House of Delegates

Board of Directors Report: Policy Recommendations for the June 2025 House of Delegates

COUNCIL ON PUBLIC POLICY
POLICY RECOMMENDATIONS

The Council on Public Policy is concerned with ASHP professional policies related to laws and regulations that have a bearing on pharmacy practice. Within the Council's purview are (1) federal laws and regulations, (2) state laws and regulations, (3) analysis of public policy proposals that are designed to address important health issues, (4) professional liability as defined by the courts, and (5) related matters.

Kristi Gullickson, Board Liaison

1. Funding, Expertise, and Oversight of State Boards of Pharmacy

To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,

To advocate representation on state boards of pharmacy and related agencies by pharmacists and pharmacy technicians; further,

To advocate that hospitals and health systems are adequately represented on state boards of pharmacy; further,

To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies to carry out expected duties; further,

To advocate for established training of state board of pharmacy inspectors in diverse pharmacy practice areas and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the

pharmaceutical supply chain, the protection of the public, and to establish variances from any documented rule by the board of pharmacy; further,

To advocate that inspections be performed only by individuals with demonstrated competency in the applicable area of practice.

Note: This policy would supersede ASHP policy 2021.

Rationale

In recent years, the regulatory scope of boards of pharmacy has grown to address new and expanded scopes of practice and healthcare while fulfilling their mission of protecting the public health. In addition, coordination with federal agencies (e.g., Food and Drug Administration, Drug Enforcement Administration) and related state agencies adds to the complexity of a state board's mission. With this expanded scope and mission comes the need for additional resources, both financial and human. Specific knowledge acquired by pharmacists and pharmacy technicians is essential to the safe regulation of practice. Thus, inspectors need to have demonstrated competency in the applicable area of practice in order to assure the health and safety of the public. Further, inspectors should provide evidence for variance to established BOP rules to ensure that rules are applied as objectively and consistently as possible.

Background

The Council reviewed 2021, Funding, Expertise, and Oversight of State Boards of Pharmacy, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To advocate appropriate oversight of pharmacy practice and the pharmaceutical supply chain through coordination and cooperation of state boards of pharmacy and other state and federal agencies whose mission it is to protect the public health; further,

To advocate representation on state boards of pharmacy and related agencies by pharmacists and pharmacy technicians; further,

To advocate that hospitals and health systems are adequately represented on state boards of pharmacy; further,

To advocate for dedicated funds for the exclusive use by state boards of pharmacy and related agencies to carry out expected duties, ~~including funding for the training of state board of pharmacy inspectors and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the pharmaceutical supply chain, and protection of the public~~; further,

To advocate for established training of state board of pharmacy inspectors in diverse pharmacy practice areas and the implementation of adequate inspection schedules to ensure the effective oversight and regulation of pharmacy practice, the integrity of the

pharmaceutical supply chain, the protection of the public, and to establish variances from any documented rule by the board of pharmacy; further,

To advocate that inspections be performed only by individuals with demonstrated competency in the applicable area of practice.

The Council felt that the policy needed updating to reflect the need for additional training for board of pharmacy inspectors, especially for setting-specific training. Discussion focused heavily on problems from inspectors applying the same standards to every inspection, even when those standards might not be relevant to certain settings.

2. Payment Parity for Pharmacists' Services

To advocate that any physician or non-physician practitioner be reimbursed in accordance with services provided within their scope of practice; further,

To recognize that pharmacists, as healthcare providers, provide patient care and bridge existing gaps in healthcare as members of the healthcare team.

Note: This policy would supersede ASHP policy 1502.

Rationale

Recognition of pharmacists as healthcare providers is emerging and is being codified in state law as well as in current federal legislative proposals (e.g., H.R. 592, S. 314). In some cases, this recognition also includes specified compensation through existing payment mechanisms (e.g., federal Medicare Part B or state Medicaid programs). With recognition, pharmacists should be sustainably compensated for their patient-care services by all public and private payers using standardized billing processes.

Background

The Council reviewed ASHP policy 1502, Pharmacist Recognition as a Healthcare Provider, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

~~To advocate for changes in federal (e.g., Social Security Act), state, and third-party payment programs to define pharmacists as healthcare providers; further,~~

~~To affirm that pharmacists, as medication-use experts, provide safe, accessible, high-quality care that is cost-effective, resulting in improved patient outcomes; further,~~

~~To recognize that pharmacists, as healthcare providers, improve access to patient care and bridge existing gaps in healthcare; further,~~

~~To collaborate with key stakeholders to describe the covered direct patient-care services provided by pharmacists; further,~~

~~To advocate for sustainable compensation and standardized billing processes used by payers for pharmacist services by all available payment programs.~~

The Council opted to revise the policy completely without maintaining verbiage from the previous version, including a change of title. During the Council's extended discussion on this issue, there was consensus that the current focus on pharmacist status is becoming counterproductive because it invites opposition from physicians' groups due to scope creep concerns. The Council agreed that this should remain a priority issue for ASHP, but that a focus on payment for our services commensurate with what other providers receive might provide a refresh for the issue and prove a more productive strategy. The Council felt that this strategy has worked well in states and would translate well to federal advocacy.

3. Pharmacists Cross-State Licensure

To advocate that state boards of pharmacy collaborate to streamline the licensure process through standardization and improve the timeliness of application approval across state lines; further,

To advocate that state boards of pharmacy collaborate with third-party vendors to streamline the licensure transfer or reciprocity process; further,

To advocate that boards of pharmacy grant licensed pharmacists in good standing temporary licensure, permitting them to engage in practice, while their application for licensure transfer or reciprocity is being processed.

Note: This policy would supersede ASHP policy 1621.

Rationale

Pharmacists sometimes face challenges from delays in obtaining licensure by transfer or reciprocity when moving their practice from one jurisdiction to another. Such delay may be due to the need for boards to review pharmacists' licensure records in all jurisdictions in which they are licensed, administer a state pharmacy law exam, complete a criminal background check, and, in some cases, schedule an interview with the board. To address these challenges, boards of pharmacy should allow pharmacists in good standing to immediately practice in a different jurisdiction when they change employment or enter a residency program. Granting pharmacists a temporary license for a period of up to six months while the board completes its review would help meet workforce demands while continuing to safeguard the public health. In some cases, pharmacists who are unable to obtain a license in a timely manner are unable to fully use

the skills in which they have been trained. Without a license, the pharmacist may temporarily have to function as a technician or perform other tasks. For pharmacists participating in residency programs outside their jurisdiction of licensure, several months of their residency program can elapse before they receive licensure transfer or reciprocity. Upon completion of a year-long residency program, many residents move to another jurisdiction to practice and have to start the transfer or reciprocity process again.

Members in several states have reported that in recent years boards of pharmacy have been slow to issue pharmacy licenses. This delay is especially problematic for pharmacy residents from another jurisdiction who rely on boards to grant them a license prior to performing in a clinical capacity. Given that the licensing period can take several months, this delay has presented a problem for pharmacy residents who have a limited timeframe to successfully complete their duties, typically one year. In some cases, state boards are urging residents to obtain a pharmacy technician license; however, this is inappropriate given the expertise and education residents have and the level of practice they're expected to engage in. Given its national scope, NABP is well-positioned to explore a broad solution to this problem rather than the current, incremental, state-by-state approach.

Background

The Council considered the issue of cross-state licensure, particularly the difficulty of quickly transferring licensure and/or maintaining licenses in multiple states. The discussion focused on the inconsistency of state requirements, including the elimination of the Multistate Pharmacy Jurisprudence Examination in some states and regional compacts or agreements in others. While there is a National Association Boards of Pharmacy (NABP) process for quickly attaining licensure, it is pricey and again, can be dependent on state requirements. Further, servicemembers and spouses continue to face hurdles to license transfer/multistate licensure despite the passage of the Servicemembers Relief Act, which streamlined professional licensure requirements for those groups.

The Council discussed whether to draft new policy, but felt that it made more sense to review policy 1621, Timely Board of Pharmacy Licensing, which is a CPuP policy. Specifically, the Council recommended revising the policy 1621 as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To advocate that ~~the National Association of Boards of Pharmacy (NABP)~~ state boards of pharmacy collaborate ~~with boards of pharmacy~~ to streamline the licensure process through standardization and improve the timeliness of application approval across state lines; further
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> To advocate that ~~NABP collaborate with~~ state boards of pharmacy collaborate with third-party vendors to streamline the licensure transfer or reciprocity process; further,
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> To advocate that boards of pharmacy grant licensed pharmacists in good standing temporary licensure, permitting them to engage in practice, while their application for licensure transfer or reciprocity is being processed.

4. Patient's Right to Choose

To support the patient's right, or that of their representative, as allowed under state law, to make informed decisions as part of their overall plan of care; further,

To acknowledge that patients have the right to be fully informed about their medication options, including benefits, risks, costs, and alternatives, and to be involved in the decision-making process; further,

To support the right of patients to request specific medications, and to have their preferences considered, within the limits of clinical appropriateness, evidence-based practice, formulary restrictions, and legal requirements; further,

To recognize the right of patients to refuse medications or request changes in their prescribed therapy after being informed of the potential consequences of such decisions.

Note: This policy would supersede ASHP policy 0013.

Rationale

ASHP supports the right of the patient, or their representative as allowed under law to make informed decisions regarding the patient's care plan. The patient's right to choose includes being entitled to be informed of their health status, involved with care and treatment, allowed to request or refuse treatment, execute advance directives, and have healthcare practitioners adhere to those directives.

Background

The Council reviewed 0013, Patient's Right to Choose, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To support ~~the right of the patient or his or her representative~~ the patient's right, or that of their representative as allowed under state law, to ~~develop, implement, and~~ make informed decisions ~~regarding his or her~~ as part of their overall plan of care; further,
>
> To acknowledge that ~~the patient's rights include being informed of his or her health status~~ that patients have the right to be fully informed about their medication options, ~~being involved in care planning and treatment, and being able to request or refuse treatment~~ including benefits, risks, costs, and alternatives, and to be involved in the decision-making process; further,

To support the right of patients to request specific medications, and to have their preferences considered, within the limits of clinical appropriateness ~~the patient in accord with state laws to (a) formulate advance directives and (b) have health care practitioners who comply with those directives.~~, evidence-based practice, formulary restrictions, and legal requirements; further,

To recognize the right of patients to refuse medications or request changes in their prescribed therapy after being informed of the potential consequences of such decisions.

The Council felt that the policy needed updating to focus more generally on informed consent generally, rather than focusing on informed consent for more controversial issues, such as end-of-life directives. The Council felt those issues were already addressed in policy, so they could be moved into the rationale to make it clear this policy would apply in those situations, while remaining flexible enough to apply to other situations as well.

5. Support of Global Health Organizations

To strongly support the mission and work of global health organizations in their role in public health preparedness, prevention, and control to improve the health and well-being of people globally.

Note: This policy would supersede ASHP policy 2037.

Rationale

In an age of global travel between and among countries, efforts to prevent, control, treat, and eradicate diseases and conditions that decrease health and well-being are critical to all countries, regardless of factors such as income and education. New vectors of disease transmission and behavioral conditions related to lifestyle and environmental conditions continue to provide challenges that need to be addressed. Domestic and international organizations that provide evidence-based warnings, guidelines, education, research, and advocacy, and that collect data to help countries prepare their public health infrastructure, are essential in providing people around the world with the tools and resources needed to address critical health issues globally.

Background

During Policy Week 2024, the Council discussed ASHP policy 2037, Support of the World Health Organization, as part of sunset review. At that time, the Council recommended discontinuation of the policy. When the Board considered CPuP's 2024 policy discontinuations, it recommended that CPuP reconsider the discontinuation. During the 2025 winter call, the Council felt that

discontinuing the policy could create the perception that ASHP does not support public health organizations, including domestic agencies. At the April 2025 Board of Directors meeting, the Board decided to edit the policy language to support broader global health efforts as follows (underscore indicates new April Board text; ~~strikethrough~~ indicates April Board deletions):

> To strongly support the mission and work of ~~the World Health Organization~~ global health organizations in ~~its~~ their role in public health preparedness, prevention, and control to improve the health and well-being of people globally.

The Council slated a discussion of policy indicating broad support for public health organizations, including FDA, CDC, and NIH for a future Council meeting.

COUNCIL ON PHARMACY MANAGEMENT POLICY RECOMMENDATIONS

The Council on Pharmacy Management is concerned with ASHP professional policies related to the leadership and management of pharmacy practice. Within the Council's purview are (1) development and deployment of resources, (2) fostering cost- effective use of medicines, (3) payment for services and products, (4) applications of technology in the medication-use process, (5) efficiency and safety of medication-use systems, (6) continuity of care, and (7) related matters.

Vivian Bradley Johnson, Board Liaison

1. Recovery and Assistance Programs for Healthcare Workers with Substance Use Disorder

To advocate that hospitals and health systems establish recovery and assistance programs for healthcare workers with substance use disorders, including those who have diverted controlled substances to support their own drug addiction; further,

To encourage state licensing boards to support structured rehabilitation programs that demonstrate a clear pathway for recovery and return to practice upon successful completion of the program.

Rationale

At least one in every 100 healthcare workers (HCWs) is estimated to have diverted medication. Because most drug diversion goes undetected, the true number is likely much higher. Moreover, an estimated 10-15% of HCWs will misuse substances within their career. Due to the physical demands of the job, increasing levels of burnout, and ease of access to controlled substances (CS), occupational risk factors contribute to substance misuse in the healthcare setting. Substance use disorders (SUDs) are formally recognized by *The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, with decades of research linking these disorders to changes in brain chemistry. Historically, the stigma associated with such diagnoses and the fear of license revocation have prevented HCWs from seeking treatment. Many

hospitals and health systems have begun to offer confidential faculty and staff assistance programs; however, these resources continue to be underutilized. Even after diverters have been caught, many will not admit to any wrongdoing for fear of loss of employment. These situations can lead to the diverter resigning and seeking employment elsewhere. Often, the behavior will continue, putting patients and co-workers at risk for safety events. Furthermore, the risk of suicide is high after personnel are confronted about diversion.

To prevent poorer overall health and financial instability, HCWs need to retain their healthcare insurance and access treatment on while on leave of absence or disability, with return to work after completing state board-mandated protocols. ASHP supports employer-sponsored drug programs that promote the recovery of impaired individuals (see ASHP Statement on the Pharmacist's Role in Substance Abuse Prevention, Education, and Assistance). Less punitive approaches are recommended in the ASHP Guidelines on Preventing Diversion of Controlled Substances, which state that sanctions should take into account whether the HCW is supporting his or her own substance use disorder (or that of an associate) or there has been theft of CS for sale and financial gain. The guidelines further recommend that when an HCW is diverting to support a substance use disorder, the diversion should be reported to applicable licensing boards, and the HCW should be referred to a substance abuse program. The guidelines encourage healthcare organizations to establish a process to support recovery for HCWs who are diverting CS for an active substance abuse problem (i.e., an employee assistance program process, which may include mandatory program referral, reporting to the relevant state board or professional assistance program, and a contract for the HCW's return to work). Also known as alternatives to discipline programs (APDs), APDs are non-punitive monitoring programs that allow HCWs to return to work after receiving treatment for an SUD.

The intent of these programs is to support decriminalization of SUDs to avoid interfering with an empathetic approach to employee substance use disorders. However, this must be balanced with other priorities, including patient safety, legal and regulatory compliance, and employee protection. A 2021 ASHP survey found that 83% of surveyed healthcare organizations supported employee substance use recovery programs, and 65% had return-to-work policies for employees who wanted to re-enter the workforce following recovery. SAMHSA defines recovery as a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential. State boards of pharmacy have embraced employee substance use recovery programs and return-to-work policies. Given their essential role in enabling HCWs to return to practice, ASHP encourages all state bodies responsible for licensing HCWs to support accessible, affordable, and structured rehabilitation programs for HCWs with substance use disorders that lead to return to practice upon successful completion.

Background

An ASHP Committee on Resolutions submission during the 2024 ASHP House of Delegates meetings was referred to Council for further review. The resolution led to this policy recommendation, which expresses a nuanced stance on the issue. Since ASHP policy 2042, Controlled Substances Diversion Prevention was slated for sunset review, the Council considered this discussion an opportunity to amend the policy. However, the council decided this topic should be treated as a new policy recommendation versus amending ASHP policy

2042. The existing policy is focused on diversion prevention, and the resolution discussion focused on recovery after an episode of diversion has already occurred. The Council was generally not in favor of including the term “alternatives to discipline programs” in the proposed policy clauses, as they felt it may provoke an emotional response that would interfere with the utility of the policy position. Specifically, when considering whether 1) an HCW is supporting their own substance use disorder, or 2) there has been criminal intent for financial gain; there may be punitive consequences in both cases. One may include a pathway to recovery and return to practice but is still subject to civil penalties; whereas, the other may lead to immediate termination with associated criminal and civil penalties. The Council suggested that ASHP could help members by promoting knowledge of these recovery and assistance programs through education and resources to gain support from hospitals and health systems (e.g., equity and access considerations for licensed and unlicensed personnel) and boards of pharmacy (e.g., clear pathway to re-licensure and return to practice, intra/interstate communication about known or suspected diverters).

2. Cellular and Gene Therapies

To affirm that pharmacists serve key roles in the use of cellular and gene therapies (CGTs), spanning supply chain management, operational oversight, and clinical consultation on individual patients; further,

To recognize that CGTs are therapeutics that are managed as such in the medication-use process; further,

To assert that health-system decisions on the selection, use, and management of CGTs are part of the formulary system; further,

To advocate for outcomes-based innovative payment models that facilitate patient access to CGTs, including full coverage of approved indications and full reimbursement for CGTs.

Note: This policy would supersede ASHP policy 1802.

Rationale

Currently, cellular and gene therapies (CGTs) are defined as "Advanced Therapy Medicinal Products", comprising a large group of cellular types that are either alone or in combination with gene and tissue engineering technology. The U.S. Food and Drug Administration (FDA) recognizes cellular therapy products as cellular immunotherapies, cancer vaccines, and other types of both autologous and allogeneic cells for certain therapeutic indications, including hematopoietic stem cells and adult and embryonic stem cells. The FDA regulates CGTs as biological products, meaning they are considered therapeutics subject to standard drug regulations. The FDA recognizes human gene therapy seeks to modify or manipulate the

expression of a gene or to alter the biological properties of living cells for therapeutic use. Together, CGTs are a rapidly growing and important area of medicine. The 2023 *AJHP* article Role of Pharmacy in Cellular-Based Therapy cites the need for pharmacists to take a leadership role in managing CGTs and delineates three major areas for pharmacy leadership: biologic drug management, multidisciplinary team coordination, and supportive care management. Additionally, the pharmacist, working collaboratively with the interdisciplinary team, should take the lead in ensuring successful use of CGTs (e.g., patient navigation, care coordination lead, proactive review, and assessment for eligibility and reimbursement, measuring and monitoring outcomes). Like other therapeutics, CGT agents should be managed as a part of the formulary system. As described in more detail in the ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System, a fundamental characteristic of the formulary system is that all decisions are made based on evidence-based clinical, ethical, legal, social, logistical, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care; include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals, as well representatives with expertise in finance, law, and informatics; and are not based solely on economic factors.

However, as reported in the ASHP/ASHP Foundation Pharmacy Forecast 2024, the ultra-high expense of these therapies, coupled with uncertain reimbursement, warrants careful financial, service-line, and external partnership analyses. Pharmacy leadership, service-line stakeholders, and the pharmacy and therapeutics committee should collaborate with health-system finance experts to gauge budget impact and measure financial risk associated with the provision of CGTs. Pharmacy should be integral in the development of procedures regarding storage, prescribing, dosing, preparation, labeling, dispensing, transport, safe and compliant administration, clinical decision support tools, and disposal when working with CGTs. To ensure the accuracy of the dose, product, and labeling, pharmacists should have the ability to verify the product when it's prepared in the pharmacy and should be involved when order sets or labeling procedures are developed. Well-known challenges are presented by the use of these agents in structuring clinical decision support tools. These agents are often measured in volumetric dosing (e.g., vector genomes per kilogram), and their documentation often requires use of exponents. Therefore, ASHP recognizes, as part of the medication-use process, the need for innovation in electronic health records and pharmacy workflow systems so that these doses can be displayed accurately while avoiding the use of free text in the electronic health record, which may lead to dosing and entry errors. Safety checks, including robust double check systems, should be in place to avoid errors due to compounding and order entry. Finally, advocacy for patient access to, full coverage of, and reimbursement for CGTs is necessary to develop new capabilities and enable pharmacy services to adapt to these new ultra-high-cost therapeutic innovations.

Public and private payers lack coverage policies and restrictions for CGTs. Many payers use traditional pricing models, such as fee-for-service or utilization management tools, to manage CGT but these models are not suitable for ultra-high-cost therapies. Some hospitals may lack economies of scale to support CGTs and may choose to opt-out of providing them to patients due to insufficient reimbursement. For instance, many hospitals consistently lose revenue on CAR T-cell therapy due to the high readmission rates within 72 hours that are then tied to the diagnostic related groups. CGTs are time intensive therapies, requiring hospitals to

take on financial risk. Hospitals should be paid at cost plus and reimbursement, which should not be dependent on readmission factors due to CGT drug-related events. Several payers plan to leverage reinsurance (e.g., annuity payments) as well as increase their use of value- and outcomes-based contracting. However, legal and regulatory barriers currently prevent or limit the use of innovative, value-based payment models. One value-based agreement under consideration ties reimbursement to value and durability, such as CGT developers reimbursing payers when therapy does not provide sufficient benefit. This approach has the potential to incentivize manufacturers to develop effective therapies, while also ensuring patients receive the best possible treatment. Reimbursement and pricing challenges faced by CGT are complex and require innovative solutions. Value-based arrangements and reinsurance are potential models that could help address these challenges.

Background

The Council previously reviewed ASHP policy 1802, Gene Therapy, in response to an intercouncil referral from the Council on Therapeutics, during its January 31, 2024 winter call. Due to the subject of the joint topic session, a decision was made by Council to revisit the Board-approved CGT policy recommendation to consider for further study. The Council voted to recommend amending the Board-approved amendments to policy 1802 as follows (underscore indicates new June Board text; ~~strikethrough~~ indicates June Board deletions; double underscore indicates new Policy Week Council text; ~~double strikethrough~~ indicates Policy Week Council deletions):

> To affirm that pharmacists serve key roles in the use of cellular and gene therapies (CGTs), spanning supply chain management, operational oversight, and clinical consultation on individual patients; further,
>
> To recognize that ~~cellular and gene therapies (~~CGTs~~)~~ are ~~biologic drugs~~ therapeutics that ~~should be~~ are managed as such in the medication-use process; further,
>
> To assert that health-system decisions on the selection, use, and management of ~~gene therapy agents~~ CGTs ~~should be managed as~~ are part of the ~~medication~~ formulary system ~~in that (1) decisions are based on clinical, ethical, legal, social, philosophical, quality-of-life, safety, comparative effectiveness, and pharmacoeconomic factors that result in optimal patient care; and (2) such decisions must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals~~; further,
>
> ~~To advocate that electronic health record and pharmacy workflow systems be designed to ensure accurate documentation of CGTs; further~~
>
> ~~To advocate that gene therapy be documented in the permanent patient health record; further~~,
>
> ~~To advocate that documentation of gene therapy in the permanent patient health~~

~~record accommodate documentation by all healthcare team members, including pharmacists.~~

To advocate for outcomes-based innovative payment models that facilitate patient access to CGTs, including full coverage of approved indications and full reimbursement for CGTs.

The Council generally agreed with amendments approved by the Board and proposed adding the role of the pharmacist in the successful utilization of CGTs (e.g., patient navigation, care coordination lead, proactive review and assessment for eligibility and reimbursement). The Council stressed this does not mean that pharmacists should execute all functions of process but rather play a significant role and collaborate with other disciplines. Secondly, the Council recommended striking the clause related to electronic health record documentation and including this content in the rationale. The Council suggested documentation is part of the medication-use process which is captured in the proposed second clause. Finally, the Council reviewed the ASHP House of Delegates recommendation "Cellular Therapy Products" to determine if content might be considered for a policy, statement, guidelines, or other action. Council members recommended ASHP consider creating a drafting team to evaluate and guide the application of CGTs for use in pharmacy practice. ASHP's guidance document could advise the development of safe and appropriate manipulation, dispensing, and handling of cellular and gene therapeutics (investigational and commercial) for health systems. The guidance could also help establish pharmacy leadership in this field and identify opportunities for pharmacy practice that lead to an improved patient care experience. Additional practice needs and considerations for the guidance are:

- Regulatory regime and compliance, including provider knowledge of changes and/or recent FDA drug approval processes (e.g., FDA accelerated approval, CMS Cell and Gene Therapy Access Model).
- Infrastructure and facilities requirements, including those for biosafety.
- Hospital and health-system management of CGTs.
- Patient engagement and communication.
- Technology integration.
- Creating sustainable models for CGT research and development.
- Ethical framework considerations and concerns (e.g., rationing due to high costs, germ line manipulation, benefit-risk determination, use of human fetal tissue to source embryonic stem cells).
- Advanced training and education of students and current practitioners.
- Education of the pharmacy profession on innovative practice models with an associated resource center that is responsive to rapid changes in CGT.

The Council acknowledged that ASHP must help prepare the pharmacy workforce for CGTs by providing education and training. This effort should address the future impact CGTs will have on pharmacy resource allocation and traditional pharmacy roles as well as CGTs role in providing opportunities for a safer medication-use process, improved patient access to care,

and advocacy for fiscally solvent payment models.

3. Interstate Pharmacist Licensure

To discontinue ASHP policy 2030, Interstate Pharmacist Licensure, which reads:

To advocate for interstate pharmacist licensure to expand the mobility of pharmacists and their ability to practice.

Background

The Council recognizes this topic is still a profession-focused priority but suggests that the policy be discontinued with an opportunity to consolidate the central point within existing ASHP policy. The Council suggests the Council on Public Policy or Council on Education and Workforce Development consider reviewing ASHP policy position(s) 0909, Regulation of Interstate Pharmacy Practice; 1621, Timely Board of Pharmacy Licensing; 2201, State-Specific Requirements for Pharmacist and Pharmacy Technician Continuing Education; or 2420, Opposition to Pharmacy Jurisprudence Examination Requirement at a future meeting to determine if consolidating with ASHP policy 2030, Interstate Pharmacist Licensure, is a possibility.

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.

1. Safe and Secure Transfer of Controlled Substances

To advocate for the standardization of policies, procedures, and practices in the handling of controlled substance medications throughout the care process, including transfers between emergency medical services and during interfacility transport; further,

To promote closed-loop communication processes related to controlled substance medication management during patient transfers; further,

To collaborate with emergency medical services and other stakeholders involved in pre- and post-hospital and interfacility transfers of controlled substances to improve patient safety, minimize variation, and ensure compliance.

Rationale

Compliance with Drug Enforcement Administration (DEA) regulations and applicable state laws and regulations is crucial for protecting public health and preventing misuse and diversion of controlled substances (CS). Health systems are required to provide leadership and oversight of handling and storage of CS. They are also required to comply with laws and regulations in the transfer of CS between institutions and other DEA registrants. This can be a complex process, particularly in the absence of clear federal and state policies.

There is a lack of uniformity and clarity in allowances and processes for the transfer of CS from a hospital or health system to nonhospital-based emergency medical services (EMS) (e.g., state or local government-owned agencies) and vice versa. To address this, the Protecting Patient Access to Emergency Medications Act of 2017 (PPAEMA) authorized the DEA to amend the Controlled Substances Act to clarify the receipt, movement, and storage of CS for an EMS agency.[4,5] PPAEMA states that CS can be stored in the DEA-registered EMS agency location, in EMS vehicles used by the agency, and in unregistered locations as long as the US Attorney General is notified of the location at least 30 days before the CS is initially delivered for storage. In addition, hospitals may restock CS for an EMS agency following an emergency response. However, the DEA has not finalized regulations as authorized by PPAEMA, creating challenges for states and hospitals to interpret federal regulations while implementing systems and solutions for the safe and lawful transfer of CS to EMS. A uniform approach or standard development may assure accountability and prevent diversion while meeting patient care needs.

Background

The Council examined this topic in response to a recommendation from Council members who observed practice challenges with ambiguous state and federal regulations related to the transfer of controlled substances between healthcare settings and emergency medical services agencies. Council members expressed concern over patient safety and risks of worsening outcomes after changing administration methods during patient transfers, which are due to compliance issues and the need for more standardization. Council members suggested that future revisions to the ASHP Guidelines on Preventing Diversion of Controlled Substances include content related to safely and securely transferring CS.

2. Addressing and Preventing Moral Distress and Injury in the Healthcare Workforce

To acknowledge the acute and chronic exposure of the healthcare workforce to potentially morally injurious events across the continuum of care; further,

To recognize the risk of moral distress and moral injury when a healthcare worker is unable to provide ethical, safe, and effective care due to system-level constraints; further,

To advocate for consistent and equitable allocation of resources across care teams and health systems to ensure that healthcare workers can provide safe and comprehensive patient care services; further,

To advocate for proactive and corrective approaches within organizations that are co-designed with members of the healthcare team to prevent and address moral distress and injury among healthcare workers.

Rationale

Moral injury is defined as the "perceived betrayal by a legitimate authority in a high stakes situation, which leads one, through action or inaction, to deeply transgress held moral beliefs and expectations." It is considered to be a syndrome associated with clinical symptoms such as psychological distress, increased thoughts of self-harm and various mental illnesses. Moral injury occurs when workers begin to question the moral framework of the system and their own moral framework for continuing to work within that system. It is increasingly being included in discussions with occupational burnout, as a differentiating factor for healthcare workers from other professional fields struggling with occupational burnout in their workforces and due to exposures to potentially morally injurious events that occur in healthcare environments. It provides an important insight for healthcare workers who believe that occupational burnout, a syndrome of emotional exhaustion, depersonalization, and a low sense of accomplishment, is a symptom of a larger problem, beyond individual well-being and resilience.

Moral injury has been described as a process, or continuum, in which an individual progresses through a range of experiences from moral dilemma, to moral distress, and then to moral injury. The Workforce Change Collaborative advanced a National Framework for Addressing Burnout and Moral Injury in the Health and Public Safety Workforce which overlays the continuum of moral injury and burnout and depicts environmental, relational, and operational drivers and outcomes impacting workers and learners, patients and community, organizations, and society. Left unresolved, moral injury has not only consequences for the individuals experiencing it, but also for patients who are impacted by increased risk of errors, threats to safety, and diminished quality of service. Organizations may experience significant employee turnover and declines in quality and patient satisfaction ratings.

Moral injury was originally a military term used to describe a soldier's response to serving during times of conflict depicted as a "deep soul wound that pierces a person's identity, sense of morality, and relationship to society." In the context of healthcare, moral injury is not comparable to a soldier's actions taken during a war; however, it occurs when a healthcare worker feels unable to provide high-quality care due to ethical dilemmas experienced in their workplace. Calls for action include commitments from leadership and organizations to be proactive and corrective in addressing patterns that lead to moral distress and moral injury and ensuring equitable allocation of resources for healthcare workers to perform their jobs in an ethical, safe, and effective manner.

Background

The Council examined this topic as a response to a recommendation from Council members who felt moral injury was not addressed in current ASHP policy positions. The Council felt the policy should recognize the existence and impact of exposure to potentially morally injurious events throughout the careers of healthcare professionals and advocate for organizational and leadership decisions that equitably allocate scarce resources without increasing the risk of patient harm. Council members also spoke to experiences in their work environment where safety and quality was compromised for the sake of financial performance.

3. Pharmacy Services to Optimize Patient Throughput

To support the integration of pharmacy services as systems are optimized to improve health system-wide patient throughput; further,

To advocate for pharmacists to serve as key decision-makers for improving patient flow throughout the health system; further,

To develop resources related to incorporating pharmacy services into patient throughput action plans and process maps; further,

To identify measures and tracking systems that demonstrate the impact of pharmacy-driven services to optimize patient throughput.

Rationale

Efficient patient throughput, or hospital-wide patient flow, is important for care outcomes and organizational productivity. Increases in patient demand for healthcare services, high-acuity patient needs, healthcare worker staffing shortages, and constraints on organizational capacity create tensions in the flow of a patient's hospital stay from admission through discharge (*Health Policy*. 2022;126:87-98).

Barriers to patient throughput in emergency departments is also a hospital-wide problem as it leads to long wait times and crowding, compromises quality of care, decreases patient and healthcare worker satisfaction, and increases costs. Root causes identified as contributors to these barriers are lack of staff, lack of standards and routines, insufficient operational planning, lack of technology functions, insufficient discharge routines, insufficient facilities and layout, insufficient communication, insufficient transfer coordination, random internal disturbances, unpredictable patient problems, lack of beds, medical quality priorities, lack of ancillary services, increased demand, and lack of separate tracks (*Health Policy*. 2022;126:87-98).

The Institute for Healthcare Improvement white paper, "Achieving Hospital-wide Patient Flow" identifies the following principles to achieve optimal patient throughput:

- System-wide approach to patient flow,
- Hospital-wide learning system,
- Integration of various approaches,
- Utilization of advanced data analytics, and
- Focus on reducing and shaping demand.

The white paper also suggests following three rules for clinicians and staff as a means for ensuring patients receive the right care, in the right place, at the right time:

1. Right Care, Right Place: Patients are placed on the appropriate clinical unit with the clinical team that has disease- or condition-specific expertise.

2. Right Time: There are no delays greater than two hours in patient progression from one hospital unit or clinical area to another, based on medical readiness criteria.
3. Available Capacity: Ensure each unit or clinical area has some capacity at the beginning of each day.

There are numerous reports focused on improving throughput and efficiencies with processes within the pharmacy department; however, there is limited literature about pharmacy department contribution to hospital-wide patient throughput processes. One report suggests a framework for establishing pharmacy services to support a co-located long-term acute care hospital within a health system, which offers some insight. The suggested framework includes operationalizing processes, ensuring licensure and regulations compliance, enhancing information technology, aligning staffing models, managing pharmacy operations and distribution services, implementing clinical services, and demonstrating quality. Pharmacy service interventions included medication clarification, therapy optimization, discharge process support, antimicrobial stewardship, discontinuation of unnecessary or inappropriate medications, IV to oral medication conversion, dose adjustment, preventative care, and managing duplicate medications ordered as needed. The report identifies coordination with pharmacy team leaders and collaboration with other healthcare disciplines as instrumental for seamless integration.

Pharmacy services are highly innovative and process-driven; however, they are often siloed from systemwide interventions for improving patient throughput. Expertise from the pharmacy workforce would add value to action plans and process improvements aimed at improving patient throughput in emergency departments and acute and ambulatory care settings.

Background

The Council examined this new policy topic as it relates to the pharmacy workforce's role in improving patient throughput in emergency departments and acute care settings. Council members felt this topic was not covered in existing policy and that there is limited information on the integration and impact of pharmacy services on systemwide patient throughput. Council members reflected that pharmacy services are process-driven and innovative and that systemwide efforts to improve patient throughput would benefit from greater involvement.

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.

1. Accurate and Timely Height and Weight Measurements

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

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

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

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

To advocate for federal and state laws and regulations to include weight, height, and date obtained as a required component of prescriptions for medications that are dosed based on height and weight.

Note: This policy would supersede ASHP policy 1721.

Rationale

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

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

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

Dosing medications based on height and weight presents important concerns, particularly for pediatric patients, whose variables can change often, but also for oncology patients and aging populations, for whom toxicities or adverse events are a concern (Lubsch L et al. Patient Weight Should Be Included on All Medication Prescriptions. *J Pediatr Pharmacol Ther.* 2023;28:380–1). Therefore, regulations that mandate recording of height and weight on orders for medications that are dosed based on height and weight would enhance patient safety.

Background

The Council reviewed ASHP policy 1721, Clinical Significance of Accurate and Timely Height and Weight Measurements, as part of a discussion of mandatory recording of pediatric weights on

all prescriptions. The Council believed that while most weight-based dosing for medications is for the pediatric population, it is not the only population for which weight-based dosing is used. The Council therefore recommended amending policy 1721 with language that would include all patients for whom medication doses are based on height and weight, as follows (underscore indicates new text):

> To encourage pharmacists to participate in interprofessional efforts to ensure accurate and timely patient height and weight measurements are recorded in the patient medical record to provide safe and effective drug therapy; further,
>
> To encourage drug product manufacturers to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,
>
> To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,
>
> To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes; further,
>
> To advocate for federal and state laws and regulations to include weight, height, and date obtained as a required component of prescriptions for medications that are dosed based on height and weight.

2. Clinical and Safety Considerations of Naming Drug Moieties and Complexes

To oppose the consolidation of existing drug classes that include drugs that have distinct pharmacologic effects and pharmacokinetic/pharmacodynamic profiles; further,

To encourage regulatory agencies to consider clinical, operational, access, and safety factors when approving and classifying medications with different moieties or complexes that are used to deliver the active drug; further,

To advocate for the pharmacist's active role in these processes; further,
to foster increased pharmacist, provider, and public awareness when changes in approved drug products with therapeutic equivalence occur.

Rationale

The Food and Drug Administration (FDA) publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, identifies drug products approved by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and contains therapeutic equivalence evaluations for approved multisource prescription drug products.

In May of 2021, the FDA changed four iron-carbohydrate drugs with distinct, established, names with different dosing and administration practices and consolidated them under a singular active ingredient, ferric oxyhydroxide. The intravenous formulations of ferric oxyhydroxide, iron sucrose, sodium ferric gluconate, and iron dextran all have different dosing and administration requirements including test infusions, different infusion rates, doses spread out over multiple days and at different concentrations and different monitoring parameters and safety considerations (Iron dextran has a black box warning due to an increased rate of anaphylaxis than other IV iron therapies), Furthermore, the oral formulation is not used for the treatment of iron deficiency anemia, further complicating the clinical and operational picture.

Additionally, this consolidation introduces several areas of concern including risk for incorrect usage of these medications, formulary considerations, administration of the iron-carbohydrate drug, patient safety, and adverse drug event reporting.

This also creates the potential for the FDA to change labeling of drugs with the same active ingredient but different molecular delivery attributes, such as metoprolol tartrate and succinate which have different frequencies, or liposomal amphotericin B and amphotericin deoxycholate, which have different doses.

In general, the FDA considers an active ingredient to be the active moiety as "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance." However, because the dosing, administration and monitoring are distinct for different drugs-complexes, even if the active moiety is the same – they should be distinguished by name.

Further, this change was performed under the auspices of a response to a regulatory request in a citizen petition, and therefore did not follow the statue requirement delineated in the FD&C Act that includes an opportunity for comment on this change. While the goal of this consolidation appears to mitigate potential abuse of new chemical entity exclusivity, the negative safety and clinical implications necessitate an examination of this approach, particularly when it is retroactive in nature.

Background

The Council discussed the Food and Drug Administration's (FDA) Orange Book reclassification of four iron-carbohydrate drugs with distinct, established, names with different, dosing and administration practices to a singular entity, ferric oxyhydroxide. The Council discussed the risks associated with reclassifying these drug products including: safety concerns over drug mismatches; errors in ordering, dispensing, and administration; and confusion during patient access and insurance coverage. The Council appreciated the probable intent of the FDA which was to garner innovation and to avoid the over proliferation of patented drugs that contain the

same active ingredient. However, because chemical structures that deliver the drug can include different pharmacokinetic and pharmacodynamic properties as well as delivery mechanisms, consolidation of existing drug products should be avoided. The Council did acknowledge that if consolidation had been presented from the beginning, as what was done with amphotericin products, that it would have been amenable. Council members were most concerned that they were largely unaware of this consolidation and that the change was made without consideration for safety and could be retroactively applied to other drug classes with similar molecular drug delivery systems.

3. Clinical, Operational, and Safe Use of Manipulated Drug Products and Alternate Administration Routes

To support clinically appropriate, evidence-based use of manipulated drug-products or alternate drug administration routes when it supports optimal patient care; further,

To promote research that further delineates the pharmacokinetic and pharmacodynamic properties of drugs when manipulated or when given through alternate administration routes and investigate the interrelationship between drug exposure and safety and efficacy outcomes including the potential role of artificial intelligence in advancing model development and validation; further,

To encourage manufacturers to develop drug products in ready-to-use devices and diverse formulations; further,

To foster pharmacist-led interdisciplinary teams to provide institutional guidance, best practices, and safety recommendations regarding drug products that are manipulated or administered through alternative routes.

Note: This policy would supersede ASHP policies 2041, 2242, and 2314.

Rationale

Administration of drug products through alternative routes of administration including intranasal, nebulization, intrathecal, intraosseous, and enteral routes that deliver medications to alternate sites of absorption are increasingly more prominent in practice as patient needs evolve. For example, novel delivery mechanisms through the nebulization of antibiotics and antifungals that are formulated for intravenous (IV) administration are used adjunctively to treat pulmonary infections in critically ill patients. Intranasal administration is often the route of choice in the emergency department due to access issues, safety concerns, and the characteristics of specific patient populations (e.g., children). Soluble drugs such as naloxone can be converted for intranasal administration without altering the substance simply by use of an aerosolizer. The intranasal route is frequently used to treat pain when oral and intravenous routes are not available or optimal, and intranasal midazolam is often used for sedation in the

pediatric population, although that route of administration has not been approved by the Food and Drug Administration.

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 for various reasons including when a patient a) requires the medication administered enterally but is unable to take the medication by mouth, b) requires a dose that is not readily available and so a specific dose requires it to be compounded, or c) 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 drugs as liquid formulations because they may not be available, thus necessitating crushing them.

Studies reveal that oral drug products pass through the stomach, exposing them 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. 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. When drug products are manipulated or administered through alternative sites or means, consideration for the properties of formulations, including but not limited to drug molecule size, viscosity, surface tension, solubility, stability, osmolality, tonicity, and pH must also be included as these can affect pharmacokinetics and pharmacodynamics.

It is important to recognize that the need to manipulate or administer drug products through an alternate route is because there is not a commercially available formulation and as such, need may require compounding with both sterile and nonsterile ingredients. Due to this variability and potential source for sterile compounding and administration errors, manufacturers should be encouraged to create commercially available formulations to meet clinical needs where there is evidence that supports the use of manipulated drug products or alternate administration methods.

There is also a lack of resources that provide guidance on how manipulation and alternative sites of drug administration 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 and those administered via alternate routes or delivery systems. ASHP encourages 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 drug dosing for manipulated drug products. Given that the frequency that some of these medications are manipulated or administered is often based on small case studies, consideration for the potential role of artificial intelligence in advancing model development and validation should also be explored.

Manipulation of drug products and alternate administration are also not without risk.

Nebulized drugs that are not commercially available may be compounded with both sterile and nonsterile ingredients and that, when possible, should be compounded with preservative- and additive-free formulations to improve patient tolerability and considerations for drug stability, safety for patient and personnel administering nebulized drug products, and methods for preparation and delivery. Drug products administered intranasally often vary in pharmacokinetic and pharmacodynamic properties due to the presence of preservatives and viscosity of the agents and efficacy may depend on the use of additional devices such as atomizers. There are also exposure risks to caregivers preparing or administering manipulated drug products that are carcinogenic or teratogenic. Medications compounded for administration in the epidural space or intrathecal administration also bear consideration for the presence of preservatives. To this end, ASHP strongly recommends that when medications are manipulated or being considered for alternative administration, a multidisciplinary team that includes a pharmacist is convened to assess clinical, safety and operational needs and provide institutional guidance.

Background

The Council discussed the expansion of how drug products are used in practice based on clinical need, drug shortages, and patient access for administration. The Council also discussed operational challenges, safety considerations when administering or manipulating medications outside of their original dispensed form or intended route of administration (e.g. intravenous medications being administered intranasally, crushing medications for tube administration, nebulized intravenous medications, intraosseous administration and more), as well as the lack of data surrounding these drug products that are manipulated or administered to meet patient need. Council members reviewed existing ASHP policies 2041, Safety of Intranasal Route as an Alternative Route of Administration, 2242, Use of Intravenous Drug Products for Inhalation, and 2314, Manipulation of Drug Products for Alternate Routes of Administration and determined that these policies all addressed similar needs. Instead of additional individualized policies for intrathecal, intraosseous and other non-traditional routes of administration, the Council consolidated the existing policies into one that includes provisions for manipulation of drug products and alternate methods for drug product delivery. The Council also considered consolidating policies 1804, Drug Dosing in Conditions That Modify Pharmacokinetics or Pharmacodynamics and 1725, Drug Dosing in Extracorporeal Therapies but decided that since these policies are changes in the way the patient affects the drug as opposed to changes to the drug-product, they are not appropriate for consolidation.

4. Expedited Partner Directed Therapy

To affirm that the pharmacy workforce improves patient access to therapies that prevent and treat sexually transmitted infections in all settings; further,

To support legislation that promotes expedited partner therapy (EPT); further,

To affirm that interpreting test results, prescribing, dosing, and dispensing therapies as clinically indicated is within pharmacists' scope of practice; further,

To affirm that drug products for EPT should be provided to individuals in a manner that ensures safe and appropriate use; further,

To encourage surveillance of EPT as a public health effort.

Rationale

Expedited Partner Directed Therapy (EPT) is an approach to treating sexual partners of patients who are seeking therapy for a sexually transmitted infection (STI). According to the Center for Disease Control and Prevention (CDC), chlamydia, gonorrhea, and syphilis are on the rise throughout the United States and are a source of significant morbidity and mortality. EPT has demonstrated to be an effective tool in combating the spread of STIs by treating the sex partners of patients with an STI by providing prescriptions or medications to the patient to take to their partner without the health care provider first examining the partner.

EPT is a generally accepted approach to treating certain STIs, but legislation across the United States varies from state to state with 47 states identifying EPT as permissible and three states that identify it as potentially allowable. "Permissible" is described as allowable for certain practitioners and conditions while "potentially allowable" means that EPT is potentially allowable subject to additional actions or policies. Relevant legal provisions include: existing statutes and regulations that specifically address the ability of authorized health care providers to provide a prescription for a patient's partner(s) without prior evaluation for certain STDs, specific judicial decisions concerning EPT, laws that incorporate via reference guidelines as acceptable practices, and statutory or regulatory provisions that relate to prescription drug laws in each jurisdiction – to the extent they may impact EPT.

Because the variety and complexity of these policies could present potential barriers to care, ASHP supports model legislation that articulates the authorization of a pharmacist to voluntarily offer preventative services, patient assessment, and patient care for sexual and reproductive health conditions, including EPT. When appropriate, pharmacists may recommend a referral to seek a higher level of care through the use of counseling and clinical decision-making tools. The proposed model legislation authorizes appropriately trained pharmacists to provide these services when consistent with the standard of care.

Finally, ASHP recognizes that any legislation should define these services, provide clear authority for pharmacists to provide person-centered health services independently and through collaboration, create a mechanism for state and commercial insurance companies to pay for these services, include federal preemption and severability language, and should remove any pre-existing state barriers to pharmacist provision of health services.

Background

The Council discussed the public health need to support EPT as well as the barriers to treatment with this approach to patient care including coverage of EPT by insurance companies, technology limitations, social stigmas, and cost. Some Council members also shared that while

they have laws that promote EPT, providers can often be a barrier to care as some may wish to see partners before providing prescriptions or may be unaware of nuances of the legislation that permits EPT.

5. Quality Consumer Medication Information

To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, accessibility, targeting, and simplicity of consumer medication information (CMI); further,

To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment of a universal literacy level and standardized, patient-focused templates for CMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that the FDA explore alternative models of CMI content development and maintenance that will ensure the highest level of accuracy, consistency, currency,and conformity with health literacy requirements; further,

To advocate that the FDA maintain a highly structured, publicly and easily accessible central repository of CMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of CMI.

Note: This policy would supersede ASHP policy 2005.

Rationale

Providing easy-to-read and accurate information to patients about medications is essential for ensuring their safety and efficacy. Nonadherence to and incorrect use of medications can lead to hospital admissions, treatment failures, and death. Multiple types of written information are provided to patients with prescription medications and biological products, but much of this information can be conflicting, confusing, and incomplete. Furthermore, only 12% of Americans have proficient health literacy skills according to the National Assessment of Adult Literacy, decreasing the likelihood that these patients will comprehend the provided information.

Consumer medication information (CMI) is written information for patients or caregivers about a prescription drug. CMI is developed by individuals or organizations; drug companies and the FDA do not review or approve CMI. Currently available patient labeling available in the United States include Medication Guides (MG), Patient Package Inserts (PPI), and Instructions for Use. Medication Guides are a type of labeling for patients or caregivers that

are required by the FDA if certain criteria are met, for example, when the medication has serious side effects or if following the directions is particularly important for effectiveness or avoiding serious side effects. PPIs provide patient information that can be a part of FDA-approved labeling and are developed by the manufacturer and approved by the FDA. PPI are required for estrogen-containing products and estrogens, but creation of PPI for other prescription medications is voluntary.

In 2023, the FDA proposed a rule that would create a new medication guide called "Patient Medication Information" (PMI) for prescription medications and biological products that are administered, dispensed, or used in an outpatient setting. These manufacturer-developed, FDA-approved, standardized, one-page documents will be provided in either paper or electronic format. PMI would replace the current MG and PPI and will be stored electronically in FDA's labeling repository. The FDA is in the process of reviewing comments and a final rule has not been issued.

The Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health's Healthy People 2030 initiative defines health literacy in two ways: personal health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others; and organizational health literacy is the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Programs that support education and training around self-assessment of health literacy and general communication skills and methods for practitioner assessments of patient health literacy are needed to ensure full adoption and appropriate implementation. Barriers to health literacy include language barriers such as limited English proficiency and communication barriers such as those experienced by the deaf or hard of hearing community. Each of these barriers, along with disability, transportation, and cultural barriers require practice resources to accommodate patients with specific communication needs.

Use of plain-language and patient-centered formats of CMI is essential for optimal health-related outcomes of medication use. Design elements and interventions, however, lack high-quality evidence and are thus unable to be considered "best-practice." Incorporating new methods of providing CMI and innovative practices should be a focus of future investigations.

Background

The Council reviewed ASHP policy 2005, Quality Consumer Medication Information, as part of sunset review and voted to recommend amending it as follows as the FDA has assumed the responsibility for editorial control in CMI: (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To support efforts by the Food and Drug Administration (FDA) and other stakeholders to improve the quality, consistency, accessibility, targeting, and simplicity of consumer medication information (CMI); further,
>
> To encourage the FDA to work in collaboration with patient advocates and other stakeholders to create evidence-based models and standards, including establishment

of a universal literacy level and standardized, patient-focused templates, for CMI; further,

To advocate that research be conducted to validate these models in actual-use studies in pertinent patient populations; further,

To advocate that FDA explore alternative models of CMI content development and maintenance that will ensure the highest level of accuracy, consistency, currency, and
conformity with health literacy requirements; further,

To advocate that the FDA maintain ~~engage a single third-party author to provide editorial control~~ a highly structured, publicly and easily accessible central repository of CMI in a format that is suitable for ready export; further,

To advocate for laws and regulations that would require all dispensers of medications to comply with FDA-established standards for unalterable content, format, and distribution of CMI.

COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATIONS

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.

Jennifer Tryon, *Board Liaison*

Council Members
Michelle Estevez, *Chair* (Florida)
Kate Taucher, *Vice Chair* (Colorado)
Jaclyn Boyle (Ohio)
Aliyah Cruz (Wisconsin)
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Travis Dick (New York)
Johnnie Early II (Florida)
Ifeanyi Egbunike-Chukwuma (Maryland)
Daniel Kudo (California)
Donald Moore (North Carolina)
Kimberly Zammit (New York)
Rebecca Ohrmund (Illinois)
Travis Schubert, *Student* (Texas)
Sophia Chhay, *Secretary*

1. Support for Caregiving Responsibilities in the Pharmacy Workforce

To affirm that an individual's life circumstances can change and influence their workplace needs, further;

To foster psychologically safe environments that promote dialogue around individual workplace needs, further;

To advocate for organizational policies and resources that reduce disparities caused by caregiving responsibilities including eldercare and lactation support, further;

To empower individuals to advocate for their own needs related to work-life integration.

Rationale

Throughout an employee's career, work dynamics often shift in response to life changes such as caregiving and lactation responsibilities. These situations introduce unique challenges that can significantly impact an employee's ability to balance personal and professional demands. In the pharmacy profession, organizations and leaders have a critical role in addressing these needs by providing supportive resources, ensuring benefit options are clearly communicated, and

fostering an environment where employees feel comfortable discussing their circumstances.

Breastfeeding and lactation support are essential aspects of employee well-being, as breastmilk offers proven health benefits for both individuals and their children. Although the PUMP Act was enacted in 2022, pharmacy workplaces may still lack adequate, clean, and private spaces for expressing breastmilk. Variability in paid parental leave policies further complicates this issue, as many breastfeeding individuals return to work while still nursing and need support to maintain their breastfeeding relationships. Employers of pharmacy personnel must consider how to best support breastfeeding employees, promoting access to resources and lactation-friendly environments.

Eldercare is becoming an increasingly critical issue, particularly as the U.S. population over the age of 65 continues to grow. Unlike childcare, eldercare is not widely supported by current benefits policies, including FMLA. According to the 2022 National Pharmacist Workforce Study, women represent a majority of the pharmacy workforce and may face career disruptions due to caregiving responsibilities. By incorporating eldercare policies and benefits, employers of pharmacy personnel can improve employee retention, reduce absenteeism, and enhance productivity.

Supporting employees with caregiving and lactation needs requires employers of pharmacy personnel to advocate for policies that reduce disparities, ensure flexible work environments, and address the well-being of the workforce.

Background

The Council discussed lactation support and resources within the pharmacy workforce in response to a recommendation from the ASHP House of Delegates. The Council also discussed the topic of addressing eldercare to promote pharmacy workforce well-being. The Council determined that ASHP needs a broader policy to encompass support for caregiving responsibilities in the pharmacy workforce to include lactation, eldercare, and other work-life integration needs.

2. Cultural Competency and Trauma Informed Care

To foster the ongoing development of cultural humility and competency within the pharmacy workforce and promote a whole-person-health approach to care; further,

To educate the pharmacy workforce on how to interact with patients, caregivers, and other healthcare professionals in a manner that demonstrates respect for and responsiveness to all; further,

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

Note: This policy would supersede ASHP policy 2231.

Rationale

Culture influences a patient's belief and behavior toward health and illness. Healthcare workers who demonstrate cultural humility and competence can improve clinical outcomes. Cultural humility is having an awareness of how a person's culture can impact health behaviors and then using this knowledge to approach the patient's treatment. Research has shown that overlooking cultural beliefs may lead to negative health consequences. Cultural competence is a set of congruent behaviors, attitudes, and policies that come together in a system, agency or among professionals and enable that system, agency or those professions to work effectively in cross-cultural situations. According to the National Center for Cultural Competency, there are numerous examples of benefits derived from cultural competence on quality and effectiveness of care in relation to health outcomes and well-being. Further, pharmacists can contribute to providing "culturally congruent care," which can be described as "a process of effective interaction between the provider and patient," by recognizing that "[p]atients and families bring their own values, perceptions, and expectations to healthcare encounters."

Whole person health includes consideration of how biological, behavioral, environmental, and social factors impact a patient's health outcomes. When considering holistic approaches to patient care, clinicians should recognize and respond effectively to all personal and social identities. Spiritually congruent care may be expressed in prayer requests, in clinician-chaplain collaborations, and through health care organizations' religious accommodations for patients and staff. Numerous publications have outlined the role of spirituality in overall health, longevity, and quality of life, especially for patients with severe illness. The pharmacy workforce should be educated on the importance of individual patient spirituality and its impact on health and on ways to facilitate patient access to spiritual care services.

Trauma is a widespread public health issue that can stem from various sources, including abuse, neglect, poverty, and other emotionally harmful experiences. Trauma-informed care (TIC) is an essential healthcare approach that recognizes and responds to the impact of trauma on patients' physical and mental health. Increasing evidence shows that implementing TIC can improve patient outcomes, including engagement, satisfaction, and adherence, while addressing complex patient needs. For pharmacy professionals, integrating TIC is crucial to providing tailored care. Additionally, TIC can help healthcare workers, who face higher risks of trauma post-pandemic, recognize signs and symptoms of trauma thereby reducing burnout and turnover. Training healthcare providers to understand the effects of trauma at both the clinical and organizational levels is vital for improving patient care and outcomes.

Background

The Council reviewed ASHP policy 2231, Cultural Competency, in response to a recommendation from the ASHP House of Delegates on the role of the pharmacy workforce in trauma informed care voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

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

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

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

The council updated the rationale.