Summary of Actions of the November Virtual House of Delegates

November 13-20, 2020
The House of Delegates

Ultimate authority over ASHP professional policies

One annual session consisting of 4 meetings: 2 meetings at the ASHP Summer Meeting and 2 virtual meetings in the spring and fall

- Reviews policy proposals that have been approved by the Board of Directors
- Most of these professional policy proposals are contained in reports from ASHP councils
ASHP Policy Process

Governance

House of Delegates

Board of Directors

ASHP Professional Policy

Operations

Councils
Other Appointed Groups
Component Groups

Members
Results of November virtual House of Delegates

Delegates approved the following 8 recommendations by 85% or more, the threshold for final approval.
COT: Complementary, Alternative, and Integrative Medicine Products

To promote awareness of the impact of complementary, alternative, and integrative medicine (CAM) products on patient care, particularly drug interactions, medication safety concerns, and the risk of contamination and variability in active ingredient content; further,

To advocate for the documentation of CAM products in the health record to improve transparency and optimize patient safety; further,

To advocate for the inclusion of up-to-date and readily available information about CAM products and their characteristics in medication-related databases; further,

To provide education on the impact of CAM product administration on patient care within healthcare organizations.

Note: This policy supersedes ASHP policy 1511.
To advocate that Congress grant the Food and Drug Administration (FDA) authority to require premarketing comparative clinical trials when appropriate alternative agent(s) exist on the market, to elucidate the new agent’s role and place in therapy for the proposed indication; further,

To recommend that drug manufacturers include a summary of premarketing comparative study results in official product labeling, when available; further,

To advocate that Congress provide adequate funding to FDA and other agencies to support the additional tasks required by such premarketing comparative studies.

Note: This policy supersedes ASHP policy 1506.
COT: Mandatory Labeling of the Presence of Latex

To discontinue ASHP policy 0501, Mandatory Labeling of the Presence of Latex, which reads:

To urge the Food and Drug Administration to mandate that manufacturers of medications and medication-device combination products include labeling information on whether any component of the product, including its packaging, contains natural rubber latex.
COT: Safety of Intranasal Route as an Alternative Route of Administration

To encourage the development of institutional guidance and advocate for further research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for intranasal administration; further, To foster the development of educational resources on the safety of intranasal administration of drugs not approved for that route; further, To encourage manufacturers to develop intranasal formulations in ready-to-use devices.

Note: This policy supersedes ASHP policy 1601.
To enhance awareness by the pharmacy workforce, other healthcare workers, and the public of the potential threats to the public and patient care and safety presented by diversion of controlled substances; further,

To encourage healthcare organizations to develop controlled substances diversion prevention programs (CSDPPs) and supporting policies that delineate the core administrative elements and system- and provider-level controls needed to deter diversion of controlled substances at all stages of medication use; further,

To encourage healthcare organizations to address in their CSDPPs the roles, responsibilities, and oversight of all workers who may have access to controlled substances to ensure compliance with applicable laws and scopes of practice; further,
To encourage healthcare organizations to ensure that all healthcare workers are appropriately screened for substance abuse prior to initial employment and that surveillance, auditing, and monitoring are conducted on an ongoing basis to support a safe patient-care environment, protect co-workers, and discourage controlled substances diversion; further,

To advocate that pharmacists take principal roles in collaborative, interdisciplinary efforts by organizations of healthcare professionals, patient advocacy organizations, and regulatory authorities to develop and promote best practices for preventing drug diversion and appropriately using controlled substances to optimize and ensure patient access and therapeutic outcomes; further,

To advocate that the Drug Enforcement Administration and other regulatory authorities interpret and enforce laws, rules, and regulations to support patient access to appropriate therapies, minimize burdens on pharmacy practice, and provide reasonable safeguards against fraud, misuse, abuse, and diversion of controlled substances.

*Note: This policy supersedes ASHP policies 1614 and 1709.*
To encourage the Food and Drug Administration (FDA) and relevant state authorities to take the steps necessary to ensure that (1) all drug products entering the supply chain are thoroughly inspected and tested to establish that they have not been adulterated or misbranded and (2) patients will not receive improperly labeled and packaged, deteriorated, outdated, counterfeit, adulterated, or unapproved drug products; further,

To encourage FDA and relevant state authorities to develop and implement regulations to (1) restrict or prohibit licensed drug distributors (drug wholesalers, repackagers, and manufacturers) from purchasing legend drugs from unlicensed entities and (2) ensure accurate documentation at any point in the distribution chain of the original source of drug products and chain of custody from the manufacturer to the pharmacy; further,

To advocate for the establishment of meaningful penalties for companies that violate current good manufacturing practices (cGMPs) intended to ensure the quality, identity, strength, and purity of their marketed drug product(s) and raw materials; further,
To advocate for improved transparency so that drug product labeling includes a readily available means to retrieve the name and location of the facility that manufactured the specific lot of the product and the country of origin of the active pharmaceutical ingredient; further,

To advocate that this readily retrievable manufacturing information be available prospectively to aid purchasers in determining the quality of a drug product and its raw materials; further,

To foster increased pharmacist and public awareness of drug product supply chain integrity; further,

To urge Congress and state legislatures to provide adequate funding, or authority to impose user fees, to accomplish these objectives.

Note: This policy supersedes ASHP policy 1602.
CPhP: Drug Names, Labeling, and Packaging Associated with Medication Errors

To urge drug manufacturers, drug packagers and repackagers, outsourcing pharmacies, and the Food and Drug Administration to involve patients, practicing pharmacists, nurses, and physicians in decisions about drug names, labeling, and packaging to help eliminate (a) look-alike and sound-alike drug names, and (b) labeling and packaging characteristics that contribute to medication errors; further,

To inform pharmacists and others, as appropriate, about specific drug names, labeling, and packaging that have documented association with medication errors.

Note: This policy supersedes ASHP policy 0020.
To discontinue ASHP policy 9609, Human Factors Concepts, which reads:

To encourage pharmacists to apply human factors concepts (human errors related to inadequate systems or environment) in the prevention, analysis, and reporting of medication errors; further,

To encourage research (in conjunction with other groups, as appropriate) to identify human factors causes of medication errors and opportunities for their prevention.
Questions or Suggestions?

Feel free to contact:

Casey White, Chair, ASHP House of Delegates:
  hodchair@ashp.org

ASHP: https://www.ashp.org/Pharmacy-Practice/Policy-Positions-and-Guidelines/Participate-in-Guidance-Development