

House of Delegates

Board of Directors Report: Policy Recommendations for the June 2023 House of Delegates

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COUNCIL ON PHARMACY PRACTICE POLICY RECOMMENDATIONS

The Council on Pharmacy Practice is concerned with ASHP professional policies related to the responsibilities of pharmacy practitioners. Within the Council's purview are (1) practitioner care for individual patients, (2) practitioner activities in public health, (3) pharmacy practice standards and quality, (4) professional ethics, (5) interprofessional and public relations, and (6) related matters.

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Council Members

Vivian Johnson, Board Liaison

1. Emergency Medical Kits

- 1 To recognize the importance of immediate, readily accessible emergency medical kits
- 2 (EMKs) in locations inaccessible to emergency medical services; further,
- 3 To advocate for the inclusion of pharmacist expertise in the interprofessional decisions
- 4 related to stocking and maintaining medications in EMKs; further,
- 5 To collaborate with other professions and stakeholders to determine appropriate
- 6 locations for EMKs.

Rationale

A social media movement called attention to the lack of standardization in emergency medical kits (EMKs) during an in-flight medical emergency. U.S. CFR 121.803 – Emergency Medical Equipment – requires certain medications and supplies for flights in case of medical emergencies but does not require the stocking of naloxone for reversing opioid overdoses or epinephrine autoinjectors for ease of administration, among many other medications and supplies. Many locations that are not accessible to emergency medical services (EMS), such as airplanes, contain a stock of emergency supplies and medications that are not standardized and may not be adequate to



manage some emergencies. In 2019, the Aerospace Medical Association Air Transport Medicine Committee sent recommendations to the Federal Aviation Administration regarding the contents of emergency medical kits, including recommendations to add naloxone and an epinephrine autoinjector (EpiPen).

The World Health Organization (WHO) has developed standardized health kits of medicines and medical supplies to meet different health needs in humanitarian emergencies and disasters. These kits are developed to provide reliable and affordable medicines and supplies quickly to those in need. The kits are used by United Nations agencies, nongovernmental organizations, and national governments. The contents of these kits are based primarily on the WHO's Essential Medicines list and guidelines on treatment of specific medial conditions. The contents of the kits are frequently reviewed and updated to adapt to changing needs based on experience in emergency situations. However, the WHO List of Essential Medicines does not specify an auto-injector for use in anaphylaxis.

There is growing concern regarding the need to standardize requirements set by a governing body to ensure that EMKs contain appropriate medications and supplies that are easy to use in an emergency, have been audited to ensure they contain the required items, have been stored appropriately, and do not contain expired products. Standardization of EMK contents would simplify flight crew and staff training requirements, which would include what products are contained within the EMKs, how to use them (when appropriate), and when to provide the kits in the case of an emergency. Finally, it is critical to collect and track incident and outcomes data to promote improvement in emergency response, and pharmacist involvement in the interprofessional evaluation of that data is essential.

Background

The Council examined this topic in response to suggestions from ASHP members. The recommendation came after a physician shared her experience assisting a passenger with a medical emergency on a flight to Europe. In an online article, the physician stated that if she and the crew had really needed to do something emergently to help a patient in distress, she would have been unprepared. The EMK she was provided included a disposable stethoscope and a disassembled blood pressure cuff and lacked a pulse oximeter, glucometer, and EpiPen. As the Council discussed this situation, they agreed that ASHP policy regarding stocking and maintaining EMKs is needed.

2. Raising Awareness of the Risks Associated with the Misuse of Medications

- To encourage pharmacists to engage in community outreach efforts to provide
- education on the risks associated with use of medications for nonmedical purposes or
- 3 from nonmedical sources; further,
- 4 To encourage pharmacists to advise authorities, patients, and the community on the
- 5 dangers of using medications for nonmedical purposes.



Rationale

Misuse of medications involves the use of prescription and over-the-counter medications in ways that are not prescribed or directed. The use of medications for nonmedical purposes is also a category of misuse. Misuse may lead to serious consequences, such as emergency department visits, hospitalization, and death. While most of the evidence regarding medication misuse is related to opioids, central nervous system depressants, and stimulants, misuse of any medication may result in patient harm. As such, efforts to raise awareness of the risks of misusing any medication needs to prioritized, in addition to specific medications and medication classes. Pharmacists, as medication experts, can identify red flags and patterns of medication misuse and support community outreach efforts to help patients understand the risks associated with the misuse of medications.

Background

While the Council reviewed ASHP policy 1305, Education about Performance-Enhancing Substances, during sunset review, they noted a gap in ASHP policy related to the misuse of medications broadly. The Council felt that this proposed new policy would fill a gap between existing policies related to abuse and misuse of performance-enhancing and controlled substances.

3. Standardization of Medication Concentrations

- 1 To support adoption of nationally standardized drug concentrations and dosing units for
- 2 medications administered to adult and pediatric patients, and to limit those
- 3 standardized concentrations and dosing units to one concentration and one dosing unit
- 4 when possible; further,
- 5 To encourage interprofessional collaboration on the adoption and implementation of
- 6 standardized drug concentrations and dosing units across the continuum of care;
- 7 further,
- 8 To encourage manufacturers and outsourcing facilities to provide medications in those
- 9 standardized concentrations when it is clinically appropriate and feasible.

Note: This policy would supersede ASHP policy 1306.

Rationale

Standardization and simplification are widely accepted methods for reducing variability in processes and risk for error. With increased adoption of intelligent infusion devices, use of standard concentrations has enhanced infusion safety by eliminating most dosing and rate calculations. Standardizing concentrations reduces the potential for errors, particularly during transitions of care; simplifies ordering by providing fewer choices, which decreases provider



uncertainty; reduces operational variations, which enhances provider efficiency; and streamlines manufacturing, which accelerates production and allows for the formulation of premixed medications. In addition, broader use of standard concentrations might stimulate industry to offer a broader array of ready-to-administer infusions and facilitate the development of drug libraries.

In 2015, ASHP launched the Standardize 4 Safety (S4S) initiative. Funded by the U.S. Food and Drug Administration (FDA) and helmed by ASHP, S4S is the first national, interprofessional effort to standardize medication concentrations to reduce errors resulting from confusion over nonstandardized drug concentrations and errors that result from concentration differences when patients transition their care from one setting to another. To date, the expert committees have developed four lists—standardized concentrations for adult continuous infusions, pediatric continuous infusions, compounded oral liquids, and PCA/epidural infusion—and the S4S Initiative offers the pharmacy workforce other resources to help implement standardized concentrations.

Background

The Council reviewed ASHP policy 1306, Standardization of Intravenous Drug Concentrations, as part of sunset review and voted to recommend amending it as follows (<u>underscore</u> indicates new text; <u>strikethrough</u> indicates deletions):

To develop support adoption of nationally standardized drug concentrations and dosing units for commonly used high risk drugs that are given as continuous infusions medications administered to adult and pediatric patients, and to limit those standardized concentrations and dosing units to one concentration and one dosing unit when possible; further,

To encourage all hospitals and health systems to use infusion devices that interface with their information systems and include standardized drug libraries with dosing limits, clinical advisories, and other patient-safety-enhancing capabilities; further,

To encourage interprofessional collaboration on the adoption and implementation of standardized drug concentrations and dosing units in hospitals and health systems across the continuum of care; further,

To encourage manufacturers and outsourcing facilities to provide medications in those standardized concentrations when it is clinically appropriate and feasible.

The Council suggested these amendments to broaden the scope of the policy beyond commonly used high-risk drugs to include a wider range of medications, to encourage limiting the standardized concentrations and dosing units to one where feasible, and to encourage manufacturers and outsourcing facilities to provide medications in those concentrations when appropriate and feasible.



4. Pharmacoequity

- 1 To recognize that disparities in standards of care negatively impact healthcare
- 2 outcomes and compromise pharmacoequity in marginalized and underserved
- 3 populations; further,
- 4 To recognize the impact of social determinants of health on pharmacoequity and
- 5 patient outcomes; further,
- To advocate that the pharmacy workforce identify and address threats and patient
- vulnerabilities to pharmacoequity as part of comprehensive medication management
- 8 services; further,
- 9 To advocate for resources, including technology, that improve access to care for
- underserved populations where pharmacy access is limited; further,
- To raise awareness about implicit and unconscious bias in healthcare decision-making
- that may compromise pharmacoequity; further,
- To advocate for drug availability, drug pricing structures, and insurance coverage
- determinations that promote pharmacoequity.

Rationale

Pharmacoequity aims to ensure that all individuals regardless of race and ethnicity, socioeconomic status, or availability of resources, have access to the highest quality medications required to manage their health needs. Barriers contributing to the lack of pharmacoequity include decreased access to care, increased costs of care, and differences in care based on provider bias (Essien UR, Dusetzina SB, Gellad WF. A policy prescription for reducing health disparities—achieving Pharmacoequity. *JAMA*. 2021;326(18):1793. doi:10.1001/jama.2021.17764). These barriers have helped raise awareness of the ABCs of solutions for promoting pharmacoequity: access, bias, and costs.

Decreased access to care may be due to insufficient prescription drug coverage or residing in a pharmacy desert. The current trends in the price of prescription drugs, combined with lack of insurance or underinsurance, results in lower use of prescribed medication and non-adherence. Pharmacists can help build culturally competent structures to reduce racial and ethnic disparities in healthcare through various means including promoting a more diverse work force, increasing awareness of disparities, promoting culturally competent care and services, researching and implementing best practices for providing culturally competent care, and ensuring effective communication with patients and among providers (ASHP Statement on Racial and Ethnic Disparities in Health Care, *Am J Health-Syst Pharm.* 2008; 65:728–33, doi.org/10.2146/ajhp070398).

Ensuring that all individuals regardless of race and ethnicity, socioeconomic status, or



availability of resources have access to the highest quality medications required to meet their needs will require a multifaceted approach. Promotion of culturally competent structures through increased awareness of disparities and diversification of the workforce, in addition to improving medication affordability and pharmacy access, are all steps needed to attain pharmacoequity.

Background

The Council examined this topic in response to suggestions from ASHP members. The Council considered existing ASHP policies, such as 2029, Preserving Patient Access to Pharmacy Services by Medically Underserved Populations, and 2231, Cultural Competency, and felt there was still a need to address pharmacoequity in a separate policy.

5. Medication Administration by the Pharmacy Workforce

- To support the position that the administration of medications is part of the routine
- scope of pharmacy practice; further,
- 3 To support the position that members of the pharmacy workforce who administer
- 4 medications should be skilled to do so; further,
- 5 To advocate that states grant pharmacists and appropriately supervised student
- 6 pharmacists and pharmacy technicians the authority to administer medications; further,
- 7 To support the position that pharmacists should be participants in establishing
- 8 procedures in their own work settings with respect to the administration of medications
- (by anyone) and monitoring the safety and outcomes of medication administration.

Note: This policy would supersede ASHP policy 9820.

Rationale

Laws, regulations, and local policies on medication administration vary greatly. Medications are routinely administered by many different practitioners, including nurses, physicians, radiology and nuclear medicine technologists, nurses aides, laboratory technologists, dental hygienists, respiratory therapists, and physical therapists. ASHP believes that administration of medications is part of the routine scope of pharmacy practice and supports laws, regulations, and local policies that allow for it and for medication administration by appropriately trained and supervised student pharmacists and pharmacy technicians. Decisions about pharmacists' involvement in medication administration should be made by individual healthcare organizations, which have an awareness of their resources and the adequacy of their medication administration processes. Patient need should be the primary factor in deciding who administers medications in any institution. In any case, all persons who administer medications, including pharmacists, student pharmacists, and pharmacy technicians, should be



appropriately trained to do so. Those who administer medications should be knowledgeable and skilled in the use of all medication administration and monitoring devices they use (e.g., syringes, infusion pumps, and blood glucose monitors). Finally, pharmacists should be involved in the institution's decision-making process regarding procedures used to administer medications.

Background

The Council reviewed ASHP policy 9820, Medication Administration by Pharmacists, as part of sunset review and voted to recommend amending it as follows (<u>underscore</u> indicates new text; strikethrough indicates deletions):

To support the position that the administration of <u>medications</u> medicines is part of the routine scope of pharmacy practice; further,

To support the position that pharmacists members of the pharmacy workforce who administer medications medicines should be skilled to do so; further,

To advocate that states grant pharmacists and appropriately supervised student pharmacists and pharmacy technicians the authority to administer medications; further,

To support the position that pharmacists should be participants in establishing procedures in their own work settings with respect to the administration of medicines medications (by anyone) and monitoring the safety and outcomes of medication administration.

The Council suggested the amendments to acknowledge the medication administration roles of other members of the pharmacy workforce (student pharmacists, pharmacy technicians) and to add language advocating for recognition of those roles in state laws and regulations. Prior to this sunset review, policy 9820 did not have rationale. It has been added to these minutes and will move forward to be included in the next update of ASHP policies.

6. Reducing Healthcare Sector Carbon Emissions to Promote Public Health

- 1 To promote reducing carbon emissions from the healthcare sector through
- 2 collaboration with other stakeholders; further,
- 3 To encourage members of the pharmacy workforce to seek out opportunities to engage
- 4 in efforts to reduce carbon emissions in their workplaces and communities.

Rationale

ASHP acknowledges the scientific consensus on the adverse impact of carbon emissions on human health and the environment and recognizes the need to reduce carbon emissions, including from the healthcare sector. Climate change negatively impacts human health and



increases strain on the healthcare system. Health-related consequences of climate change that lead to increased morbidity and mortality include but are not limited to heat-related illnesses, respiratory illnesses, and vector-borne diseases. The 2015 Lancet Commission on Health and Climate Change concluded that addressing climate change is the greatest public health opportunity of the 21st century and that failure to adequately address climate change could undo most of the past century's progress in global health.

Carbon emissions are a target for addressing climate change. It has been estimated that the healthcare sector is responsible for 8.5% of carbon emissions in the U.S. Sources of healthcare carbon emissions rank as follows: healthcare facility operations (estimated to account for 7% of healthcare sector emissions); purchased sources of energy, heating, and cooling (11%); and healthcare sector procurements or supply chain for services and goods (>80%).

Healthcare organizations have been called upon to reduce their carbon footprint ("decarbonize") as a measure to promote patient and public health. The federal government has goals to decrease carbon emissions by 50% by 2030 and to achieve net-zero levels by 2050. Many healthcare-related organizations have made climate change and decarbonization pledges, including the members of the Medical Society Consortium on Climate & Health and organizations engaged in the National Academy of Medicine (NAM) Action Collaborative on Climate Change and as. In the fall of 2021, NAM launched the Action Collaborative on Decarbonizing the U.S. Health Sector (the "Climate Collaborative"), mobilizing four work groups: healthcare supply chain and infrastructure; healthcare delivery; health professional education and communication; and policy, financing, and metrics.

The pharmacy workforce has an important role in reducing carbon emissions from healthcare-related sources (Beechinor RJ et al. Climate change is here: what will the profession of pharmacy do about it? *Am J Health-Syst Pharm*. 2022; 79:1393-6). ASHP encourages collaboration with stakeholders that share a commitment to reducing carbon emissions from the healthcare sector and encourages members of the pharmacy workforce to seek out opportunities to engage in efforts to reduce carbon emissions in their workplaces and communities. To fill their roles in reducing carbon emissions, the pharmacy workforce will require education, training, and resources on emissions-reduction strategies. The development of evidence-based strategies will require research and dissemination of information on ways to reduce carbon emissions.

Background

The Council examined this topic in response to suggestions from ASHP members and staff. The Biden-Harris Administration and the Health and Human Services have called on healthcare stakeholders to (1) reduce their organization's emissions by 50 percent by 2030 and achieve net zero by 2050; (2) publicly report on their progress; (3) complete an inventory of Scope 3 (value chain) emissions; and (4) develop climate resilience plans for their facilities and communities. Since then, over 650 hospitals, health systems, suppliers, pharmaceutical and medical device companies, and other industry stakeholders submitted pledges to the White House with their commitments. Providence Health, Kaiser Permanente, The Joint Commission, the American College of Physicians, and NAM are among those organizations.

The Council noted that although many healthcare-related organizations have made



climate change and decarbonization pledges, there is a notable absence of pharmacy organizations, which offers ASHP an opportunity provide leadership in these important efforts. The Council suggested that ASHP express support for the NAM initiative as well as other collaborative efforts to reduce the healthcare sector's carbon footprint and pledge to foster education, training, and the development and dissemination of resources to support the pharmacy workforce in reducing carbon emissions. Further, the Council suggested that the Board of Directors consider developing an ASHP commitment statement on reducing healthcare carbon emissions, similar to the <u>ASHP Commitment Statement on Diversity, Equity, and Inclusion</u>.



COUNCIL ON THERAPEUTICS POLICY RECOMMENDATIONS

The Council on Therapeutics is concerned with ASHP professional policies related to medication therapy. Within the Council's purview are (1) the benefits and risks of drug products, (2) evidence-based use of medicines, (3) the application of drug information in practice, and (4) related matters.

Council Members

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Pamela K. Phelps, Board Liaison

1. Availability and Use of Fentanyl Test Strips

- 1 To affirm that fentanyl test strips (FTS) have a place in harm reduction strategies for
- 2 people who use drugs; further,
- To support legislation that declassifies FTS as drug paraphernalia; further,
- 4 To promote continued widespread availability of and access to FTS at limited to no cost
- 5 to the public; further,
- 6 To foster research, education, training, and the development of resources to assist the
- 7 pharmacy workforce, other healthcare workers, patients, and caregivers in the use and
- 8 utility of FTS; further,
- 9 To support the pharmacy workforce in their roles as essential members of the
- healthcare team in educating the public and healthcare providers about the role of FTS
- in public health efforts.

Rationale

In April 2021 the National Center for Health Statistics reported that in the past 12-month period there were over 100,000 drug overdose deaths in the United States, with fentanyl responsible



for over two thirds of those deaths. Fentanyl, a synthetic opioid, is 50 to 100 times more potent than morphine, and therefore the risk of overdose is higher than with other opioids, particularly when the person consuming the fentanyl is not aware of its presence or has not developed a tolerance to it.

Studies have shown that fentanyl test strips (FTS) are used by people who use drugs (PWUD) to check their drugs for the presence of fentanyl and mitigate overdose risk by making informed decisions about their safety when consuming. The findings of a 2018 study suggest that the distribution and use of rapid fentanyl test strips are a feasible and PWUD-accepted harm reduction tool to detect the presence of fentanyl in illicit drugs. As a result, as part of the effort to reduce overdoses and promote harm reduction, state and county health departments and community organizations across the United States have started to distribute FTS as a low-barrier, inexpensive drug-checking strategy. Through the SUPPORT Act, the Centers for Disease Control and Prevention, the U.S. Department of Health and Human Services, and the Substance Abuse and Mental Health Services Administration are permitted to provide funding to be used to purchase FTS as a part of harm reduction efforts.

Currently, a little more than half the states in the U.S. have laws that declassify FTS as drug paraphernalia. Laws in the remaining states that designate FTS as drug paraphernalia may prevent states and organizations from applying for those grants or using their own funds to purchase FTS. Although many states have legislation in the works to remove this barrier, some states are reluctant to make this change, due to the perception that the use of FTS as quality control devices could encourage PWUD to seek out a stronger high rather than reduce the use of fentanyl, reinforcing risky behavior.

Further research is needed to test the effectiveness of FTS use in combination with behavioral interventions to increase use of established harm reduction practices and risk-reduction behaviors, prevent or reduce the risk of opioid overdose, and to better understand how social and drug-using networks could be leveraged for dissemination of novel strategies such as fentanyl testing interventions into existing overdose education and naloxone distribution programs.

The pharmacy workforce is well equipped meet the needs of PWUD and the use of FTS. For example, in June of 2022, the Illinois General Assembly passed H.B. 4556, which expands the ability of pharmacists and other healthcare professionals to distribute FTS. The Ohio State University School of Pharmacy offers a naloxone and FTS training and distribution event as an effort to reduce harm, to meet patients where they are, and to provide services along a continuum of care. Legislation and programs like these demonstrate the value of the pharmacy workforce and should be expanded throughout the United States.

Background

The Council discussed the role fentanyl has played in exacerbating the overdose and death toll in the opioid epidemic. The Council reviewed the Office of National Drug Control Policy's harm reduction strategy, which focuses on syringe exchange services, naloxone distribution, and FTS; the availability federal funding for organizations to purchase FTS; and the research supporting their use. The Council noted that although the American Medical Association has brief statements on FTS, there are no other pharmacy organizations that support the use of FTS and that the public health benefits of a policy on FTS would be advantageous for ASHP.



2. Manipulation of Drug Products for Alternate Routes of Administration

- To advocate that the Food and Drug Administration encourage drug product
- 2 manufacturers to identify changes in pharmacokinetic and pharmacodynamic
- properties of drug products when manipulated for administration through an alternate
- delivery system or different route than originally studied, and to make this information
- 5 available to healthcare providers; further,
- 6 To collaborate with stakeholders to increase research on clinically relevant changes to
- 7 pharmacokinetic and pharmacodynamic properties of drug products when manipulated
- 8 or administered through a different route and to enhance the aggregation and
- 9 publication of and access to this data; further,
- To research and promote best practices for manipulation and administration of drug
- products through alternate routes when necessary; further,
- To foster pharmacist-led development of policies, procedures, and educational
- resources on the safety and efficacy of manipulating drug products for administration
- through alternate routes.

Rationale

Manipulation of a drug product can include crushing, splitting, or suspending it in a solvent, which can alter the pharmaceutical properties of the original dosage form. These manipulations are often performed because a patient requires the medication administered enterally but is unable to take the medication by mouth, requires a dose that is not readily available and so can only be delivered through manipulation, or is unable to swallow or has a feeding tube placed necessitating manipulation. For patients who lose the ability to swallow easily (e.g., due to stroke or cancer), it is sometimes quite difficult to provide all their drug products via liquid formulations or those that can be crushed, due to lack of such products.

Complicating the clinical picture is that in many studies of oral drug products the dose passes through the stomach, exposing it to a specific set of pH conditions. The stomach may be bypassed when drug products are administered via feeding tube to organ systems in the body that may have a different pH, affecting the adsorption, metabolism, or distribution of the drug. Some drug products cannot be administered because they are insoluble in aqueous solutions. In addition, the physical properties of the manipulated formulation may also cause obstruction and clogging of enteral tubes used for feeding and medication administration, leading to undesirable outcomes, including supra- or subtherapeutic concentrations in the body, which could lead for example to organ rejection in transplant patients, loss of viral suppression in HIV-positive patients, or toxicities when manipulating an extended-release tablet. There are also exposure risks to caregivers preparing or administering manipulated drug products that are carcinogenic or teratogenic.

Additionally, there are too few resources that provide guidance on how manipulation



may affect the bioavailability of the drug product or whether the manipulated drug product remains bioequivalent with the original dosage form. There is even less research or publicly available information on the clinical effects of manipulated drug products. ASHP encourages manufacturers and independent clinical and practice-based researchers to conduct studies on these subjects and to disseminate this information via journal articles and other easily accessible resources. ASHP also encourages education of the pharmacy workforce and other healthcare providers regarding the basic principles of and drug dosing for manipulated drug products.

Background

The Council discussed current challenges in treating patients who may be unable to take drug products in their original form by mouth due to issues with swallowing, dose titration, and the presence of feeding tubes. Members shared experiences in which the only way to find out whether a drug product can be crushed or crushed and dissolved/suspended is to call the manufacturer, who may or may not have information on a particular drug product. Members also noted that the increasing sophistication of manufacturing has included the use of binders that may not permit manipulation at all. The Council stated that information is not easy to find or does not exist and that questions about manipulation go far beyond inquiries on whether or not an extended-release tablet can be cut. Council members agreed that the FDA could incentivize manufacturers to perform studies on manipulation of original dosage forms, but they recognized that such incentives may lead to unintended negative consequences, including recommendations that drug products not be manipulated, which could lead to loss of therapy options. The Council also noted that an incentive may not be enough for manufacturers to pursue such studies. Therefore, the Council also recommended that ASHP pursue partnerships with other stakeholders in an approach similar to the Standardize for Safety Initiative to set standards and recommendations for manipulation and administration of drug products.

3. DEA Scheduling of Controlled Substances

- To advocate that the Drug Enforcement Administration (DEA) establish clear,
- 2 measurable criteria and a transparent process for scheduling determinations; further,
- 3 To urge the DEA to use such a process to re-evaluate existing schedules for all
- 4 substances regulated under the Controlled Substances Act to ensure consistency and
- 5 incorporate current science-based evidence concerning scheduling criteria; further,
- 6 To advocate that the United States Congress define the terms potential for abuse,
- 7 currently accepted medical use, and accepted safety for use in the Controlled
- 8 Substances Act; further,
- 9 To monitor the effect of DEA scheduling of products under the Controlled Substances
- Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to



- assess the impact on patient access to these medications and on the practice burden of healthcare providers; further,
- To advocate for the alignment of federal and state laws to eliminate barriers to research on and therapeutic use of Schedule I substances.

Note: This policy would supersede ASHP policy 1315.

Rationale

Since its passage in 1970, the Controlled Substances Act (CSA) has served as the foundation of modern drug control policy by regulating the manufacture, importation, possession, use, and distribution of certain substances. The CSA lists eight factors to be considered by the Drug Enforcement Administration (DEA) when deciding if a molecular entity should be scheduled: (1) the potential for abuse; (2) scientific evidence of its pharmacological effect; (3) state of current scientific knowledge regarding the substance; (4) history and current pattern of abuse; (5) scope, duration, and significance of abuse; (6) risk to public health; (7) its psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled. The CSA then specifies that the three criteria used to determine the schedule of a substance include (1) its potential for abuse; (2) whether it has a medical use; and (3) its safety and risk of dependence. Several limitations of the aforementioned factors and criteria are worth noting. First, the eight factors are redundant and lack clarity. Second, the CSA does not specify the relationship between the eight factors and the three criteria for scheduling, and the DEA has not yet clarified this matter.

Additionally, the CSA does not explicitly define the terms *potential for abuse* or *accepted medical use*, giving the DEA much discretion to apply the scheduling criteria. The DEA has maintained broad discretion when scheduling substances according to their abuse potential, through court rulings that have upheld the DEA's comparison of the substance in question to already-scheduled substances. The DEA has formally defined the term *currently accepted medical use* in response to repeated litigation regarding the classification of Schedule I substances. The criteria under this definition include: (1) the drug's chemistry must be known and reproducible; (2) adequate safety studies; (3) adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.

The lack of regulatory clarity of the CSA has led to a complicated process and inconsistent scheduling of substances. The language of the CSA implies that for a substance to be placed into a particular schedule, it must fulfill all three criteria. It is entirely possible, however, for one substance to fail to meet all three criteria of one schedule. Nonetheless, the DEA maintains that all scheduled substances without an accepted medical use must be classified as Schedule I, illustrating the conflicting scheduling practices used.

Furthermore, the existing schedules do not take into account evolving evidence about the abuse potential of these drugs. For example, gabapentin and pregabalin are structural analogues of gamma-aminobutyric acid, with pregabalin being classified as Schedule V under the CSA. Gabapentin, however, remains federally uncontrolled. An increase in its abuse has led some states to classify this medication as a Schedule V substance and/or mandate prescription



reporting.

Finally, the CSA also places many restrictions on medical research into Schedule I substances, creating barriers that hinder the discovery of their potential therapeutic uses. Therefore, ASHP first recommends that the United States Congress use their legislative authority to define the aforementioned terms in the CSA to simply the scheduling process. ASHP also advocates that the DEA establish clear, measurable criteria, to the extent possible for this complex subject, and a transparent process for scheduling determinations. Further, the DEA is encouraged to use those criteria to re-evaluate current schedule assignments for all controlled substances based on recent evidence. Finally, the DEA is urged to ease the burden on applicants for research on Schedule I substances.

Background

The Council reviewed ASHP policy 1315, DEA Scheduling of Controlled Substances, as part of sunset review and voted to recommend amending it as follows (<u>underscore</u> indicates new text; strikethrough indicates deletions):

To advocate that the Drug Enforcement Administration (DEA) establish clear, measurable criteria and a transparent process for scheduling determinations; further,

To urge the DEA to use such a process to re-evaluate existing schedules for all substances regulated under the Controlled Substances Act to ensure consistency and incorporate current <u>science-based</u> evidence concerning <u>scheduling criteria</u> the abuse potential of these therapies; further,

<u>To advocate that the United States Congress define the terms potential for abuse,</u> <u>currently accepted medical use, and accepted safety for use in the Controlled Substances</u> Act; further,

To monitor the effect of DEA scheduling of products under the Controlled Substances Act and other abuse-prevention efforts (e.g., prescription drug monitoring programs) to assess the impact on patient access to these medications and on the practice burden of healthcare providers; further,

<u>To advocate for the alignment of federal and state laws to eliminate barriers to research on and therapeutic use of Schedule I substances.</u>

- 4. Pharmacist Prescribing Authority for Antiretroviral Therapy for the Prevention of HIV/AIDS
- To affirm that drug products for pre-exposure prophylaxis (PrEP) and post-exposure
- 2 prophylaxis (PEP) for human immunodeficiency virus (HIV) infection prevention should
- be provided to individuals in a manner that ensures safe and appropriate use; further,



- 4 To oppose reclassification of currently available drugs used for PrEP and PEP to
- 5 nonprescription status; further,
- 6 To advocate for legislation and regulation that expands pharmacist scope of practice to
- 7 encompass initiation of PrEP and PEP therapy; further,
- 8 To advocate that the therapies and associated care for PrEP and PEP are available to
- 9 patients with zero cost-sharing; further,
- To support establishment of specific and structured criteria to guide comprehensive
- pharmacist interventions related to PrEP and PEP; further,
- To support the research, education, and training of the pharmacy workforce on the
- therapeutic, psychosocial, and operationalization considerations of pharmacist-provided
- 14 PrEP and PEP therapy; further,
- To support educating the public regarding the public health benefits of PrEP and PEP.

Rationale

Increasing access to pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for human immunodeficiency virus (HIV) infection prevention is a public health priority. Despite the increase in the availability of antiretroviral therapies for such prophylaxis, much of the patient population that would benefit from access, particularly those in the black, indigenous, and people of color communities, has been limited by stigma and other barriers, including a requirement for a prescription in many parts of the U.S. One of those barriers to access is that many states do not provide pharmacists independent authority to order and initiate PrEP and PEP therapy. Given the time-sensitive nature of these therapies, patients and their partners would benefit from being able to access them at community pharmacies. Those forced to seek medications through a physician's office or other site of care may struggle to find a timely appointment, especially if they do not have an established primary care provider. In contrast to physicians, community pharmacists are often available without an appointment and pose a potential solution to expanding access to therapy. Through policy, education, and infrastructure changes, pharmacists can be an alternate source for PrEP, expanding availability and further reducing HIV transmission.

ASHP advocates expanding pharmacists' scope of practice to include initiation of PrEP and PEP therapy, including associated screening, testing, monitoring, referrals, product selection, and counseling, as well as the establishment of specific and structured criteria for prescribing, dosing, and dispensing of PrEP and PEP by pharmacists. As one example, California Bill 159, approved in October 2019, authorizes pharmacists who undergo a board-approved training program to supply PrEP and PEP every two years, with a 60-day supply cap and certain conditions under which the therapies can be prescribed. In addition, insurance companies are not allowed to require prior authorization for these drug products. The goal of this law is to get patients on PrEP and then direct them to a prescriber for further care management. Other



states, including New York, Colorado, Missouri, and New Hampshire, are exploring similar programs. As these practices and programs vary from state to state, ASHP also recommends structured criteria be set that optimizes patient care and access to these drug products.

Expanding collaborative practice, in which pharmacists are permitted under an agreement with a prescriber to prescribe a defined list of medications along with associated monitoring, provides an effective way to advance the scope of pharmacy practice nationwide. A Seattle pharmacy operationalized such a program by forming a clinic in which pharmacists perform a history, risk assessment, lab testing, and education before dispensing PrEP. Implementation of a standing order for pharmacists to furnish PrEP for their patients may provide longitudinal benefit, and infrastructure for pharmacists to bill for these services, as well as the facilities to see patients, must accompany such policy changes. To ensure that patients who present for HIV prophylaxis receive comprehensive care, pharmacists should be allowed to order tests for other sexually transmitted infections at the patient's request when possible, as some community pharmacies and other sites of care may not have the ability to provide certain tests onsite.

ASHP opposes reclassification of currently available drugs used for PrEP and PEP (tenofovir and emtricitabine) to nonprescription status, because existing models for nonprescription dispensing do not provide the safeguards required to ensure safe and effective use.

Other barriers to access include a lack of insurance coverage and high out-of-pocket costs, insurers' refusal to cover brand medications when necessary, and insurers failing to cover all formulations, including pediatric formulations. Modifications to national, regional, and local drug coverage decisions are needed to ensure that payer policies do not unintentionally restrict or prevent access. To promote the broadest possible access, ASHP advocates that PrEP and PEP be available to patients with zero cost-sharing, regardless of income or insurance coverage.

Pharmacist initiation of PrEP and PEP therapies will likely result in an increased workload and potential liability associated with provision of this care, which includes patient screening (including point-of-care testing, if applicable), patient education, dosing, counseling, and documentation of the care provided in the pharmacy and medical record. ASHP policy 2020, Care-Commensurate Reimbursement, states that pharmacists should be compensated for these kinds of clinical and patient care services.

A survey of community pharmacists revealed that education and training are needed to advance pharmacy practice in PrEP and PEP therapy. Training in necessary laboratory testing, trauma-informed care, destigmatization, and appropriate follow-up should be done to ensure an adequate knowledge base for pharmacists unfamiliar with the procedures. Finally, ASHP supports public education regarding the public health benefits of PrEP and PEP therapy.

Background

The Council reviewed the combined policy recommendations from the Council on Public Policy and the Council on Therapeutics from the 2021 Policy Week meetings. The Council also discussed the complex considerations for patients, including the following: presenting for treatment of other infectious diseases that may warrant screening as they may be ideal candidates for PreP; comorbidities that may affect therapy; state reportable illnesses requirements; harm reduction strategies; gender-affirming care; safeguarding for



administration, as some new therapies are injectables; and special populations, including pregnant women and children. The Council also discussed the logistical barriers for training pharmacists for PReP and PEP prescribing, as Council members shared that most states where such prescribing is permitted may only require a little as 90 minutes of training, frequently only on the drugs themselves and not on other aspects such as screening, trauma-informed care, safe spaces, and other psychosocial aspects in caring for patient populations who may seek out PrEP or PEP. This level of training seems inadequate; in comparison, immunization programs often require more than 20 hours of training to certify pharmacists as an immunizer. The Council also discussed the role of the hospital and health system when considering initialing PrEP or PEP, particularly when dispensing from hospital supply to cover the transition of care from hospital to home. In many smaller institutions or in underserved areas, these drugs may need to be ordered or pharmacies may not be open when the patient is discharged. In addition, many hospitals and health systems only dispense a 3-day supply of medications upon discharge. The Council also recognized that much of what should be considered for standards of care would be too much for an ASHP policy and recommended that the ASHP Guidelines on Pharmacist Involvement in HIV Care be updated to reflect the changes in practice and therapies since its publication in 2016.

5. Point-of-Care Testing and Treatment

- 1 To advocate for laws and regulations that would include performing point-of-care
- testing (POCT) and associated diagnosis, referral, prescribing, dosing, and dispensing
- 3 clinically indicated by POCT in pharmacists' scope of practice; further,
- 4 To support the development of specific and structured criteria for pharmacist
- diagnosis, referral, prescribing, dosing, and dispensing based on POCT; further,
- 6 To support the diagnosis and tracking of reportable diseases through pharmacist-
- 7 managed POCT and reporting to public health agencies when appropriate; further,
- 8 To foster research on patient access and public health improvements, cost savings, and
- 9 revenue streams associated with pharmacist-managed POCT and related patient care
- services; further,
- To promote training and education of the pharmacy workforce to competently engage
- in POCT and related patient care services.

Note: This policy would supersede ASHP policy 2229.

Rationale

Point-of-care testing (POCT) is laboratory testing that takes place at or near the site where the patient is located. These tests are quality-assured pathology services using analytical tools such as blood gas; critical care analyzers; and meters for glucose, urinalysis, and other metabolites.



They can be used for both communicable and noncommunicable disease states, including influenza A and B, strep throat, diabetes mellitus, hypertension, anticoagulation, congestive heart failure, and stroke. POCT can be performed by patients in their home, using for example a device that monitors international normalized ratio (INR) for warfarin management, or in the field by healthcare providers, such as rapid strep testing in community pharmacies. POCT devices fall under the Federal Food, Drug, and Cosmetic Act and therefore are also subject to pre- and post-marketing surveillance and review.

As the shortage of primary care providers continues and POTC technology improves, there is ample opportunity to expand the pharmacy workforce's roles in disease screening, diagnosis, and management. POCT provides fast results, which can reduce the time to therapeutic intervention through test-to-treat services, often at a lower cost to patients than an office visit. Pharmacists are well positioned to conduct risk assessments, provide appropriate treatment and referrals when necessary, provide disease state monitoring services, and in turn, improve adherence and identify unnecessary or inappropriate medications. For example, the availability of rapid influenza tests allows pharmacists to quickly diagnose and recommend treatment for influenza A and B, which has been found to reduce the time to first dose of antiviral drugs among individuals with influenza-like illness, compared to those referred to prescribers. The combined benefits of telehealth and test-to-treat services should not be discounted. Newer technology that patients can use in the home, including smart scales that monitor changes in weight for congestive heart failure patients, home blood glucose monitoring systems for diabetic patients, and INR monitoring have already demonstrated improved patient outcomes in conjunction with pharmacist care. Numerous studies demonstrate that home POCT can be implemented to streamline healthcare services to patients with chronic and acute disease states and also limit hospital admissions, readmissions, and delays in care and can ultimately lead to better outcomes as well as cost savings for patients and providers.

State legislation concerning pharmacist-managed POCT varies widely. For example, in California, pharmacists are able to perform routine patient assessment procedures through POCT that includes testing for HIV antibodies, total cholesterol, glucose and hemoglobin A1c levels, opiates, blood ketones, thyroid-stimulating hormone, hematocrit, and prothrombin time. Most common is legislation that permits pharmacists in collaborative practice agreements to perform rapid testing to diagnose group A streptococcal pharyngitis and prescribe antimicrobial therapy when a test is positive. This practice model has been shown to decrease the cost of diagnosis and treatment for children and adults and has demonstrated increased patient satisfaction.

ASHP advocates development of specific and structured criteria for pharmacist prescribing, dosing, and dispensing of antimicrobials for this purpose, under a variety of models (e.g., autonomous prescribing authority for pharmacists, delegation protocols, or collaborative practice agreements). A 2018 study found that 69% of pharmacists are willing to perform POCT in a community pharmacy setting, and 86% either strongly agreed or agreed to be willing to recommend appropriate treatment for influenza and group A streptococcal pharyngitis. With collaborative practice agreements in place, patients can bypass visiting a primary care provider, empowering pharmacists to assume an active role not only in treating patients but also in promoting public health by reporting positive cases to local health departments, should rapid



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

Background

The Council reviewed ASHP policy 2229, Pharmacist's Role in Respiratory Pathogen Testing and Treatment, with the goal of broadening it to more generally address the pharmacy workforce's role in POCT and recommending amending it as follows:

To advocate <u>for laws and regulations that would include in pharmacists' scope of practice</u> for performing point-of-care testing (POCT) and associated diagnosis, referral, <u>prescribing</u>, dosing, and dispensing that as clinically indicated by <u>POCT</u> that state board of pharmacy regulations include respiratory pathogen testing and associated prescribing or dispensing under pharmacists' scope of practice; further,

To support the development of specific and structured criteria for pharmacist <u>diagnosis</u>, <u>referral</u>, prescribing, dosing, and dispensing <u>based on POCT of antimicrobials for treatment of respiratory infections</u>; further,

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

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

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

To foster research on patient access and public health improvements, cost savings, and revenue streams associated with pharmacist-managed POCT and related patient care services; further,

To promote training and education of the pharmacy workforce to competently engage in <u>POCT and related patient care services</u> respiratory pathogen testing and treatment when clinically indicated.

The Council discussed the depth and breadth of the availability of POCT and the various ways these tests can be leveraged by pharmacists to provide patient-centered care across multiple sites of care. The Council also discussed the need for interoperable reports, standardized education and training, and successful reimbursement models. They also discussed how ASHP could provide education and training in the myriad of devices and further steps needed to integrate POCT into practice.



6. Nonprescription Availability of Oseltamivir

- 1 To support a behind-the-counter practice model that expands access to oseltamivir;
- ₂ further,
- 3 To support interoperable documentation of oseltamivir dispensing and associated
- 4 testing accessible by all members of the healthcare team in outpatient and inpatient
- 5 settings; further,
- 6 To support diagnosis and tracking of influenza through pharmacist-driven influenza
- 7 point-of-care testing and reporting to the appropriate public health agencies prior to
- 8 oseltamivir dispensing; further,
- 9 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
- 14 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.

Note: This policy would supersede ASHP policy 2116.

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 supports the availability of oseltamivir via a behind-the-counter practice model. Use of this practice model, which has already been adopted for medications such as pseudoephedrine and emergency contraception, would facilitate appropriate use of oseltamivir and provide the pharmacist with an opportunity to provide patient assessment and professional consultation.

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. ASHP policy 2020, Care-Commensurate Reimbursement, states that pharmacists should be compensated for these kinds of clinical and patient care services.

Background

The Council reviewed ASHP policy 2116, Nonprescription Availability of Oseltamivir, as part of sunset review and voted to recommend amending it as follows (<u>underscore</u> indicates new text; strikethrough indicates deletions):

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 toprescribe medications, rather than nonprescription designation; further,

<u>To support a behind-the-counter practice model that expands access to oseltamivir;</u> <u>further,</u>

<u>To support interoperable documentation of oseltamivir dispensing and associated</u> testing accessible by all members of the healthcare team in outpatient and inpatient settings; further, [MOVED FROM BELOW]

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, [MOVED ABOVE]

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.

7. Over-the-Counter Availability of Oral Contraceptives

- To advocate that over-the-counter (OTC) oral contraceptives be available without age
- restriction only under conditions that ensure safe use, including the availability of
- pharmacist consultation to ensure appropriate self-screening and product selection;
- 4 further,
- 5 To support the development, implementation, and use of clinical decision-making tools
- 6 and education to facilitate pharmacist consultation; further,
- 7 To encourage the Food and Drug Administration to require manufacturers to include all
- 8 patients of childbearing age, including adolescents, in studies to determine the safety
- 9 and efficacy of OTC oral contraceptives; further,
- To advocate that the proposed reclassification of these products be accompanied by
- coverage changes by third-party payers to ensure that patient access is not
- compromised.

Note: This policy would supersede ASHP policy 1410.

Rationale

There have been repeated calls to make oral contraceptive products more widely available, with the intent of expanding access to women's reproductive health therapies and reducing unintended pregnancies. The American College of Obstetricians and Gynecologists (ACOG), American Medical Association (AMA), and American Academy of Family Physicians (AAFP) have positions statements in support of over-the-counter (OTC) access to oral contraceptives to reduce unintended pregnancies, regardless of the age of the patient. ASHP agrees that there is no clinical justification to restrict access to oral contraceptives by adolescents past menarche.



As with other OTC medications, there is recognition that both progestin-only and combined oral contraceptive use carries a very small amount of risk of adverse events and should be determined to be safe and effective for self-use. OTC oral contraceptives should therefore be available where a patient has access to a pharmacist. Patient self-screening and product selection would be improved through pharmacist-provided consultation that assists patients in identifying absolute and relative contraindications (e.g., hypertension, heart or kidney disease), assessing other patient-specific factors (e.g., adherence practices), and determining when to recommend a referral to seek a higher level of care through the use of counseling and clinical decision-making tools. This process would guide the determination of whether a progestin-only or combination oral contraceptive product would be more safe and effective for an individual patient. ASHP does not believe that the current model for behind-the-counter access to some drug products (e.g., pseudoephedrine, emergency contraception) is appropriate for oral contraceptives because it would place the pharmacist in a gatekeeping rather than the clinical role that is necessary to ensure safe and effective use of these therapies.

Manufacturers will need to submit a supplemental new drug application for conversion from prescription to OTC status, including post-marketing surveillance reports and studies of consumer behaviors. It is critical that adolescents be included in these studies to assess their label comprehension, aptitude to self-select, and ability to effectively use the OTC oral contraceptives.

Given the intent to expand access to these therapies, ASHP advocates that the proposed reclassification to OTC should not result in increased costs to patients and should include full insurance coverage without cost sharing. Modifications to national, regional, and local drug coverage decisions may be needed to ensure that payer policies do not unintentionally restrict or prevent access to OTC oral contraceptives.

Background

The Council reviewed ASHP policy 1410, Access to Oral Contraceptives Through an Intermediate Category of Drug Products, as part of sunset review and voted to recommend amending it as follows (<u>underscore</u> indicates new text; <u>strikethrough</u> indicates deletions):

To advocate that <u>over-the-counter (OTC)</u> oral contraceptives be <u>provided</u> <u>available</u> <u>without age restriction</u> only under conditions that ensure safe use, including the availability of <u>counseling pharmacist consultation</u> to ensure appropriate self-screening and product selection; further,

To support the development, implementation, and use of clinical decision-making tools and education to facilitate pharmacist consultation; further,

To encourage the Food and Drug Administration to require manufacturers to include all patients of childbearing age, including adolescents, in studies to determine the safety and efficacy of OTC oral contraceptives; further,

To support expanded access to these products through a proposed intermediate category of drug products, as described by ASHP policy, that would be available from all-



pharmacists and licensed health care professionals (including pharmacists) who are authorized to prescribe medications; further,

To advocate that the proposed reclassification of these products 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.

8. Responsible Medication-Related Clinical Testing and Monitoring

- 1 To recognize that overuse of clinical testing leads to unnecessary costs, waste, and
- 2 patient harm; further,
- 3 To encourage the development of standardized measures of appropriate clinical testing
- 4 to better allow for appropriate comparisons for benchmarking purposes and use in
- 5 research; further,
- 6 To promote pharmacist accountability and engagement in interprofessional efforts to
- 7 promote judicious use of clinical testing and monitoring, including multi-faceted,
- 8 organization-level approaches and educational efforts; further,
- 9 To promote research that evaluates pharmacists' contributions and identifies
- opportunities for the appropriate ordering of medication-related procedures and tests;
- 11 further,
- To promote the use of interoperable health information technology services and health
- information exchanges to decrease unnecessary testing.

Note: This policy would supersede ASHP policy 1823.

Rationale

As the prevalence of collaborative practice grows and as pharmacist care expands into direct patient care services, so too do the responsibilities held by these practitioners. In many institutions, pharmacists' responsibilities now include ordering blood draws as a part of initiating a medication regimen, assessing drug levels, monitoring for adverse effects, or ordering imaging such as ultrasound for evaluating a deep vein thrombosis or an electrocardiogram to evaluate a QTc interval.

Overuse of medical care is a long-recognized problem in clinical medicine, and more spending and treatment do not translate into better patient outcomes and health. The number of articles on overuse nearly doubled from 2014 to 2015, indicating that awareness of overuse is increasing, despite little evidence of improved practice, which may mean that the overuse of diagnostic tests and lab monitoring is leading to patient harm and could outweigh benefits. Healthcare continues to be enthralled by high-technology innovation, including both therapies and tests. Once practice norms are established, clinicians are slow



to de-implement services, even those that are found to be potentially dangerous. Reasons for excessive ordering of tests by healthcare providers include defensive behavior, fear, uncertainty, lack of experience, the use of protocols and guidelines, routine clinical practice, inadequate educational feedback, and clinician's lack of awareness about the cost of examinations. Inappropriate testing causes unnecessary patient discomfort, may lead to iatrogenic anemia from over-testing, entails the risk of generating false-positive results and unnecessary treatment, leads to overloading of diagnostic services, wastes valuable healthcare resources, and is associated with other inefficiencies in healthcare delivery, thus undermining the quality of health services. Furthermore, ordering unnecessary tests may also disproportionately affect vulnerable populations, including pediatric patients; trigger unnecessary therapies, such as for asymptomatic bacteriuria; and introduce bias, such as when screening for illicit drugs is performed but not as part of a differential diagnosis. A multi-faceted approach is recommended to reduce waste and support the judicious use of clinical testing. Key strategies include use of interoperable health information technology services and health information exchanges; optimization of test ordering through use of clinical decision support systems; provider and pharmacist education; benchmarking; and organization-level guidance, such as through establishment of a laboratory formulary committee that includes formulary control. Additionally, a key limitation of current literature surrounding appropriateness of clinical testing is a lack of standardized definitions of "appropriateness." Guideline and professional organization-endorsed standards may be used to benchmark clinical testing, although variations by country or institutional practices may confound these definitions.

Choosing Wisely is a national program designed to help raise provider and public awareness and garner support for appropriate test utilization, with the goal of promoting conversations between providers and patients about choosing appropriate care in order to reduce both harm and waste. In 2016, ASHP announced its partnership with the ABIM Foundation on the Choosing Wisely campaign, and in 2017 became the first pharmacy organization to contribute recommendations to the campaign. ASHP has continued to support this partnership through regular review and updates of its recommendations.

Background

The Council reviewed ASHP policy 1823, Responsible Medication-Related Clinical Testing and Monitoring, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To recognize that overuse of clinical testing leads to unnecessary costs, waste, and patient harm; further,

To encourage the development of standardized measures of appropriate clinical testing to better allow for appropriate comparisons for benchmarking purposes and use in research; further,

To <u>promote</u> encourage pharmacist accountability and engagement in interprofessional efforts to promote judicious use of clinical testing and monitoring, including multi-faceted, organization-level approaches and educational efforts; further,



To promote research that evaluates pharmacists' contributions and identifies opportunities for the appropriate ordering of medication-related procedures and tests; further,

To promote the use of interoperable health information technology services and health information exchanges to decrease unnecessary testing.

9. Therapeutic and Psychosocial Considerations of Patients Across the Gender Identity Spectrum

- To advocate for access to and broad insurance coverage of gender-affirming care,
- including medication, medical, and surgical therapies; further,
- To advocate that patients across the gender identity spectrum have access to
- 4 pharmacist care to ensure safe and effective medication use without discriminatory
- 5 barriers; further,
- 6 To advocate that gender identity be considered in medication and disease management
- of patients across the gender identity spectrum; further,
- 8 To promote research on, education about, and development and implementation of
- 9 therapeutic and biopsychosocial best practices in the care of patients across the gender
- identity spectrum; further,
- To encourage the incorporation of specific education and training regarding patient
- gender identity into educational standards and competencies for the pharmacy
- workforce; further,
- To encourage easily accessed, structured documentation of a patient's sex assigned at
- birth, self-identified gender, and relevant medical history in electronic health records.

Note: This policy would supersede ASHP policy 1718.

Rationale

Transgender people are at risk for health and access inequities as a direct result of biases and stigma. Insurance coverage for medication therapies, corrective surgeries, and associated medical needs such as mental health and endocrine services may be limited or nonexistent due to these discriminatory barriers.

In its National Survey on LGBTQ Youth Mental Health 2020, which surveyed over 40,000 lesbian, gay, bisexual, transgender, queer, and questioning (LGBTQ) young people, the Trevor Project found that 29% of those who responded experienced housing instability; 40% seriously



considered attempting suicide in the past 12 months, with more than half of transgender and nonbinary youth having seriously considered suicide; 68% reported symptoms of generalized anxiety disorder in the past 2 weeks, including more than 75% of transgender and nonbinary youth; and 48% reported engaging in self-harm in the past 12 months, including over 60% of transgender and nonbinary youth. The authors also reported that 60% of respondents identified that the ability to afford care was the strongest barrier to receiving mental health care, and that nearly half of transgender and nonbinary youth did not receive wanted mental healthcare due to concerns related to the LGBTQ competence of providers. Further, they found that when transgender and nonbinary youth had access to binders, shapewear, and genderaffirming clothing, they reported lower rates of suicide attempts compared to transgender and nonbinary youth without access. These findings are echoed by Safer and colleagues, who also identify a lack of providers who are sufficiently knowledgeable on the topic, financial barriers, discrimination, lack of cultural competence by providers, health-system barriers, and socioeconomic barriers to this patient population.

There are guidelines to help practitioners identify the health and biopsychosocial needs of transgender and gender-nonbinary people as well as inclusive language guidelines for all practitioners to incorporate into their lexicon.

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

Those caring for these patients should be knowledgeable regarding the clinical, social, and access needs of this patient population. Student pharmacists, pharmacy residents, pharmacists, and pharmacy technicians therefore should all be trained to appropriately care for this patient population. The Affordable Care Act prohibits pharmacists from making their own decisions about the suitability of a prescribed medication in situations that would constitute discrimination against patients. Although ASHP policy 0610, Pharmacist's Right of Conscience and Patient's Right of Access to Therapy, recognizes the pharmacist's right of conscience, the



policy also recognizes "the patient's right to obtain legally prescribed and medically indicated treatments" and states that "a pharmacist exercising the right of conscience must be respectful of, and serve the legitimate healthcare needs and desires of, the patient, and shall provide a referral without any actions to persuade, coerce, or otherwise impose on the patient the pharmacist's values, beliefs, or objections."

Background

The Council reviewed ASHP policy 1718, Therapeutic and Psychosocial Considerations of Transgender Patients, as part of sunset review and recommended amending it as follows (<u>underscore</u> indicates new text; strikethrough indicates deletions):

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

To advocate for access to and broad insurance coverage of gender-affirming care, including medication, medical, and surgical therapies; further,

To advocate that transgender patients across the gender identity spectrum have access to pharmacist care to ensure safe and effective medication use without discriminatory barriers; further,

To advocate that gender identity be considered in medication and disease management of patients across the gender identity spectrum; further,

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

To encourage the incorporation of specific education and training regarding patient gender identity into educational standards and competencies for the pharmacy workforce; further,

To encourage <u>easily accessed</u>, structured documentation of both a patient's birth sex <u>assigned at birth</u>, and self-identified gender, <u>and relevant medical history</u> in electronic health records.

The amended policy consolidates policy recommendations from the Council on Therapeutics, Council on Public Policy, and members of the ASHP House of Delegates to reflect more modern and appropriate terminology and current events that impact this patient population.

10. Removal of Injectable Promethazine from Hospital Formularies

1 To advocate that injectable promethazine be removed from hospital formularies; further,



- 2 To encourage the Food and Drug Administration to review the patient safety data and
- 3 consider withdrawing injectable promethazine from the market.

Note: This policy would supersede ASHP policy 1831.

Rationale

In its 2020-2021 Targeted Medication Best Practices for Hospitals, the Institute for Safe Medication Practices (ISMP) included a recommendation to eliminate injectable promethazine from hospitals. This recommendation includes removal of injectable promethazine from all areas of the hospital, including the pharmacy; classification of injectable promethazine as a nonstocked, nonformulary medication; implementation of a medical staff-approved automatic therapeutic substitution policy; conversion of all injectable promethazine orders to another antiemetic; and removal of injectable promethazine from all computerized medication order screens and from all order sets and protocols. In 2018, only 56% of ISMP Survey respondents believed promethazine to be a high-alert medication, which was a decrease from 59% in 2014. The 2018 survey also found that 54% of respondents also thought that "IV promethazine" should be changed to "injectable promethazine," also underscoring the need for broader protections from intravenous administration use. This recommendation reiterated the identical 2018-2019 ISMP Best Practice recommendation, which was a change from previous ones in which ISMP promoted safe use by raising awareness about risks associated with intravenous (IV) promethazine administration. Despite the efforts to improve the safety of injectable promethazine use, sporadic and significant patient harm continues to occur.

Promethazine is a known vesicant that can cause tissue damage and necrosis when extravasation occurs during IV administration, and it has negative effects on cardiac conduction. Although therapeutic alternatives are available for most indications, the alternative therapies are also not without risk and may not be as effective in some clinical situations. Processes to limit the potential for patient harm when IV administration of promethazine is indicated include but are not limited to use of therapeutic alternatives (e.g., 5-HT₃ receptor antagonists, antipsychotic agents, antihistamines); use of alternate routes and modalities of administration (e.g., oral, rectal); and restrictions on use (e.g., nonformulary, nonstocked status and removal from order sets and protocols). While prior guidance provided practice recommendations to mitigate the risk of injectable promethazine use (e.g., minimum drug dilution, continuous nurse monitoring of infusion, administration through a running IV line), a 2006 ISMP survey of hospitals revealed poor adherence to these recommendations, despite the well-documented risks of circumventing them. Although medication regimens for some specific patient populations may include injectable promethazine, many guidelines for management of disease states in which promethazine may have a role do not recommend injectable promethazine as an agent of initial choice, indicating it should be used as last line/salvage therapy. Often, these guidelines do not include injectable promethazine as a therapeutic option at all; given the number and variety of suitable alternatives, the risks of using this medication outweigh the benefits. Finally, since ISMP has recommended injectable promethazine's removal from formularies, there is not much data on its safety and efficacy, as implementation of the recommendation has varied across the U.S., and what data is available has been mostly



anecdotal or case-based reports. ASHP encourages the Food and Drug Administration to aggregate this information and evaluate injectable promethazine's patient safety data to reevaluate its market status.

Background

At its June 2022 meeting, the Council reviewed ASHP policy 1831, Safe and Effective Use of IV Promethazine, as part of sunset review and voted to recommend amending it as follows (<u>underscore</u> indicates new text; <u>strikethough</u> indicates deletion):

To advocate that <u>injectable</u> intravenous promethazine be <u>removed from hospital</u> <u>formularies</u> used only when medically necessary; further,

<u>To encourage the Food and Drug Administration to review the patient safety data and</u> consider withdrawing injectable promethazine from the market.

The Council recommended revising policy 1831 to align with ISMP standards because risks to patient harm outweigh any therapeutic advantage injectable promethazine may have against refractory therapies. Since this policy originated in 2017, there has been a proliferation of more cost-effective therapeutic alternatives for most indications for which injectable promethazine is used. The Council also discussed the role the Food and Drug Administration should have in removing this formulation from the market, given the significant harm to patients when administered incorrectly and the decrease in awareness of injectable promethazine as a high-alert medication.

After the Board approved the amended policy recommendation at its September 2022 meeting, the House of Delegates considered it at the November virtual House and did not approve the amended policy by the necessary 85%. In addition, the proposed revised policy generated a great deal of discussion on the House of Delegates Connect community, prompting the Council to reconsider the proposed amendments. After review, the Council revised the amended policy recommendation again to ensure alignment with ISMP and address considerations for patient populations for which injectable promethazine is medically necessary. The amendments the Council made at its January 31 meeting to the revised policy language it proposed in June are as follows (underscore indicates new text; strikethough indicates deletion):

To advocate that injectable promethazine be removed from hospital <u>and health-system</u> formularies; further,

To recommend that hospitals and health systems that continue to use injectable promethazine develop policies that strictly limit use to specific patient populations and utilize administration techniques that minimize risk of preventable harm; further,

To encourage the Food and Drug Administration to review the <u>most current</u> patient safety data and <u>consider withdrawing injectable promethazine from the market reevaluate injectable promethazine's market status.</u>



At its April 13 meeting, the Board of Directors voted to not approve the Council's amended recommendation from its January 31 meeting. The Board noted that at the November 2022 virtual House a majority of delegates voted to approve the Council's June 22 proposed amendments, just not the 85% supermajority necessary for approval at a virtual House. The Board further noted the contradictory messages in policy language that would simultaneously advocate removal of injectable promethazine from hospital and health-system formularies and an FDA safety review while recommending that hospitals and health systems develop policies to ensure its safe use. The Board expressed its unanimous opinion that the Council's earlier language from its June 2022 meeting, advocating for removal of injectable promethazine from hospital formularies, more closely aligns with ASHP's medication safety mission and would more clearly serve its advocacy agenda.



COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATION

The Council on Education and Workforce Development is concerned with ASHP professional policies, related to the quality and quantity of pharmacy practitioners. Within the Council's purview are (1) student education, (2) postgraduate education and training, (3) specialization, (4) assessment and maintenance of competence, (5) credentialing, (6) balance between workforce supply and demand, (7) development of technicians, and (8) related matters.

Kim Benner, Board Liaison

Council Members

Angela Bingham, Chair (Pennsylvania)
Joshua Blackwell, Vice Chair (Texas)
Stacy Dalpoas (North Carolina)
Johnnie Early II (Florida)
Michelle Estevez (Wyoming)
Glen Gard (Illinois)
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Joshua Raub (Michigan)
Jennifer Robertson (Tennessee)
Caroline Sierra (California)
Ted Walton (Georgia)
David Zimmerman (Pennsylvania)
Sophia Chhay and Erika Thomas, Secretaries

1. Well-Being and Resilience of the Pharmacy Workforce

- To affirm that occupational burnout adversely affects an individual's well-being and
- 2 healthcare outcomes; further,
- 3 To acknowledge that the healthcare workforce encounters unique stressors throughout
- 4 their education, training, and careers that contribute to occupational burnout; further,
- 5 To declare that healthcare workforce well-being and resilience requires shared
- 6 responsibility among healthcare team members and between individuals and
- 7 organizations; further,
- 8 To encourage individuals to embrace well-being and resilience as a personal
- 9 responsibility that should be supported by organizational culture; further,
- To promote that pharmacy leadership collaborate with their institutions to assess the
- well-being and resilience of the pharmacy workforce and identify effective prevention
- and intervention strategies; further,



- To encourage hospitals and health systems to invest in the development and
- assessment of programs aimed at prevention, recognition, and treatment of
- occupational burnout, and to support participation in these programs; further,
- 16 To encourage education, research and dissemination of findings on stress, burnout, and
- well-being; further,
- To collaborate with other professions and stakeholders to identify effective prevention
- and intervention strategies that support well-being at an individual, organizational, and
- 20 system level.

Note: This policy would supersede ASHP policy 1825.

Rationale

Clinician burnout can have serious, wide-ranging consequences on individual clinicians and learners, health care organizations, and patient care. Occupational burnout is a syndrome characterized by a high degree of emotional exhaustion, high depersonalization (e.g., cynicism), and a low sense of personal accomplishment from work due to both internal and external factors. The results follow a 2018 study in the *American Journal of Health-System Pharmacy* (AJHP) that found 53 percent of health-system pharmacists self-reported a high degree of burnout caused by increasing stresses and demands. Occupational burnout affects today's pharmacy workforce at unprecedented rates. At the individual level, pharmacy staff burnout can result in medication errors and increased patient harm. At the hospital or healthcare system level, the consequences of occupational burnout include disengagement, loss of productivity, and employee turnover, which can lead to inefficiency and financial problems for healthcare organizations. Stress in our clinical learning environment can affect all healthcare learners, with negative outcomes ranging from poor well-being to substance abuse to depression, even suicide. A 2017 AJHP article reported that pharmacy residents working more than 60 hours per week reported high levels of stress, depression, and hostility.

ASHP joined the National Academy of Medicine (NAM) Action Collaborative on Clinician Well-Being and Resilience in 2017. The goals of the Collaborative are to 1. Raise the visibility of clinician anxiety, burnout, depression, stress, and suicide, 2. Improve baseline understanding of challenges to clinician well-being, and 3. Advance evidence-based, multidisciplinary solutions to improve patient care by caring for the caregiver. The NAM Action Collaborative Conceptual Model depicts both individual and external factors affecting well-being and resilience and indicates that it requires a combined effort from the individual and the system to address and prevent occupational burnout.

Studies suggest that burnout is a problem of the entire healthcare organization as well as individual clinicians, so maintaining clinician well-being and resilience requires a combined effort by the individuals and their employers. To be successful, interventional programs must promote prevention, recognition, and treatment of burnout, and healthcare organizations must foster a culture that supports not just participation in these programs but a sense of personal



responsibility for developing and maintaining resilience. A healthcare organization with a resilient workforce will provide the best healthcare outcomes.

Supporting the well-being of the pharmacy workforce requires sustained attention and action at organizational, state, and national levels, as well as investment in research and information sharing to advance evidence-based solutions. A pharmacy workforce with the ability to thrive during adversity—a resilient workforce—is essential to combat burnout and support higher-quality care, increased patient safety, and improved patient satisfaction.

Background

The Council reviewed ASHP policy 1825, Clinician Well-Being and Resilience, as part of sunset review and voted to recommend amending it as follows (<u>underscore</u> indicates new text; strikethrough indicates deletions):

To affirm that <u>occupational</u> burnout adversely affects an individual's well-being and healthcare outcomes; further,

To acknowledge that the healthcare workforce encounters unique stressors throughout their education, training, and careers that contribute to occupational burnout; further,

To declare that healthcare workforce well-being and resilience requires shared responsibility among healthcare team members and between individuals and organizations; further,

To encourage individuals to embrace well-being and resilience as a personal responsibility that should be supported by organizational culture; further,

To promote that pharmacy leadership collaborate with their institutions to assess the well-being and resilience of the pharmacy workforce and identify effective prevention and intervention strategies; further,

To encourage <u>hospitals and health systems to invest in</u> the development <u>and assessment</u> of programs aimed at prevention, recognition, and treatment of <u>occupational</u> burnout, and to support participation in these programs; further,

To encourage education, and research, and dissemination of findings on stress, occupational burnout, and well-being; further,

To collaborate with other professions and stakeholders to identify effective preventive and treatment prevention and intervention strategies at an individual, organizational, and system level.



SECTION OF PHARMACY EDUCATORS POLICY RECOMMENDATION

The mission of the ASHP Section of Pharmacy Educators is to support pharmacy educators in preparing, engaging, and advancing the pharmacy workforce to optimize health.

Melanie A. Dodd, Board Liaison

Executive Committee

James A. Trovato, *Chair* (Maryland) Cher Enderby (Florida) Marie A. Chisholm-Burns (Tennessee) Tim Brown (Georgia) Jennifer D. Arnoldi (Illinois) Kevin W. Chamberlin (Connecticut) Gina G. Luchen, *Director*

- 1. ASHP Statement on Precepting as a Professional Obligation
- To approve the ASHP Statement on Precepting as a Professional Obligation (Appendix).



Appendix:

ASHP Statement on Precepting as a Professional Obligation

Position

The American Society of Health-System Pharmacists (ASHP) believes that all pharmacists have a professional obligation to give back to the profession through involvement in the precepting process of students and postgraduate trainees. ASHP encourages pharmacy practice leaders, practitioners, postgraduate trainees, and faculty members to embrace the responsibility to be involved in the precepting process in an effort to advance pharmacy practice and improve patient care. To this end, ASHP urges all pharmacists and healthcare institutions to accept this responsibility and commit time and resources to the precepting process and the development of precepting skills.

ASHP encourages pharmacy practice leaders to create a culture of teaching and learning, integrate precepting as a practice philosophy, support an organizational commitment to well-being, and facilitate the integration of learners into patient care services and scholarly work. Pharmacy leaders and administrators, colleges of pharmacy, faculty, and current preceptors have a responsibility to foster and support the evidence-based development of the precepting skills of all pharmacy practitioners and postgraduate trainees, facilitate the development of practice models that provide regular opportunities to precept learners, encourage all pharmacists to be involved in the precepting process, and support the assessment of training programs' outcomes.

Background

Upon graduation, all pharmacists pledge to use their knowledge, skills, experiences, and values to train the next generation by taking the Oath of a Pharmacist.¹ The apprenticeship model of "see one, do one, teach one" is grounded in centuries of tradition across many healthcare disciplines. Current apprenticeship models, such as the Cognitive Apprenticeship Model, encourage the development of observable skills and critical thinking skills that are fundamental to contemporary practice.² The evolution of the current pharmacy education system and apprenticeship models requires preceptor supervision during experiential learning and postgraduate training.

Precepting consists of providing a learner with practical experiences in a practice setting in which they can develop and apply principles of pharmacy practice. The precepting process begins within the college of pharmacy curricula and co-curricula and extends through advanced pharmacy practice experiences (APPEs) and postgraduate trainee experiences. Throughout this prolonged process, preceptors serve vital roles by providing instruction, mentorship, coaching, facilitation, assessment, and feedback to learners. The precepting process teaches more than clinical skills by promoting skill development in professionalism, communication, teamwork, interprofessional collaboration, leadership, time management, and professional values as well as facilitating professional identity formation (PIF).³ Involvement in the precepting process and experiential learning consists of more than serving as the primary preceptor on rotations and may extend to opportunities such as team precepting, shadowing experiences, speaking engagements, providing feedback to learners, facilitating topic discussions, learner mentoring, learner supervision, and more.

Experiential learning is fundamental to the application of knowledge and skills gained during didactic curricula.^{3,4} To determine if students are practice ready, colleges of pharmacy utilize entrustable professional activities (EPAs), which are workplace tasks or responsibilities students are entrusted to perform in the experiential setting with direct or distant supervision.⁵ Evaluation of entrustability levels of EPAs requires input from preceptors to assign a degree of trust in student competence. While mastery of EPAs requires the learner to gain foundational knowledge, skills, and attitudes in didactic curricula, these activities cannot be adequately replicated in the classroom; therefore, they should be fully elucidated and evaluated in the experiential setting.⁴ Likewise, postgraduate programs require qualified preceptors to provide appropriate training, supervision, and guidance to all postgraduate trainees as they progress toward competence using the postgraduate trainee program's defined assessment scale.⁶

Preceptors are necessary to ensure learners attain the desired level of competency for practice; however, a dearth of preceptors has been a long-standing problem. Experiential site and preceptor capacity are frequent concerns of experiential education directors. There are several contributing factors to this persistent preceptor shortage. First, colleges of pharmacy must adhere to the Accreditation Council for Pharmacy Education (ACPE) accreditation standards, which require enough preceptors to deliver and evaluate students in the experiential setting. Between 2000 to 2020, there was a greater than 70% increase in the number of colleges of pharmacy, and since 2013, there has been a 65% increase in postgraduate training programs. Furthermore, preceptors of postgraduate trainees require advanced training and/or experience to meet postgraduate training standards. These requirements and expansion of programs may limit the number of experiential sites or individuals available to precept at any given time, which may worsen if all pharmacists do not accept precepting as a professional responsibility.

Another contributing factor to these shortages may be pharmacist burnout. Burnout is increasingly associated with work-related stressors, resulting in decreased clinician job satisfaction, productivity, interprofessional teamwork, and mental health. Increasing concerns about the personal ability to effectively balance patient care, administrative, teaching, and other roles may negatively influence pharmacists' interest in precepting. The consequences of burnout to patient care reinforce the need of colleges of pharmacy and healthcare institutions to systematically commit to the well-being of all pharmacy practitioners, pharmacy technicians, and learners.

Within the challenges of our ever-evolving healthcare and educational systems, high-quality preceptors are needed now more than ever. Their contributions continue the rich tradition of pharmacists as one of the most trusted healthcare professionals and bring value to healthcare institutions, learners, and patients.

Value of precepting

The amount of literature demonstrating mutual benefit for learners, preceptors, healthcare institutions, and patients is vast.^{3,10} Ultimately, a synergistic relationship among stakeholders can improve patient care by aligning the goals of colleges of pharmacy, learners, preceptors, and healthcare institutions and embracing precepting as a practice philosophy.¹¹ Additionally, when learners are used as pharmacist extenders, clinical productivity increases, personal and



professional growth ensues, and institutional metrics improve.^{3,10}

Value to learners. Preceptors are often one of the most influential teachers learners encounter as part of their training. They significantly influence learners' PIF through instructing, modeling, coaching, and facilitating as learners internalize and demonstrate the values and behaviors of pharmacists in practice. Preceptors' provision of feedback on learners' performance and their intraprofessional and interprofessional interactions are instrumental in learners' professional socialization and identity development. Preceptors also significantly impact learners' career choices and trajectories, personal and professional development, involvement in professional advocacy, and participation in scholarly activities. Learners also benefit from collaborating with various professionals in their interprofessional practice experiences.

Value to preceptors. There is tangible value for preceptors who incorporate students and postgraduate trainees into experiential learning opportunities. Incorporation of learners as pharmacist extenders helps preceptors expand their clinical services to patients and allows them to accommodate more learners, particularly when the Layered Learning Practice Model (LLPM) is used. The LLPM is the teaching approach in which seasoned clinical preceptors supervise learners' clinical and precepting experience and train postgraduate trainees to precept students. Learners may also serve as productive members of the LLPM. In addition to gaining supervised autonomy, learners develop foundational precepting skills by participating in near-peer teaching as appropriate for their development. This model utilizes a team approach so that pharmacists, postgraduate trainees, students, and technicians within larger healthcare teams maximize and extend the reach of pharmacy services.

Incorporating learners also allows preceptors to increase scholarly activities. Preceptors have ample opportunities to collaborate with learners for presenting and publishing abstracts, posters, and manuscripts.³ These partnerships can help advance preceptors' research goals while developing learners' scholarly skills. Preceptors can leverage journal clubs or presentations on upcoming literature or clinical topics to maintain an updated knowledge base. Precepting is a professionally rewarding opportunity to influence future pharmacy clinicians and leave an enduring legacy on the future of the profession.³

Value to healthcare institutions and patients. Abundant literature documents the benefits of learners to healthcare institutions. Utilization of learners at healthcare institutions improves institutional metrics by expanding pharmacy services and advancing research agendas and dissemination rates. 10,13 For example, literature has shown tangible benefits of learners when they participate in taking medication histories, optimizing transitions of care, performing discharge counseling, practicing medication therapy management, and administering vaccinations. 10 Involvement of learners in these activities has been associated with the prevention of errors, decreases in medication costs, increased patient interventions and encounters, and decreased pharmacist-to-patient ratios. 10,14 Finally, trainees often apply for positions within their training institution, creating a pipeline of future employees.

Responsibilities of stakeholders

- 122 Positively impacting patient care is the shared vision of learners, preceptors, healthcare
- institutions, colleges of pharmacy, and professional organizations, and preceptors are necessary



to achieve that vision.¹¹ Preceptors provide an invaluable aspect of pharmacy education as they empower learners to independently apply their knowledge and skills in real-world situations. Colleges of pharmacy uphold the responsibility to prepare APPE-ready students by adhering to ACPE standards regarding experiential learning, and postgraduate training programs uphold the responsibility to ensure postgraduate trainees are practice or advanced practice ready. Practitioners involved in the precepting process play an integral role in determining these outcomes for learners. When experiential learning is thoughtfully designed, students, postgraduate trainees, preceptors, healthcare institutions, and ultimately patients benefit.^{3,15}

Preceptors have diverse learning needs and preferences, and healthcare institutions vary in development resources available to preceptors. Preceptor development is instrumental in supporting the design of experiential learning and preparing preceptors for teaching and mentoring within the precepting process. To improve preceptor efficiency and maximize learning, development regarding in-the-moment experiential teaching is crucial, and additional training and sharing best practices in leveraging learners to help meet institutional goals should be a priority. It is imperative that professional organizations, colleges of pharmacy, and healthcare institutions collaborate to provide evidence-based preceptor development resources in a variety of media and formats and promote an inclusive and equitable culture of teaching and learning. As such, the continual professional development of preceptors is a shared responsibility among these entities.

Responsibilities of professional organizations

 Professional organizations play a pivotal role in the development of precepting standards and preceptor development resources. ASHP and ACPE provide guidance on the standards and requirements for preceptor training and development. Professional organizations should collaborate with preceptors, healthcare institutions, and colleges of pharmacy to provide practical and contemporary preceptor development resources and programming to meet the standards. These organizations are equipped to spotlight best teaching practices and practice models of their diverse members. Professional organizations are also positioned to advocate for the importance of precepting and preceptor development to pharmacists and healthcare institutions.

Responsibilities of colleges of pharmacy and postgraduate training programs

In addition to providing preceptor development resources to meet individual and group preceptor development needs, colleges of pharmacy and postgraduate training programs can assist in the creation, research, and dissemination of best practices in precepting and innovative practice models to spur the development of others. ¹¹ Colleges of pharmacy and postgraduate training programs also aid in the development of preceptors and healthcare institutions through sharing de-identified aggregate feedback from learners, quality assurance programs, and in the acknowledgement of quality precepting through recognition programs. ¹⁶

Responsibilities of healthcare institutions

It is critical to the training of the next generation of pharmacists that healthcare institutions embrace the responsibility to support preceptor development and to develop precepting as a



practice philosophy within their institutions. Practice and research models that integrate learners and leverage them to extend pharmacy services should be encouraged and highlighted. Particular importance should be placed on the well-being of busy preceptors who are balancing clinical, professional, and precepting responsibilities. While preceptors continue to adapt to newer educational models that discourage long didactic sessions, preceptors need time for the precepting process. Protected time may be necessary for planning practice experiences, orienting learners, reviewing expectations, discussing learner background and goals, completing and delivering feedback and evaluations, reviewing learner's work, and providing teaching pearls from learning activities. Although this time may vary based on the specific site and infrastructure in place, leadership discussions with precepting teams can help determine what type of support is needed and foster collaborative solutions.

Additionally, this responsibility includes providing financial support to attend preceptor development offerings, protected time to be involved in the precepting process and attend training and development programs, access to development resources, and an organizational commitment to employee well-being. The expectation of precepting as a practice philosophy should be included in role descriptions, performance appraisals, and career ladders to encourage and recognize effective precepting. Examples of competency areas on performance appraisals include commitment to precepting, advocacy for the profession, communication and collaboration, qualities of the learning environment, use of teaching and learning strategies that develop clinical reasoning and other skills, feedback and assessment practices of learners, content expertise, contribution in the area precepted, and ongoing professional engagement.^{6,17,18} These competencies may also serve as a framework for self- and peer assessment that are essential to professional development as well as guide preceptor development plans.^{17,18, 19,20}

Responsibilities of preceptors

Preceptors should approach precepting with a commitment to lifelong learning and continual personal and professional growth. Strategies to implement this philosophy include continuing professional development (CPD) and the self-directed assessment seeking (SDAS) approaches. In CPD, learning needs are identified through self-assessment and reflection; specific, measurable, achievable, relevant, time-bound (SMART) goals are developed to meet learning needs; the effectiveness of the plan is assessed; and learning is applied to teaching practices. 19,20 Recognizing the limitations of self-assessment alone, the SDAS performance improvement process involves seeking feedback and assessment from external sources such as peers and learners, self-reflecting to identify areas of strength and growth, and developing a plan for improvement.²¹ Development plans may include preceptor development offered through written, online, on-demand, live, and other resources. The Habits of Preceptors Rubric is an example of a criterion-referenced tool to support preceptors engaged in self-directed assessment to guide CPD.²² Preceptors may also create a teaching or precepting philosophy to guide their work. Postgraduate trainees and students also have important roles in preceptor development through provision of constructive and professional feedback on learning experiences and precepting practices. Preceptors should create an environment and foster dialogue that encourages and welcomes feedback from learners throughout a rotation. In



addition, colleges of pharmacy and postgraduate trainee programs should train learners to provide constructive, meaningful feedback for learning experiences and preceptors.

Incorporating precepting into practice

Serving as a liaison between classroom education and practical application, preceptors are role models for the practice of pharmacy and share the art of the profession with learners. Preceptors are vital to modeling professionalism, communication, and application of skills and knowledge when they advise, mentor, and provide feedback during thoughtfully designed experiential learning. Additionally, throughout postgraduate training, it is imperative that trainees not only learn to precept effectively, but also to employ those skills by becoming preceptors themselves following completion of postgraduate training. All pharmacists with practice experience, including those with and without postgraduate training, have a responsibility to be involved in the precepting process.

Preceptors have a responsibility to be involved not only in training learners, but also in the continuous quality improvement process of the training. Both colleges of pharmacy and postgraduate trainee programs have set standards for continuous quality improvement. ACPE 2016 Standard 20 requires that colleges of pharmacy solicit preceptors for continuous quality improvement of educational programs, especially in experiential learning, and ASHP standards require that preceptors provide input related to continuous improvement and formal postgraduate trainee program evaluation. These efforts ensure that experiential learning for both students and postgraduate trainees remain parallel with contemporary practice. Preceptors and learners are vital to these quality improvement processes to ensure patient care and outcomes and institutional metrics are optimized.

Finally, preceptors are encouraged to publish examples of the value of precepting as a practice philosophy, the value of learners as pharmacist extenders, and the impact of learners on patient outcomes through scholarly work. As precepting is incorporated into daily practice, this scholarly work reflects contemporary practice, documents value to other healthcare institutions, provides a framework for the development of effective precepting, and encourages other healthcare institutions to embrace precepting as a professional responsibility. Disseminating both positive and negative outcomes as scholarly work is vital to optimizing outcomes for all stakeholders, most importantly patients.

Conclusion

ASHP believes involvement in the precepting process of learners is the professional responsibility of all pharmacy practice leaders, pharmacists, postgraduate trainees, and faculty to advance pharmacy practice and improve patient outcomes. All pharmacy stakeholders play a vital role in embracing precepting as a practice philosophy and supporting a culture of teaching and learning in the experiential setting. Professional organizations, pharmacy leaders and administrators, colleges of pharmacy, and healthcare institutions should support pharmacists, postgraduate trainees, and pharmacy technicians in developing and utilizing precepting skills, provide resources for formal precepting training and development, and promote learner and preceptor well-being.



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Additional Information

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