with the complexity and duration of service and consistent with other healthcare providers.

Rationale

During the COVID-19 public health emergency, hospitals, health systems, and clinics quickly pivoted to providing patient services via telehealth. The Centers for Medicare & Medicaid Services, commercial payers, and state policymakers have indicated that they would like to maintain telehealth services post-pandemic. Because pharmacists are not Medicare-eligible, it has been a struggle to ensure that they can be reimbursed for services provided via telehealth. In particular, it is vital that services be reimbursed at a level commensurate with the complexity and duration of the service and consistent with other healthcare providers, to ensure that patients can maintain access to services.

2142

PHARMACY SERVICES IN A STATE OF EMERGENCY

Source: Council on Public Policy

To advocate that states grant temporary licensure, registration, or any other necessary state-mandated credentials to eligible pharmacies and members of the pharmacy workforce during states of emergency; further,

To encourage expedient licensure or registration for eligible members of the pharmacy workforce during states of emergency; further,

To advocate that state and federal regulatory agencies allow for flexibilities necessary to provide patient care during a declared state of emergency.

Rationale

During the COVID-19 pandemic, both state and federal policymakers scrambled to provide the regulatory flexibility necessary to allow patients to access pharmacist services. Although states are generally willing to be flexible about dispensing during a public health emergency, pharmacy services themselves are not subject to the same degree of flexibility. Specifically, pharmacists, more so than other clinicians, struggled to get temporary licensure across state lines, and pharmacy technicians experienced similar challenges in states that require registration. The lack of access to temporary licensure and registration impeded the ability of pharmacists and pharmacy technicians to move to areas of great need or to volunteer in states with patient surges. Further, pharmacy services require flexibility, particularly around inventory control and the ability to reallocate product and the ability to quickly establish alternate sites of care. During the COVID-19 public health emergency, remdesivir was allocated to the states, and then the state retained full control over distribution, which resulted in situations in which hospitals could not transfer product across state lines to other hospitals, even to related entities, that needed the product more.

2143

ASHP STATEMENT ON THE ROLES AND RESPONSIBILITIES OF THE PHARMACY EXECUTIVE

Source: Council on Pharmacy Management

To approve the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive.

2144

AGRICULTURAL USE OF HORMONE AND PROHORMONE THERAPY

Source: Council on Therapeutics

To advocate that the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) re-evaluate the agricultural use of hormone and prohormone therapies for purposes of animal growth promotion based on evidence demonstrating potential adverse effects on human health; further,

To advocate that the FDA and USDA eliminate approval for nontherapeutic uses in agricultural animals of hormone and prohormone therapies that are known to cause adverse effects on human health; further,

To encourage efforts to eliminate the nontherapeutic agricultural uses of hormone and prohormone therapies previously approved by the FDA and USDA; further,

To support the therapeutic use of hormone and prohormone therapies in animals only under the supervision of a veterinarian; further,

To encourage additional research on hormone and prohormone therapies to better define the public health impact of these therapies for agricultural purposes.

Note: This policy supersedes ASHP policy 1102.

Rationale

Natural (e.g., estradiol, progesterone, testosterone) and synthetic (trenbolone, zeranol, melengestrol) hormones are commonly used for growth promotion in beef cattle raised in the United States. While the European Union has banned the use of these substances for growth promotion based on safety concerns, the USDA and FDA have long supported use of these substances based on studies conducted in the 1970s. Of note, a 2002 statement from the FDA stated that the use of hormones for agricultural purposes was safe. However, more recent research has raised new concerns about potential harm to human health, including epidemiological studies demonstrating increased rates of breast cancer in women, testicular cancer and decreased fertility in men, and hormone-related developmental issues in infants and children.

Hormone therapies for agricultural purposes should be re-examined based on this new evidence and because technology for measuring exposure to hormone substances has improved since the initial decision by the USDA and FDA. In addition, research to examine the public health impact of agricultural uses of hormone and prohormone therapies needs to be encouraged.

2145

REDUCTION OF UNUSED PRESCRIPTION DRUG PRODUCTS

Source: Council on Pharmacy Practice

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

To advocate for staffing, research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, reconciled, and dispensed; further,

To advocate that the pharmacy workforce take a leadership role in reducing excess quantities of unused prescription drug products, including the provision of patient and caregiver education, raising public awareness, and supporting and integrating medication take-back programs.

Note: This policy supersedes ASHP policy 1702.

Rationale

According to the [Centers for Disease Control and Prevention](#) (CDC), almost 5% of the U.S. population over 12 years old used prescription pain relievers for nonmedical reasons in 2010, resulting in 15,000 overdose deaths. A major source of diversion is unused prescription drug products, such as those left over after a patient has gained relief from temporary pain. Although prescribers and other healthcare providers have long been aware of the dangers of unused prescription drug products, incentives for overprescribing remain. The desire to minimize office visits, concern about undertreatment of pain, and prohibitions against partial fills and refills of controlled substances contribute to overprescribing. In addition to the risk of misuse, abuse, and diversion, research reveals that as many as 10 million prescriptions go unused every year, resulting in up to \$5 billion in wasted medication (Lenzer J. *BMJ* 2014; 349:g7677). There is clearly a need for concentrated effort to minimize medication waste from unused prescription drug products.

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

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

2146**EXPIRATION DATING OF PHARMACEUTICAL PRODUCTS**

Source: Council on Pharmacy Practice

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs, such as medications in shortage or used for medical countermeasures, and reducing healthcare costs; further,

To advocate that the Food and Drug Administration implement procedures for pharmaceutical manufacturers to readily update expiration dates to reflect current evidence regarding the maximum length of drug potency and safety, using technology solutions when available; further,

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

Note: This policy supersedes ASHP policy 1712.

Rationale

Extending the expiration date of commercially available pharmaceutical products for as long as possible, while maintaining drug potency and safety, reduces healthcare costs and increases access. This is especially important with medications in short supply or those used as medical countermeasures (i.e., FDA-regulated products [biologics, drugs, devices] that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease). ASHP encourages pre- and post-marketing research on expiration dates and the use of the most current authoritative data on expiration dates in drug product management. However, the current process for updating expiration dates in drug product labeling presents barriers to timely revision and should be streamlined to allow for timely updates. Technology solutions should be leveraged when possible to determine and communicate about expiration date extensions. Until such a process is implemented, regulators and accreditation agencies should permit healthcare organizations to rely on authoritative data when determining appropriate extended expiration dates for commercially available pharmaceutical products.

2147**PHARMACIST'S ROLE IN HEALTHCARE INFORMATION SYSTEMS**

Source: Council on Pharmacy Management

To strongly advocate key decision-making roles for pharmacists in the planning, selection, design, implementation, and maintenance of medication-use information systems, electronic health records, computerized provider order entry systems, and e-prescribing systems to balance the security and integrity of data with the ability to facilitate clinical decision support, data analysis, and education of users for the purpose of ensuring the safe and effective use of medications; further,

To advocate for incentives to hospitals and health systems for the adoption of patient-care technologies; further,

To recognize that design, maintenance, and cyber-security of medication-use information systems is an interdisciplinary process that requires ongoing collaboration among many disciplines; further,

To advocate that pharmacists must have accountability for strategic planning and direct operational aspects of the medication-use process, including the successful deployment of medication-use information systems and continuity plans when the systems are unavailable.

Note: This policy supersedes ASHP policies 1211 and 1701.

Rationale

ASHP recognizes that design, maintenance, and cyber-security of healthcare information systems (e.g., medication-use information systems, electronic health records, computerized provider order entry systems, e-prescribing systems) is an interdisciplinary process that requires ongoing collaboration across many disciplines. Maintaining the privacy of health information, in compliance with the Health Insurance Portability and Affordability Act (HIPAA),

and ensuring patient safety in the face of cyber-attacks are essential concerns for every healthcare organization. Given the ever-evolving nature of pharmacist patient care, medication use, and health information technology, it is essential pharmacists have key decision-making roles in the planning, selection, design, implementation, and maintenance of such systems in order to help prevent and respond to cyber-attacks. To ensure the safe and effective use of medications, pharmacists must have accountability for strategic planning and direct operational aspects of the medication-use process, including the successful deployment of medication-use-related information systems by assessing vulnerabilities and vendor systems to validate the security and integrity of the data. Increased connectivity with vendor systems creates a mutual need to share access to patient information and other vital data, so risk mitigation must be considered at all points of access. This includes, for example, facilitating clinical decision support by assessing the minimum amount of patient health information vendors require to provide services, data analysis, education of users, and developing and implementing business continuity plans, to include fail-over testing of these plans, for when the systems are unavailable.