

House of Delegates

REPORT ON THE VIRTUAL HOUSE OF DELEGATES

November 13-20, 2020

RESULTS OF THE VOTING

From November 13 to 20, the ASHP House of Delegates (roster attached as an Appendix) voted on eight policy recommendations. Delegates approved eight recommendations by 85% or more, the threshold for final approval.

The eight policy recommendations **approved** are as follows:

Complementary, Alternative, and Integrative Medicine Products

Source: Council on Therapeutics

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 would supersede ASHP policy 1511.

Premarketing Comparative Clinical Studies

Source: Council on Therapeutics

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 would supersede ASHP policy 1506.

Mandatory Labeling of the Presence of Latex

Source: Council on Therapeutics

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.

Safety of Intranasal Route as an Alternative Route of Administration

Source: Council on Therapeutics

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 would supersede ASHP policy 1601.

Controlled Substances Diversion Prevention

Source: Council on Pharmacy Management

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 would supersede ASHP policies 1614 and 1709.

Drug Product Supply Chain Integrity

Source: Council on Pharmacy Management

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 would supersede ASHP policy 1602.

Drug names, Labeling, and Packaging Associated with Medication Errors

Source: Council on Pharmacy Practice

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 would supersede ASHP policy 0020.

Human Factors Concepts

Source: Council on Pharmacy Practice

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.

NOTES ON VOTING

A total of 93% (195) of delegates to the virtual House of Delegates participated in the voting, with 93% (149) of state delegates voting. All Board members and 99% of registered past presidents voted, and 80% of state delegations had 100% participation by their delegates.

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As of November 23, 2020

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Wyoming (2)	Jamie Homecker Tonja Woods	
SECTIONS AND FORUMS	DELEGATES	ALTERNATES
Ambulatory Care Practitioners	Jessica Skelley	Daniel Truelove
Clinical Specialists and Scientists	Joel Marrs	Douglas Slain
Inpatient Care Practitioners	Gregory Burger	Delia Carias
Pharmacy Informatics and Technology	Seth Hartman	Barry McClain
Pharmacy Practice Leaders	Philip Brummond	Jeffrey Little
Specialty Pharmacy Practitioners	Matthew Rim	Tara Kelley
New Practitioners Forum	Kellie Musch	Erin Boswell
Pharmacy Student Forum	Jeffrey Clark	Autumn Pinard
Pharmacy Technician Forum	Glen Gard	JoAnne Myhre
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U.S. Public Health Service	LCDR Carol Coats	CDR Cleveland Brown IV
Veterans Affairs	Dr. Heather Ourth	Dr. Virginia Torrise