House of Delegates

Board of Directors Report:
Policy Recommendations for the
November 2021 Virtual House of Delegates

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COUNCIL ON THERAPEUTICS
POLICY RECOMMENDATION

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.

Paul Walker Board Liaison

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Vicki Basalyga, Secretary

1. Agricultural Use of Hormone and Prohormone Therapy

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

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

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

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

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

Note: This policy would supersede ASHP policy 1102.
**Rationale**
Natural (e.g., estradiol, progesterone, testosterone) and synthetic (trenbolone, zeranol, melengestrol) hormones are commonly used for growth promotion in beef cattle raised in the United States. While the European Union has banned the use of these substances for growth promotion based on safety concerns, the USDA and FDA have long supported use of these substances based on studies conducted in the 1970s. Of note, a 2002 statement from the FDA stated that the use of hormones for agricultural purposes was safe. However, more recent research has raised new concerns about potential harm to human health, including epidemiological studies demonstrating increased rates of breast cancer in women, testicular cancer and decreased fertility in men, and hormone-related developmental issues in infants and children.

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

**Background**
The Council discussed ASHP policy 1102, Agricultural Use of Hormones and Prohormone Therapy, as part of sunset review and voted to recommend amending it as follows, to reflect similar oversight as seen in the similar policy 1922 Antimicrobial Use in Agriculture (underscore indicates new text; strikethrough indicates deletions):

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

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

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

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

To encourage additional research on hormone and prohormone therapies to better define the public health impact of using hormone therapies for agricultural purposes.
COUNCIL ON PHARMACY MANAGEMENT
POLICY RECOMMENDATION

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.

Pamela Phelps, Board Liaison

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Eric Maroyka, Secretary

1. Pharmacist’s Role in Healthcare Information Systems

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

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

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

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

Note: This policy would supersede ASHP policies 1211 and 1701.
Rationale
ASHP recognizes that design, maintenance, and cyber-security of healthcare information systems (e.g., medication-use information systems, electronic health records, computerized provider order entry systems, e-prescribing systems) is an interdisciplinary process that requires ongoing collaboration across many disciplines. Maintaining the privacy of health information, in compliance with the Health Insurance Portability and Affordability Act (HIPAA), and ensuring patient safety in the face of cyber-attacks are essential concerns for every healthcare organization. Given the ever-evolving nature of pharmacist patient care, medication use, and health information technology, it is essential pharmacists have key decision-making roles in the planning, selection, design, implementation, and maintenance of such systems in order to help prevent and respond to cyber-attacks. To ensure the safe and effective use of medications, pharmacists must have accountability for strategic planning and direct operational aspects of the medication-use process, including the successful deployment of medication-use-related information systems by assessing vulnerabilities and vendor systems to validate the security and integrity of the data. Increased connectivity with vendor systems creates a mutual need to share access to patient information and other vital data, so risk mitigation must be considered at all points of access. This includes, for example, facilitating clinical decision support by assessing the minimum amount of patient health information vendors require to provide services, data analysis, education of users, and developing and implementing business continuity plans, to include fail-over testing of these plans, for when the systems are unavailable.

Background
The Council reviewed ASHP policy 1701, Ensuring Patient Safety and Data Integrity During Cyber-Attacks, as part of sunset review and recommended revising ASHP policy 1211, Pharmacist’s Role in Health Care Information Systems, to consolidate the related concepts in those policies. ASHP policy 1701 reads:

To advocate that healthcare organizations include pharmacists in (1) assessing cyber-security systems and procedures for vulnerabilities, (2) implementing cyber-security strategies, and (3) reviewing cyber-security breaches and developing corrective actions; further,

To encourage the development of business continuity plans by pharmacy departments; further,

To advocate that healthcare organizations assess vendor systems to validate the security and integrity of data, including an assessment of the minimum amount of patient health information vendors require to provide services.

Although the Council viewed policy 1701 as relevant, it was felt the threat of cyber-attacks could be adequately addressed within the framework of policy 1211, and the Council voted to recommend amending policy 1211 as follows (underscore indicates new text; strikethrough indicates deletions):
To strongly advocate key decision-making roles for pharmacists in the planning, selection, design, implementation, and maintenance of medication-use information systems, electronic health records, computerized provider order entry systems, and e-prescribing systems to balance the security and integrity of data with the ability to facilitate clinical decision support, data analysis, and education of users for the purpose of ensuring the safe and effective use of medications; further,

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

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

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

The Council noted the pharmacy workforce must have recognition for cyber-security practices and implement an appropriate response to cyber-attacks (e.g., downtime procedures). Specific examples of medication-use systems can be considered for inclusion in the policy rationale as opposed to including in policy clause. Lastly, the Council suggested the ASHP Section of Pharmacy Informatics and Technology Executive Committee provide an opinion to this policy recommendation.
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.

Kim Benner, Board Liaison

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Anna Legreid Dopp, Secretary

1. Reduction of Unused Prescription Drug Products

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

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

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

Note: This policy would supersede ASHP policy 1702.

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

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

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

**Background**

The Council reviewed ASHP policy 1702, Reduction of Unused Prescription Drug Products, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletion):

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

To advocate for staffing, research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, reconciled, and dispensed, including but not limited to partial fills or refills; further,

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

The Council amended ASHP policy 1702 for the purpose of improving patient care outcomes and safety while minimizing waste of unused prescription drugs. The Council seeks to maintain the intent of ASHP policy 1702 to minimize risk of misuse, abuse, and diversion while emphasizing that 10 million prescriptions go unused every year, resulting in up to $5 billion in wasted medication [Lenzer J. BMJ 2014;349:g7677]. The Council believed there was an opportunity to emphasize the role of pharmacy workforce to enhance patient and public education and support take-back events in their communities.
### 2. Expiration Dating of Pharmaceutical Products

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

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

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

*Note: This policy would supersede ASHP policy 1712.*

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

**Background**
The Council reviewed ASHP policy 1712, Expiration Dating of Pharmaceutical Products, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; strikethrough indicates deletions):

To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs, such as medications in shortage or used for medical countermeasures, and reducing healthcare costs; further,
To advocate that the Food and Drug Administration implement procedures to encourage pharmaceutical manufacturers to readily update expiration dates, for as long as possible while maintaining drug potency and safety, to reflect current evidence regarding the maximum length of drug potency and safety, using technology solutions when available; further,

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

In their discussion of ASHP policy 1712, the Council felt the language should explicitly address the need for maximal extension of expiration dating for medications used as medical countermeasures and during times of medication shortages. Medical countermeasures are FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency stemming from a terrorist attack with a biological, chemical, or radiological/nuclear material, or a naturally occurring emerging disease. This emphasis on medical countermeasures and medication shortages was discussed through the context of and experiences from the COVID-19 pandemic. The Council also acknowledged innovation in the process and communication of expiration dating decisions through technology and therefore added language to encourage the use of technology solutions as they become available.

### 3. Elimination of the Apothecary System

1. To discontinue ASHP policy 8613, Elimination of the Apothecary System, which reads:

2. To recommend to all health professions and to the Pharmaceutical Manufacturers Association (PMA) (now the Pharmaceutical Research and Manufacturers of America, abbreviated “PhRMA”) that the apothecary system be eliminated in referring to dosage quantities and strengths.

**Background**

The Council felt that there is no longer a need for ASHP policy 8613, since the metric system has replaced the apothecary system in the U.S. Council members referenced international examples of apothecary system use but concluded that they do not impact pharmacy practice in the U.S.
HOUSE OF DELEGATES
NEW BUSINESS ITEM

New Business motions may be introduced by any delegate at the second meeting of the June House. The Board of Directors is not able to duly consider New Business items before the House considers them, so the House has only two options: referring a New Business item to the Board for review or rejecting the item. If the Board amends a New Business motion after House approval, the revised motion requires approval by the House.

Sponsors
Bernice Man (Illinois)
Karen McConnell (Colorado)

Co-sponsors
Laura Butkievich (Missouri)
Noelle Chapman (Illinois)
Andrew Donnelly (Illinois)
Joel Hennenfent (Missouri)
Matthew Rim (SSPP)
Ashley Ryther (Utah)

1. COVID-19 Vaccination Requirements to Advance Patient Safety and Public Health

To support employers in establishing and implementing mandatory COVID-19 vaccine requirements; further,

To advocate that healthcare organizations limit patient and staff risk of exposure to SARS-CoV-2 from individuals who are not immunized, which may include requiring unimmunized individuals to refrain from direct contact with patients and staff; further,

To urge healthcare organizations to have policies that address additional infection prevention practices required for healthcare workers who remain unimmunized against SARS-CoV-2; further,

To recognize that a small number of healthcare workers cannot be required to be vaccinated due to medical and religious reasons and therefore should be exempted from a mandate.

Rationale
COVID-19 is a vaccine-preventable disease for which there are safe and effective vaccines. The evidence is clear that the benefits of COVID-19 vaccines, as authorized by the Food and Drug Administration, far outweigh the risks associated with these medications. Universal vaccination against preventable infectious diseases among healthcare workers, including all members of the pharmacy workforce, is a safeguard to patients and public health. The Centers for Disease Control and Prevention (CDC) recommends that all healthcare personnel get vaccinated for COVID-19, and several major health systems have instituted mandatory COVID-19 vaccination
policies for their employees as of May 2021. In its recommendation regarding influenza vaccination, the CDC considers healthcare workers to include (but not be limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from healthcare workers and patients.

Limiting patient exposure to unvaccinated staff is consistent with the Code of Ethics of the American Medical Association: “Physician practices and health care institutions have a further responsibility to limit patient and staff exposure to individuals who are not immunized, which may include requiring unimmunized individuals to refrain from direct patient contact.” (AMA Code of Ethics Opinion 8.7)

**Background**

The Board of Directors revised some of the language in the New Business motion approved by the House of Delegates in June 2021 in response to changed conditions and to recognize that vaccine mandate exemptions are sometimes required by law. The revisions are as follows (underscore indicates new text; strikethrough indicates deletions):

To support employers in establishing and implementing mandatory COVID-19 vaccine requirements for COVID-19 vaccines once approved by the Food and Drug Administration (FDA) and encouraging the use of COVID-19 vaccines under emergency use authorization; further,

To advocate that healthcare organizations limit patient and staff risk of exposure to SARS-CoV-2 from individuals who are not immunized, which may include requiring unimmunized individuals to refrain from direct contact with patients and staff; further,

To urge healthcare organizations to have policies that address additional infection prevention practices required for healthcare workers who remain unimmunized against SARS-CoV-2; further,

To recognize that a small number of healthcare workers cannot be required to be vaccinated due to medical and religious reasons and therefore should be exempted from a mandate.