House of Delegates

Board of Directors Report: Policy Recommendations for the March 2026 House of Delegates

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.

Dawn Moore, *Board Liaison*

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1. Responsible Integration of Artificial Intelligence in Pharmacy Education and Training

To advocate for the responsible integration of artificial intelligence (AI) into pharmacy education and training programs to support learner development and practice readiness; further,

To advocate for development of competencies for discerning AI-generated content, including strategies to validate the accuracy, credibility, and applicability of information produced by AI systems; further,

To collaborate on the development of standards for AI use in pharmacy education and training.

Rationale

AI has the potential to evolve education and the learning environment by delivering personalized experiences, simulating clinical decision-making, and expanding access to knowledge resources. Conversely, AI also introduces unique challenges related to academic integrity, validation of information, learner overreliance, and responsible application, such as

generative AI, which uses AI to create original content.

Emerging platforms which leverage AI to analyze, synthesize, and present clinical literature demonstrate both the potential value and the risks of integrating AI into the education and training of future healthcare professionals. In a recent JAMA article, Building the AI-Enabled Medical School of the Future, the authors highlight that academic institutions must move quickly to embed AI literacy, validation skills, and ethical awareness into curricula to ensure learners are equipped for practice in AI-enabled health systems.

This pharmacy education and training-focused policy will emphasize the need to equip learners with skills to critically evaluate and responsibly apply AI outputs, prepare future practitioners with competencies to navigate AI-enabled health systems, support faculty and preceptors in integrating AI appropriately into teaching, learner assessment and professional development activities, and establish safeguards to ensure integrity and alignment with professional values.

Background

The Council's proposal for a new policy on the responsible integration of artificial intelligence (AI) in pharmacy education and training emerged from its recognition that rapid advancements in AI are reshaping healthcare and learning environments. Council emphasized that while existing ASHP policy 2413, Role of Artificial Intelligence in Pharmacy Practice, broadly addresses AI in pharmacy practice, targeted guidance is needed to support educators, learners, and training programs for this evolving landscape. Members noted that AI tools are increasingly influencing how information is accessed, synthesized, and applied in pharmacy education. The Council identified both opportunities and risks associated with these technologies, including their potential to enhance personalization and critical thinking, as well as challenges related to validation, academic integrity, and overreliance. Developing clear expectations, competencies, and collaborative standards across academic institutions, health systems, and accrediting bodies will help ensure that AI is used ethically, responsibly, and in ways that advance learner readiness and uphold professional values.

2. Fostering Leadership Development *(discontinuation)*

To discontinue ASHP policy 2104, Fostering Leadership Development, which reads:

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

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

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

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

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

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

Background

The Council recommended discontinuing ASHP policy 2104, Fostering Leadership Development, because its intent and principles are now comprehensively addressed in existing ASHP statements. The ASHP Statement on Leadership as a Professional Obligation (updated in May 2023) affirms leadership as a core responsibility of all pharmacists and pharmacy technicians, emphasizing the cultivation of leadership skills across all levels of practice. Additionally, the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive (updated in April 2025) further reinforces the importance of leadership development and succession planning within pharmacy organizations. Given the breadth and relevance of these documents, the Council determined that maintaining a separate policy was duplicative and that the concepts are better expressed through these updated statements.

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.

1. Safe Use of Controlled Substances Through Regulatory Reform

To advocate for the reform of the Controlled Substances Act (CSA) to align with contemporary healthcare practice standards, with input from pharmacists and other stakeholders; further,

To urge the Drug Enforcement Administration (DEA) to issue transparent and practical guidance when interpreting and applying laws and regulations related to the CSA and other drug laws that affect patient care; further,

To encourage the DEA and other regulatory agencies to balance regulatory requirements with patient access to medically necessary controlled substances when developing regulations and interpreting and enforcing laws and regulations; further,

To promote collaboration among the DEA, professional associations, and regulatory agencies to identify and reduce: 1) barriers to patient care; 2) burdens on healthcare workers; and 3) cost of healthcare delivery in the establishment and enforcement of controlled substance laws and regulations.

Rationale

The Drug Enforcement Administration (DEA) and Department of Justice (DOJ) routinely update regulations and measures to counter substance abuse in the US. Two major implications of

these changes include: (1) increasing regulatory burden on pharmacy operations and (2) a lack of standardized education and resources to support pharmacies in adequately responding to DEA inspections.

The mission of the DEA is to enforce U.S. controlled substance laws and regulations. The DEA has the authority to enter the controlled premises of a registered location and conduct administrative inspections both routinely and as circumstances warrant (21 U.S.C. 880 and 21 CFR 1316.03). The primary purpose of an inspection is to ensure compliance with the Controlled Substances Act (CSA) of 1970 regarding record-keeping, inventory, security, access controls, training records, and reports. Inspections can be conducted with voluntary consent of the DEA registrant or by an administrative inspection warrant by any judge of the United States or of a state court of record (21 U.S.C 880). Upon notice of CSA violations, pharmacies may face criminal investigations, civil and administrative actions, letters of admonishment, or even revocation of registration, which can be detrimental to both the organization and individual pharmacists. To mitigate or prevent avoidable CSA violations, transparency and uniformity in DEA interpretation and application of laws and regulations is essential. DEA should provide transparent and practical guidance that clearly communicates expectations, explains enforcement rationale, and maintains publicly accessible, up-to-date information about how it interprets and enforces laws and regulations under the CSA and related drug policies.

Since the original authorship of the CSA in 1970, health-system pharmacy practice has evolved significantly, yet the laws governing controlled substances have remained largely unchanged. Dissonance between practice and law presents ongoing challenges for compliance and vulnerabilities within health systems. Pharmacists and pharmacy technicians responsible for overseeing and monitoring controlled substances often face challenging situations, including how to respond to specific patient care scenarios (e.g., the handling and disposition of controlled substances brought into hospitals by patients) that conflict with the CSA or involve product-specific nuances that are not addressed by the CSA. Modernization of the CSA would provide an opportunity for the DEA to collaborate with key stakeholders, including health-system pharmacists, to achieve greater alignment with practice, improve regulatory compliance, and reduce the overall regulatory burden. Some examples to consider for the modernization of the CSA include expansion and formalization of telemedicine authority for CS prescribing; creation of a national telemedicine registration that would eliminate the need for a state-by-state DEA registration requirement; establishment of risk-based flexibility for patients with chronic conditions who need to maintain continuity of therapy during emergencies; and shifting from weight-based production quotas to dosage-form based quotas to mitigate drug shortages for clinically appropriate care.

Background

The Council reviewed existing ASHP controlled substance policies and guidelines, noting they cover aspects and risks associated with managing controlled substances and diversion prevention. Council members were in favor of including language that encourages the DEA to balance patient care and safety with regulatory aspects of care and encouraging DEA to collaborate with stakeholders. Controlled substance management is among the top risks of

healthcare organizations and, although a shared responsibility, pharmacy is held primary accountable. Council members shared experiences of recent DEA audits and noted the increasing frequency of occurrences. The members' experiences during the audit revealed challenges of translating DEA regulations into health-system practice. Audit preparation and execution were identified as an educational gap both by the Council and by other member groups. The Section of Pharmacy Practice Leaders has developed several resources, including a readiness checklist which is currently in development. ASHP also has a web-based Controlled Substances Drug Diversion Program Assessment Tool for members to use. With these resources in mind, the Council suggested that ASHP could help members by promoting knowledge of these tools and resources to help members identify risk points and gaps with controlled substance management controls.

2. Pharmacy Leadership of Infusion Services

To encourage healthcare organizations to engage pharmacists and pharmacy leaders in the development and management of infusion service lines; further,

To advocate for payment commensurate with the level and complexity of care and services provided to support sustainable infusion business models; further,

To advocate for the elimination of site of care restrictions to ensure patient preference and continuity of care in infusion services; further,

To encourage use of technology that integrates with patient medical records to enhance medication safety and streamline authorization and adjudication processes.

Rationale

Members of the pharmacy workforce practicing within the infusion business are required to be experts throughout multiple stages of the patient's treatment including knowledge of the disease states, the management of complex medication regimens, patient education, regulatory requirements, and determination of the appropriate site of care for patients based on clinical needs, policies, and payer requirements. The number of patients receiving home and specialty infusion services has grown rapidly and is projected to continue to grow given the aging population, rates of chronic disease, shift to outpatient services, and increased development of injection-based medications.

Complex payer policies and proposed reimbursement models further complicate infusion therapy. Many patients receiving infusions are shifted to lower cost sites of care, mandated by their health insurers, which may lead to lapses in care, missed infusions, and disconnect from the primary care team. Site neutral payments, prior authorizations, payer denials, and bagging practices all present unique challenges for hospital and health-system pharmacy. Given the high cost, safety considerations, and operational complexity associated with most infusion therapies, health systems have increasingly focused on the oversight and execution of these

services. Support is needed to establish sustainable reimbursement models that allow for high-quality, patient-centered infusion services.

The pharmacy workforce has unique knowledge and expertise to navigate most challenges in infusion care, which should be leveraged to provide leadership and oversight for infusion care. This includes the full scope of services encompassing preparation, administration, authorization, and adjudication of care. For example, shifting infusion care to the home setting offers potential cost-savings for health systems and payers, while providing a more convenient option for patients. This shift to home-based care requires care coordination, assessment of home care viability for specific patients, considerations for safety, adherence to regulatory requirements, and around-the-clock access to care. In support of this, pharmacy leaders must identify treatments available for safe and effective administration in the home setting and determine resources required for home-based treatments.

Successful execution of infusion services requires up-to-date technology that fully integrates with health-system electronic medical records. These systems should manage the full breadth of services, from ordering and processing to authorization and adjudication of medication claims. This ensures medications are safely prepared, authorized, and administered in an efficient manner.

Background

The Council discussed challenges associated with infusion services within their institutions. Proposed 340B changes jeopardize infusion service sustainability, highlighting the need for a scalable hospital outpatient department infusion network. Many members noted their increasing involvement with infusion services, even citing oversight for broad portions of the service. Specific challenges include site of care restrictions, Medicaid contraction, site neutral payments, frequent coverage changes for medications, and coordination of benefits. A review of current ASHP policy revealed gaps related to most of these challenges and an opportunity to address a more holistic approach to infusion services. The Council expressed a strong desire to advocate for pharmacy leadership of infusion services across practice settings given the complexity of the medications involved and the processes related to their selection and approval.

The Council was informed of the ASHP Infusion Services Strategy Committee designed to better support and represent the increasing number of pharmacy personnel involved in infusion care. It was proposed the policy recommendation be reviewed by the members who comprised the Infusion Services Strategy Committee. The Council supported pharmacy leading the infusion service effort with additional suggestions, including: 1) updating the current ASHP Guidelines on Home Infusion Pharmacy Services; 2) considering as a future session or summit topic at ASHP national meetings; and 3) development of resources and education emphasizing the need for integrated technologies that support all aspects of infusion service delivery. Members suggested there is opportunity for ASHP to strengthen pharmacy representation in national infusion organizations.

3. Name Change *(discontinuation)*

To discontinue ASHP policy 9411, Name Change, which reads:

To change the name of the American Society of Hospital Pharmacists, Inc. (ASHP) to the American Society of Health-System Pharmacists, Inc. (ASHP), effective January 1, 1995; further,

To amend the ASHP Charter, Second Article, by deleting Hospital and substituting Health-System; further,

To amend and restate the ASHP Bylaws, Article 1.1, to conform to the amended ASHP Charter; further,

To declare that this Charter amendment is advisable, and direct that the Charter amendment be submitted to the House of Delegates and the membership for consideration.

The ASHP membership approved this action by mail ballot, September 1994.

Background

The Council reviewed ASHP policy 9411, Name Change, as part of sunset review and voted to recommend discontinuation. The Council was informed of the legacy procedures for managing matters of governance within the House of Delegates. The name change to the American Society of Health-System Pharmacists was approved by members in 1994 and went into effect on January 1, 1995. Since then, ASHP has revised its bylaws and transitioned matters of governance to management by the ASHP Board of Directors. The ASHP name change to the American Society of Health-System Pharmacists is fully incorporated into the bylaws of the organization and removal as a policy position will not impact the standing of the society's name.

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.

Todd Nesbit, *Board Liaison*

1. Promoting Environmental Sustainability in Healthcare

To acknowledge the importance of environmental sustainability in promoting and preserving public health; further,

To encourage implementation of environmentally conscious clinical and operational practices that reduce waste within the healthcare system; further,

To advocate for legislation and regulation that enables waste-minimization efforts in medication-use practices; further,

To encourage members of the pharmacy workforce to seek out opportunities that promote environmental sustainability and health.

Rationale

In healthcare, sustainability refers to the implementation of cost-efficient, environmentally responsible practices that support healthy and resilient communities over time. Environmental health, a key component of public health, focuses on how natural and built environments affect human health and disease.

As part of the built environment, healthcare facilities are increasingly expected to enhance

environmental stewardship in support of patient and public health. Healthcare activities generate substantial amounts of waste, which, if improperly managed, can have serious environmental and public health consequences. According to the World Health Organization (WHO), approximately 85% of healthcare waste is non-hazardous general waste, while the remaining 15% consists of hazardous materials, including infectious, chemical, and radioactive waste. Improper disposal of both hazardous and non-hazardous healthcare waste can contribute to environmental pollution, the spread of infectious diseases, and occupational risks for healthcare workers.

In the United States, healthcare facilities produce more than six million tons of solid waste annually, with plastics accounting for 20% to 25% of that total. Approximately 91% of plastics, including those used in healthcare, are not recycled, contributing to landfill accumulation and environmental degradation. A single hospital bed is estimated to generate nearly 30 pounds of waste per day, highlighting the scale of the issue in high-volume facilities.

Background

The Council discussed whether ASHP policy was needed related to waste in healthcare and the promotion of environmental sustainability. While ASHP professional policy 2313 is entitled "Reducing Healthcare Sector Carbon Emissions to Promote Public Health," Council members felt that sustainability and waste were not adequately addressed.

The ASHP Strategic Plan, revised and released in 2025, includes a goal under the Public & Global Health strategic pillar to "lead environmental stewardship associated with sustainable medication-use practices." This goal emphasizes the importance of promoting environmentally responsible medication-use practices (e.g., disposal, procurement), advancing pharmacy's role in sustainability initiatives, and engaging with key stakeholders to address environmental sustainability and stewardship challenges. This policy aligns with the strategic plan's broader commitment to promoting environmentally responsible clinical and operational practices, reducing waste, advocating for supportive regulatory frameworks, and elevating pharmacy's leadership in sustainability efforts.

2. Body Size Inclusivity

To recognize that body size bias influences health outcomes, social interactions, and decisions across workplaces and healthcare settings; further,

To promote the use of body size inclusivity in practice to ensure a comprehensive, patient-centered approach to care; further,

To encourage adoption of best practices that minimize body size bias across professional and healthcare settings.

Rationale

Body size inclusivity is defined as "accepting and respecting a wide range of body types and ensuring that all individuals, regardless of their body size, feel valued and included." It is the intentional acknowledgment, respect, and accommodation of people of all body sizes in personal, professional, and organizational settings. In contrast, weight stigma refers to discriminatory acts and ideologies targeted towards individuals because of their weight and size, favoring smaller body sizes and perpetuating stigma, bias, and discrimination. Research demonstrates that weight-based stigma is a social determinant of health, associated with increased psychological stress, anxiety, depression, and lower self-esteem, contributing to both mental and physical health burdens for affected individuals.

Several healthcare organizations have developed policies and initiatives to promote body size inclusivity, aiming to reduce psychological harm and stigma associated with weight bias. For example, the World Obesity Foundation has advocates for system-level change to eliminate weight bias in healthcare and other sectors. The Massachusetts Medical Society emphasizes that with increased risk of weight bias comes increased incidence and prevalence of depression, social rejection, anxiety, and suicidality across all ages. Lastly, the Health at Every Size (HAES) movement promotes body size inclusivity while focusing on overall health rather than weight. HAES emphasizes holistic well-being, self-acceptance, and the removal of weight-centered biases from health assessments and social interactions. It offers the following HAES principles and framework of care:

- Healthcare is a human right for people of all sizes, including those at both extremes of weight.
- Comprehensive care is free of anti-fat bias and considerate of all body types.
- Wellbeing, care, and healing are collective and deeply personal resources.
- Health is a sociopolitical construct that is often reflective the of society's values.

Professional policies can play a central role in promoting body size inclusivity by setting clear expectations for equitable treatment, implementing anti-discrimination protections, and providing training to staff and leadership on recognizing and counteracting weight and height bias. Organizations can also audit existing policies and practices through a body-size lens to identify areas for improvement, while maintaining the collection of body size information needed for patient care decisions. By institutionalizing these changes, organizations signal a commitment to the psychological safety and dignity of all employees, reducing stigma, and promoting an environment where health, productivity, and professional success are not contingent on body size. Pharmacists and pharmacy technicians with education and training on the importance of body size inclusivity represents an opportunity to be a trusted and patient-centered professional.

Background

The Council discussed this topic in response to a recommendation from the 2025 ASHP House of Delegates which urged consideration of whether ASHP policies contribute to or mitigate potential psychological harms or stigma relate to body size. As a result, the Council determined there was a gap in policy and developed one related to body size inclusivity.

3. Ready-to-use Packaging for all Settings *(discontinuation)*

To discontinue ASHP policy 0402, Ready-to-Use Packaging for all Settings, which reads:

To advocate that pharmaceutical manufacturers provide all medications used in ambulatory care settings in unit-of-use packages; further,

To urge the Food and Drug Administration to support this goal; further,

To encourage pharmacists to adopt unit-of-use packaging for dispensing prescription medications to ambulatory patients; further,

To support continued research on the safety benefits and patient adherence associated with unit-of-use packaging and other dispensing technologies.

(Note: A unit-of-use package is a container--closure system designed to hold a specific quantity of a drug product for a specific use and intended to be dispensed to a patient without any modification except for the addition of appropriate labeling.)

Background

The Council reviewed ASHP policy 0402, Ready-to-Use Packaging for all Settings, as part of sunset review and voted to recommend discontinuing it because unit-of-use packaging has become increasingly standard. The Council felt key points from this policy are already emphasized in ASHP policy 2407, Unit Dose Packaging Availability, and 1711, Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use. In sunsetting policy 0402, Council members emphasized the need to update the rationale for ASHP Policy 2407 to include a reference to improving patient adherence.

4. ASHP Statement on Reporting Medical Errors *(discontinuation)*

To discontinue ASHP policy 0023, ASHP Statement on Reporting Medical Errors, which reads:

To approve the ASHP Statement on Reporting Medical Errors.

Background

The Council reviewed ASHP policy 0023, ASHP Statement on Reporting Medical Errors, as part of sunset review and voted to recommend discontinuing it due to this topic being covered in other ASHP policy and guidelines.

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.

Vickie Powell, *Board Liaison*

1. Integrity of Pharmacist Provided Health Information

To oppose any governmental restriction on pharmacists' ability to provide evidence-based health information to patients; further

To urge policymakers to protect pharmacists' professional autonomy in educating patients on medications, public health issues, and emerging scientific developments; further

To oppose the elimination, suppression, manipulation, or politicization of evidence-based public health data and drug safety information by any entity; further

To advocate for legislation that protects scientific integrity and ensures transparency in the dissemination of public health information; further

To affirm that pharmacists are trusted and reliable medication experts and have the professional responsibility to disseminate evidence-based, health information to patients and communities.

Rationale

Pharmacists play a vital role in public health, serving as reliable, accessible, and trusted sources

of evidence-based medical information for patients and communities. As experts in medication therapy, pharmacists ensure individuals have the knowledge and information they need to make informed decisions about their care.

However, in recent years, pharmacists' ability to share accurate, science-based health information has been threatened by political interference, unjustified restrictions, and the deliberate distortion or suppression of public health data. These threats not only undermine pharmacists' professional autonomy but also endanger the communities they serve.

Pharmacists must be free to practice in accordance with scientific evidence and professional ethics, without being curtailed by political agendas. Any effort to restrict their ability to educate the public, speak truthfully about medications, or respond to emerging health threats must be met with firm opposition.

Because misinformation can spread rapidly, it is more important than ever to uphold integrity and transparency. Silencing or censoring pharmacists risks irreparable harm. It compromises patient safety, erodes public trust, and weakens the very foundations of our healthcare system. Policymakers must ensure that pharmacists remain empowered to educate patients on medications, emerging scientific advancements, and critical public health concerns.

Background

The policy stems from a New Business Item submitted during the 2025 House of Delegates. The Council supported the proposed language, but recommended changes to the proposed rationale to make it more assertive, which are reflected above. Council members did have concerns about how "evidence-based" could be defined, noting that this language has the potential to be weaponized if the evidence in question falls outside of accepted scientific understanding. The Council felt that discussion of that issue would need to take place within the Regional Delegate Conference/House of Delegates processes. The Council further noted that it would like to slate this policy for review within a year of passage to ensure that none of the language needs to be adjusted in response to enforcement changes, etc.

2. Pharmacist Engagement in and Payment for Telehealth *(discontinuation)*

To discontinue ASHP policy 2141, Pharmacist Engagement in and Payment for Telehealth, which reads:

> To advocate for pharmacists' provision of telehealth services in all sites of care; further,
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> To advocate that reimbursement for pharmacists' provision of telehealth services be commensurate with the complexity and duration of service and consistent with other healthcare providers.

Background

The Council reviewed ASHP policy 2141, Pharmacist Engagement in and Payment for Telehealth, as part of sunset review and voted to recommend discontinuing because the same content is covered by policy 2220, Promoting Telehealth Pharmacy Services. The Council recommended that the language in 2141 regarding advocacy for pharmacists' provision of telehealth services "in all sites of care" be added to the rationale for policy 2220 to clarify that advocacy on this issue extends across the entire healthcare system.

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. Deregulation of Prescription Drugs

To oppose legislation or regulations that permit reclassification of prescription medications to over-the-counter (OTC) status outside of the established Food and Drug Administration (FDA) review and approval process.

Rationale

The FDA requires manufacturers seeking to market a prescription drug product as nonprescription (Rx-to-OTC switch) to demonstrate that the medication is safe and effective for self-care. Regulation requires OTC drug labeling that is easily understood without the guidance of a healthcare professional, and that OTC drugs should treat conditions suitable for self-diagnosis, such as allergies or headache. Approval decisions are predicated on robust evidence from clinical trials, consumer behavioral studies, and post-marketing surveillance data. Manufacturers may also switch a prescription drug to OTC by including an Additional Condition for Nonprescription Use (such as a required questionnaire or pharmacist consultation before purchase) to address safety concerns and ensure patients have the information needed to choose the right medication for their condition.

State-level efforts to deregulate prescription drugs outside of this established framework (e.g., state laws authorizing OTC sale of ivermectin) bypass FDA safety standards and may pose significant risks to patients. While ASHP strongly supports initiatives (such as expansion of pharmacist prescribing authority) that increase patient access to clinically appropriate, evidence-based healthcare services and drug therapies, deregulation of prescription drugs outside the FDA process eliminates essential safeguards. Many prescription medications have important contraindications, toxicities, drug-drug interactions, or monitoring needs that require evaluation by a pharmacist or prescriber or are used to treat conditions requiring a medical diagnosis. Removing the opportunity for patient education and clinical assessment undermines safe medication use, increases the risk of harm, and weakens public trust in the medication-use process.

Drug deregulation also carries significant legal, regulatory, and liability concerns to pharmacists. Although some state laws include provisions for civil or criminal immunity or prohibit license revocation for pharmacists who dispense drugs under such statutes, selling medications without FDA-approved nonprescription labeling may constitute misbranding under the Food, Drug, and Cosmetic Act. This conflict between federal and state law has not yet been adjudicated, creating substantial legal uncertainty. Pharmacies may elect not to offer deregulated drugs under these conditions, further confusing patients and limiting access while failing to achieve the intended goal of expanding medication availability.

Background

This policy was generated from the topic “Non Prescription Status of Ivermectin” during policy week. The Council recognized that while Ivermectin was currently the drug that was circumventing the established regulatory framework in place, that a policy specific to ivermectin alone would not be sufficient if in the future there were other efforts to do the same with other drugs. Therefore, broader policy language was developed to address this current legislative effort by states as well as potential future efforts. Council members strongly believed that deregulation of prescription drugs outside the FDA process eliminates essential safeguards and could cause significant patient harm.

2. Dosing of Combination Antibiotics

To advocate for Food and Drug Administration approved labeling of combination antibiotics with dosing instructions that include each component; further,

To support the reduction of available formulations; further,

To encourage healthcare organizations to adopt strategies that ensure appropriate dosing of combination antibiotics; further,

To educate stakeholders and the public regarding the safe dosing and administration of combination antibiotics for pediatrics and adults.

Rationale

Combination antibiotics pose a unique challenge for pharmacists because each product contains two active components, each with its own strength, and variations in how doses are calculated can create confusion in dosing, dispensing, and administration. In adults, dosing and dispensing of these drugs is done with standard doses equivalent to the sum of the two antibiotic components and are provided from manufacturers in standardized formulations, often in ready to administer bags. Conversely, pediatric patients are often dosed based on the weight-based dosing of one component of the combination drug (e.g the beta-lactam or the trimethoprim component) with a few exceptions based upon the goal of treatment. While most intravenous concentrations of these medications are standardized, there are 11 dosage formulations of amoxicillin-clavulanate on the US market, including five different amoxicillin to clavulanate ratios (i.e., 2:1, 4:1,7:1, 14:1, 16:1). These multiple ratio formulations further increase the risk of prescribing, dispensing, and administration errors which can impact the effectiveness and/or the toxicity of these antibiotics. While this phenomenon is decreasing, many manufacturers' labeling and dosing references describe doses in a variety of ways, and multiple presentations exist even within the same reference. This has also led to dosing errors with the intravenous antibacterial drugs due to confusion about the drug strength displayed on the vial and carton labels.

Furthermore, many pediatric patients are not treated at standalone children's hospitals where there is infrastructure and support, including pediatric specific order sets, pump libraries, drug information and pharmacists trained to care for pediatric patients exist. A 2024 study in Journal of Pediatric Pharmacology and Therapeutics (JPPT) surveyed pharmacists treating pediatric patients in a variety of settings cited that barriers to dosing and administration of combination drugs including: extended infusions, infusion pump interoperability challenges, CPOE (computerized physician order entry) auto-adjustments, dose rounding, drug shortages, premade adult products, non-formulary drugs, and different ordering processes for pediatric and adult patients. This study also found that order sets, guidelines, and intranet pages were the most common sources of internal antibiotic dosing recommendations, where dosing may

be different than what is found in external antibiotic dosing references including Lexicomp, Micromedex, Sanford Guide and more. A 2023 study from JPPT reviewed amoxicillin-clavulanate use at standalone and children's hospitals within acute care hospitals and found that significant formulation selection variability exists across the United States with these institutions carrying on average five amoxicillin-clavulanate products.

In the outpatient setting, medication errors during order entry and dispensing include: information and knowledge gaps about medication indications or doses for pediatric patients, communication gaps between health care providers and caregivers, and product preparation vulnerabilities. An additional study that looked at pediatric medication errors, found that antibiotics emerged as the most frequently implicated drug class.

Background

This topic was recommended by a council member who practices in pediatrics and identified this as a practice issue. Members shared their experiences treating this population with combination antibiotics, citing the differences in dosing, logistics of appropriate prescribing, and difficulties in updating and maintaining EHRs and pump libraries, especially as new combination antibiotics come to market. Members also discussed the increase of infectious disease services providing dosing recommendations that varied from pediatric dosing practices.

3. Drug Dosing in Conditions that Alter Pharmacokinetics and Pharmacodynamics

To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic conditions; further,

To encourage drug product manufacturers and other stakeholders to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, geriatric, and patients at the extremes of weight to facilitate safe and effective dosing of drugs in these patient populations; further,

To advocate healthcare provider education and training that facilitate optimal patient-specific dosing in populations of patients with altered pharmacokinetics and pharmacodynamics; further,

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and electronic health record documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic conditions.

This policy would supersede ASHP policy 1804

Rationale

The pharmacokinetic and pharmacodynamic properties of drugs found in drug information monographs are based on the drug's absorption, distribution, metabolism, and excretion in

healthy, adult patients during Phase I of a drug's clinical trials. Many patients receiving drug therapy do not fit this profile, and many have compromised organ function. The medical community has long recognized the need for a standardized approach to evaluating organ system dysfunction. Although there are methods to determine organ function (e.g., the Cockcroft-Gault equation for renal function or the Child-Turcotte-Pugh Classification for Severity of Cirrhosis), there is debate as to whether these methods are true indicators of organ function, as the components that comprise these equations may fluctuate based on severity and patient status. Traditional laboratory values used to evaluate organ dysfunction can be bidirectional and conflicting as well.

With the exception of adjustments for renal dysfunction, there is not much information regarding dosage adjustment for specific drugs. Many organ systems are involved in a drug's absorption, distribution, metabolism, and excretion. Hepatic effects, for example, are a risk area, as those effects are slower to be seen and have not been the subject of much research, and the number of drugs affected are smaller in number than renally excreted drugs. Both acute and chronic aspects of patient conditions may require monitoring and adjustment, including sepsis, encephalopathies, pregnancy, heart failure exacerbations, and cystic fibrosis. Certain protocols, such as therapeutic hypothermia, can also have clinically significant impact on a drug's pharmacokinetic and pharmacodynamic behavior. There is also need to promote research and utilization of biomarkers into practice, as these may reflect organ function and may provide pharmacists with a more complete clinical picture.

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 a clinical impact.

Background

The Council reviewed ASHP policy 1804, Drug Conditions that Modify Pharmacokinetics and Pharmacodynamics, as part of a recommendation for the ASHP House of Delegates and voted to recommend amending it as follows (<u>underscore</u> indicates new text; ~~strikethrough~~ indicates deletions):

> To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic conditions; further,
>
> <u>To encourage drug product manufacturers and other stakeholders to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, geriatric, and patients at the extremes of weight to facilitate safe and effective dosing of drugs in these patient populations, further,</u>

To advocate healthcare provider education and training that facilitate optimal patient-specific dosing in populations of patients with altered pharmacokinetics and pharmacodynamics; further,

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and electronic health record documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic conditions.~~; further~~,

~~To collaborate with stakeholders in enhancing aggregation and publication of and access to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug dosing within these patient populations.~~

4. Direct-to-Consumer Clinical Genetic Tests

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

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

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

To support FDA policies and procedures regarding advertising of direct-to-consumer clinical genetic tests, including the following requirements: (1) the relationship between the genetic marker and the disease or condition being assessed is clearly presented, (2) the benefits and risks of testing are discussed, (3) such advertising is provided in an understandable format, at a level of health literacy that allows the intended audience to make informed decisions, and includes a description of the established patient-healthcare provider relationship as a critical source for information about the test and interpretation of test results; and (4) how patient information is collected, protected, shared, and used; further,

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

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

This policy would supersede ASHP policy 2101

Rationale

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

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

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

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

Finally, DTC genomic testing is done outside of a healthcare system where they are considered assets of the company, which does not provide the same protections. In 2023, the genetic testing company, 23andMe, with over 12 million customers, suffered a cyber-attack that had compromised data for nearly 7 million users – exposing sensitive personal and genetic data, including names, photos, birth years, ethnicity, and information from family trees.

23andMe filed for bankruptcy in 2025 and placed its assets up for sale. In the wake of this, there have been multiple concerns regarding the sale of customer data (DNA, health, ancestry, etc.). and it is unknown what new owners might do with that data. Customers are also concerned that deleting their account or deleting the DNA sample is complicated or slow, and they're not confident the data is actually removed after confirmation. Currently, there is no federal genetic privacy law and few states have some consumer protections regarding data privacy which complicates this further.

Background

The Council reviewed ASHP policy 2101, Direct-to-Consumer Clinical Genetic Tests, as part of a sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> To support research to validate and standardize genetic markers used in direct-to-consumer clinical genetic tests and guide the application of test results to clinical practice; further,
>
> To encourage the Food and Drug Administration (FDA) to continue to regulate direct-to-consumer clinical genetic tests as medical devices and work with the National Institutes of Health to evaluate and approve direct-to-consumer clinical genetic tests; further,
>
> To advocate that direct-to-consumer clinical genetic tests be provided to consumers through the services of appropriate healthcare professionals who order tests from laboratories certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA); further,
>
> To support FDA policies and procedures regarding advertising of direct-to-consumer clinical genetic tests, including the following requirements: (1) the relationship between the genetic marker and the disease or condition being assessed is clearly presented, (2) the benefits and risks of testing are discussed, (3) such advertising is provided in an understandable format, at a level of health literacy that allows the intended audience to make informed decisions, and includes a description of the established patient-healthcare provider relationship as a critical source for information about the test and interpretation of test results; and (4) patient information is collected, protected, shared, and used; further,
>
> To encourage health systems to create policies and procedures addressing direct-to-consumer genetic testing results as it relates to confirmatory testing, integration of genomic information into the healthcare record, genetic counseling, and clinical decision-making; further,
>
> To encourage pharmacists to educate consumers and clinicians on the potential risks and benefits of direct-to-consumer clinical genetic tests for disease diagnosis and decisions involving drug therapy management.

5. Evidence-Based Medicine

To define evidence-based medicine as the conscientious, explicit, and judicious appraisal and application of the best-available current data integrated with provider expertise and patient values to inform the development and implementation of professional policies, standards, and clinical practice decisions.

Rationale

Evidence-based medicine (EBM), also known as evidence-based practice, evidence-based clinical practice, evidence-based healthcare, evidence-based method, and evidence-based approach are all encompassing terms that describe a methodical approach to clinical decision-making. EBM is a cornerstone of modern healthcare, emphasizing the use of the best available research evidence to guide clinical decision-making. The goal of EBM is to improve patient care by using the most current and reliable scientific research—such as randomized controlled trials, systematic reviews, and meta-analyses—to guide diagnosis, treatment, and management decisions. It involves critically evaluating and integrating evidence into the clinical decision-making process, ensuring that the interventions provided are both effective and appropriate for the individual patient.

However, there is controversy surrounding the term. This arises from its ideal of objective, standardized care, which sometimes clashes with the realities of clinical practice, patient individuality, and the inherent limitations of research. In recent years, particularly with the rapidly evolving need for safe and effective treatment during the COVID-19 pandemic, adoption of artificial intelligence, and proliferation of publications, the term evidence-based medicine has evolved from an approach to patient care that uses best available evidence, clinical expertise, and patient values to one that includes these values but also a more nuanced understanding of the complexities inherent in translating research into practice, recognizing that both organizations and clinicians are subject to their own biases. Ultimately, EBM uses diligent, explicit, and sensible use of available evidence to care for individual patients that integrates individual clinical expertise that is diverse in origin. EBM is not a replacement for individual clinical expertise and does not consist only of randomized controlled trials or meta-analyses, nor considers data that is outdated or impossible to practice.

Background

The Council discussed the term evidence-based medicine as a part of the evolution of the amount and quality of information and its role in medication misinformation, clinical decision making, and the practice of pharmacy as well as its use in ASHP Policies. Review found there that are 52 references to the term evidence-based in ASHP Policies and rationales. The Council also discussed how other professional organizations use this term, how ASHP should define the term EBM as it pertains to developing professional policy, and the impact of removing this term from ASHP policy. The Council decided that a policy affirming ASHP's position would be in the organization's best interest.