House of Delegates

REPORT ON PROPOSED AMENDMENTS

June 2020 Meetings
(as of June 7, 10:00 a.m. EDT)

This report contains proposed amendments to policy recommendations submitted through the Amending Language Form for consideration at the First Meeting of the House. Delegates may still submit proposed amendments from the floor at the First Meeting of the House.

Council on Public Policy 1: Access to Affordable Healthcare

Amendment proposed by Kethen So, CA, and Mindy Burnworth, AZ:

To advocate for access to affordable healthcare for all residents of the United States, including coverage of medications and related pharmacist patient care services; further,

To advocate that the full range of available methods be used to (1) ensure the provision of appropriate, safe, and cost-effective healthcare services; (2) optimize treatment outcomes; (3) minimize overall costs without compromising quality; and (4) ensure patient choice of healthcare providers, including pharmacy services; further,

To advocate that healthcare payers seek to optimize continuity of care in their design of benefit plans.

Note: This policy would supersede ASHP policy 1001.
No amendments have been proposed for this policy recommendation.

To advocate that reimbursement for healthcare services be commensurate with the level of care provided, based on the needs of the patient.
Council on Public Policy 3: Funding, Expertise, and Oversight of State Boards of Pharmacy

Amendment proposed by Erin Taylor, MA, and John Armitstead, Past President:

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

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

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

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

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

Note: This policy would supersede ASHP policy 1507.

Rationale for Proposed Amendment: The rationale language notes: "Specific knowledge acquired by pharmacists and pharmacy technicians is essential to the safe regulation of practice. Thus, inspectors need to have that knowledge and training in order to assure the health and safety of the public."
Amendment proposed by Jesse Hogue, MI:

To reaffirm the position that to ensure optimal patient outcomes all medication dispensing functions must be performed by, or under the supervision of, a pharmacist; further,

To reaffirm the position that any relationships that are established between a pharmacist and other individuals in order to carry out the dispensing function should preserve the role of the pharmacist in (a) maintaining appropriate patient protection and safety, (b) complying with regulatory and legal requirements, and (c) providing individualized patient care; further,

To advocate that all medication dispensing, regardless of setting, be held to the same regulatory standards that apply to dispensing by a pharmacist; further,

To urge pharmacists to assume a leadership role in medication dispensing in all settings to ensure adherence to best practices.

Note: This policy would supersede ASHP policy 0010.

Rationale for Proposed Amendment: Proposed in collaboration with Lea Eiland, with the blessings of Chair Jeff Little and Vice-Chair Steve Riddle.

- In clause 2, we think "protection and" is extraneous and should be removed.
- In clause 3, given the issues we have identified with sites of care, we think it would be meaningful to add "regardless of setting"
Council on Public Policy 5: New Categories of Licensed Pharmacy Personnel

No amendments have been proposed for this policy recommendation.

To oppose the creation of new categories of licensed pharmacy personnel.
Council on Therapeutics 1: Safety and Efficacy of Compounded Topical Formulations

Amendment proposed by Jesse Hogue, MI:

To encourage pharmacists to take a leadership role in developing policies and procedures that would ensure potency, quality, safety, and effectiveness and standardization of compounded topical formulations; further,

To advocate that public and private entities establish a process to evaluate and regulate the safety, efficacy, and composition of compounded topical formulations; further,

To advocate that ASHP expand its repository of evidence-based formulations that could serve as a resource for compounding topical formulations; further,

To advocate that public and private payers and healthcare providers collaborate to create standardized and efficient methods for authorizing payment for medically necessary compounded topical formulations; further,

To encourage hospitals and health systems to develop policies and procedures to guide clinicians in making informed decisions regarding the prescribing and use of compounded topical formulations; further,

To encourage pharmacists to take a leadership role in developing and providing education on the safety and efficacy of compounded topical formulations to providers and consumers.

Rationale for Proposed Amendment: The Michigan delegation agreed with the many RDCs who suggested streamlining the first two clauses into one clause as we have here. While COT Chair Snehal Bhatt expressed some concern with removing the word potency, we feel that most hospitals don’t have a way to objectively measure potency. Standardization of preparations would potentially help with that, though, so we have also offered an amendment to include an additional clause for a helpful member resource.
Amendment proposed by Michelle Eby, DC:

To advocate that Congress grant the Food and Drug Administration (FDA) authority to require the manufacturer of an approved drug product or licensed biologic product to conduct postmarketing studies on the safety of the product when the agency deems it to be in the public interest and to require additional labeling or withdrawal of the product on the basis of a review of postmarketing studies; further,

To advocate that Congress provide adequate funding to FDA and other agencies to fulfill this expanded mission related to postmarketing surveillance and studies; further,

To advocate that such studies compare a particular approved drug product or licensed biologic product with (as appropriate) other approved drug products, licensed biologic products, medical devices, or procedures used to treat specific diseases; further,

To advocate expansion of studies of approved drug products or licensed biologic products to improve safety and therapeutic outcomes and promote cost-effective use; further,

To encourage impartial public-private partnerships or private-sector entities to also conduct such studies.

Note: This policy would supersede ASHP policies 1004 and 0515.
Council on Therapeutics 3: Gabapentin as a Controlled Substance

Amendment proposed by Jesse Hogue, MI:

To advocate that the Drug Enforcement Administration classify reschedule gabapentin to as a Schedule V substance due to its low potential for abuse and patient harm.

Rationale for Proposed Amendment: There seems to be general support for the intent of the policy, it just needs some improvement in wording to make it more clear. Since gabapentin is not currently scheduled as a controlled substance, the use of the word reschedule is not appropriate. Additionally, using the phrase "low potential" is misleading and contrary to the intent of the policy. My proposed amendment seemed to have wide support at the RDCs, and was also supported by COT Chair Snehal Bhatt.
Council on Education and Workforce Development: Residency Training for Pharmacists Who Provide Direct Patient Care

No amendments have been proposed for this policy recommendation.

To recognize that optimal direct patient care by a pharmacist requires the development of clinical judgment, which can be acquired only through experience and reflection on that experience; further,

Pharmacists who provide direct patient care should have completed an ASHP-accredited residency or have attained comparable skills through practice experience; further,

To support the position that the completion of an ASHP-accredited postgraduate-year-one residency be required for all new college or school of pharmacy graduates who will be providing direct patient care.

*Note: This policy would supersede ASHP policies 0701 and 0005.*
Council on Pharmacy Management 1: Pharmacist’s Role in Health Insurance Benefit Design

Amendment proposed by Jesse Hogue, MI:

To advocate that pharmacy practice leaders collaborate with internal and external partners who design, negotiate, and select their own organization's health plans and pharmacy benefit management contracts to preserve patient continuity of care and the integrity of the health-system pharmacy operations enterprise; further,

To provide education and resources for all partners on the health plan development process, analysis of pharmacy benefit design, contemporary formulary review processes, and application of medication safety principles on formulary decision-making.

Rationale for Proposed Amendment: In collaboration with Dave Hager and Marianne Ivey, and after consultation with Council members, we propose adding the interest of the patient to the existing concern for the healthcare system in the first clause for completeness, and adding the second clause to include education for pharmacists who may not be familiar with health plan development processes and plan developers who may not be familiar with medication use concerns as suggested in the rationale/background.
Council on Pharmacy Management 2: Preserving Patient Access to Pharmacy Services in Medically Underserved Areas

Amendment proposed by Heather Ourth, Veterans Affairs:

To advocate for funding and innovative payment models to preserve patient access to acute and ambulatory care pharmacy services in rural and medically underserved areas; further,

To support the use of telepharmacy telehealth to maintain pharmacy operations and pharmacist-led comprehensive medication management that extend patient care services and enhance continuity of care in rural and medically underserved areas; further,

To advocate that the advanced communication technologies required for telepharmacy telehealth be available in rural and medically underserved areas; further,

To advocate for funding of loan forgiveness or incentive programs that recruit pharmacists and pharmacy technicians to practice in rural and medically underserved areas.

Rationale for Proposed Amendment: The term “telepharmacy” can be interpreted to apply to remote pharmacy dispensing rather than all-encompassing to include clinical pharmacy services. There have been instances where interpretation of the term “telepharmacy” in existing regulation has caused problems during the COVID-19 emergency response to virtually provide the broad scope of normal clinical pharmacist activities within the VA. “Telehealth” is a broader term that will more appropriately meet the intent of this policy.

Amendment proposed by Mindy Burnworth, AZ:

To advocate for funding and innovative payment models to preserve patient access to acute and ambulatory care pharmacy services in rural and medically underserved populations areas; further,

To support the use of telepharmacy telehealth to maintain pharmacy operations and pharmacist-led comprehensive medication management that extend patient care services and enhance continuity of care in rural and medically underserved populations areas; further,

To advocate that the advanced communication technologies required for telepharmacy telehealth be available in in rural and medically underserved populations areas; further,

To advocate for funding of loan forgiveness or incentive programs that recruit pharmacists and pharmacy technicians to practice in rural and medically underserved populations areas.

Rationale for Proposed Amendment: More broad terminology "telehealth" (vs. telepharmacy), and consideration for populations (vs. areas). When the Pharmacy and Medically Underserved Areas Enhancement Act was proposed the following definitions were used:

- Medically Underserved Areas (MUAs) are regions where residents have a shortage of personal health services. The designation is based on several factors, including the
number of available primary care practitioners, the infant mortality rate, poverty level, and population over 65.

- Medically Underserved Populations (MUPs) may include groups of persons who face economic, cultural or linguistic barriers to health care. The designation is based on the same variables as the MUAs above.

- Health Professional Shortage Areas (HPSAs) may be designated as having a shortage of primary medical care, dental, or mental health providers. They may be urban or rural areas, population groups or medical or other public facilities.
Council on Pharmacy Management 3: Multistate Pharmacist Licensure

Amendment proposed by Susan Teil Boyer, WA, Julie Kalabalik-Hoganson, NJ, and Mindy Burnworth, AZ:

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

Rationale for Proposed Amendment: Recommend modernizing pharmacist licensure as physicians and nurses have accomplished in their Medical Licensure Compact in 29 states and in the Nursing Licensure Compact in 26 states. Our current model is antiquated especially to respond to this current pandemic where pharmacists are needed to practice in other states and should be allowed to use their home/original state license to do so. Health systems frequently span multiple states and pharmacists support rural hospitals across state lines. Also recommend first tackling pharmacist licensure before pharmacy technicians because not all states license pharmacy technicians. The term "interstate" is used by other healthcare professions such as physicians. Delegates reflected on the specific statement, practice remotely or across state lines. This may limit the practice of pharmacy to the 50 US states, DC, and/or Puerto Rico. Other jurisdictions, such as Guam, Marshall Islands, DC, etc. may unintentionally be omitted with this restrictive descriptor. The delegates concurred that truncating the policy statement by omitting reference to a setting would broaden the language and be more inclusive. In addition, the use of "interstate" vs. multistate aligns better with the common language in the Medical and Nursing Licensure Compacts and aligns better with the intent of the policy.
Council on Pharmacy Management 4: Continuity of Care in Pharmacy Payer Networks

Amendment proposed by JoAnn Stubbings, Section of Specialty Pharmacy Practitioners:

To oppose provider access criteria that impose discriminatory requirements or qualifications on participation in pharmacy insurance payer networks that interfere with patient continuity of care or patient site-of-care options.

Rationale for Proposed Amendment: The amendment adds the word “discriminatory” to the phrase “requirements or qualifications” to describe exclusionary insurance practices that lock out health-system specialty pharmacies or infusion clinics from insurance payer networks, even when criteria for participation are met. It also refers to discriminatory practices that are financial in nature, such as 340B discriminatory pricing. The amendment also revises the phrase “pharmacy payer networks” to “insurance payer networks” to reflect the broader scope of payers beyond pharmacy.
Amendment proposed by Mindy Burnworth, AZ:

[CLAUSE MOVED] To support care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further,

To encourage hospitals and health systems not to permit administration of medications brought supplied to the hospital or clinic by the patient, caregiver, or specialty pharmacy when storage conditions or the source cannot be verified, unless it is determined that the risk of not using such a medication exceeds the risk of using it; further,

[CLAUSE MOVED] To support care models in which medications are prepared for patient administration by the pharmacy and are obtained from a licensed, verified source; further,

To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications.

Note: This policy would supersede ASHP policy 0806.
Amendment proposed by Elizabeth Shlom, NY, Jennifer McKenna, KS, and Christi Jen, AZ:

To encourage hospitals and health systems not to permit the use of medication administration devices with which the staff is unfamiliar (e.g., devices brought in by patients), unless it is determined that the risk of not using such a device exceeds the risk of using it; further,

To encourage hospitals and health systems to train staff on the handling and use of medication administration devices brought in by patients; further,

To recommend hospitals and health systems have a system in place for determining the risk versus benefit of permitting a patient to use his or her own medication administration devices; further,

To advocate that hospitals and health systems have policies and procedures, including the training of staff, on the use and management of medication administration devices and devices that augment medication administration (e.g., continuous glucose monitors); further,

[CLAUSE MOVED]To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team; further,

To advocate for adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of medications and use of related devices; further,

[CLAUSE MOVED]To advocate that hospitals and health systems ensure that pharmacists participate in the identification of medication administration devices brought in by patients and communicate those findings to the interprofessional care team.

Note: This policy would supersede ASHP policy 0806.

Rationale for Proposed Amendment: The amendments are submitted on behalf of the Emerging Sciences SAG and the NYS delegation, both which felt that this is an important policy statement since a number of patients have implantable and other types of medication administration devices when admitted to the hospital. The amendments combine the first and third clauses into one, with slight re-wording to focus the clause in a positive, patient-centric manner. The phrase "train staff" is changed to "develop processes" with the understanding that it is important to have processes in place to address what should be done when a patient is admitted with a medication administration device that the staff might not be familiar with. Lastly, the clause regarding reimbursement considerations was moved to the end of the policy statement.
Amendment proposed by Molly Billstein Leber, CT, and Samm Anderegg, Section of Pharmacy Informatics and Technology:

To encourage pharmacy leaders to work in collaboration with physicians, nurses, health-system administrators, and others to outline key pharmacist services that are essential to safe and effective patient care and employee engagement; further,

To encourage pharmacy leaders to be innovative in their approach and to factor into their thinking the potential benefits and risks of flexible staffing models, telehealth practices, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings; further,

To support the following principles:
• Sufficient qualified staff must exist to ensure safe and effective patient care;
• During periods of staff shortages, pharmacists must exert leadership in directing resources to services that are the most essential to safe and effective patient care;
• Within their own organizations, pharmacists should develop contingency plans to be implemented in the event of insufficient staff—actions that will preserve services that are the most essential to safe and effective patient care and will, as necessary, curtail other services; and
• Among the essential services for safe and effective patient care is pharmacist review of new medication orders before the administration of first doses; in settings where patient acuity requires that reviews of new medication orders be conducted at any hour and similar medication-use decisions be made at any hour, there must be 24-hour access to a pharmacist.

Note: This policy would supersede ASHP policy 0201.

Rationale for Proposed Amendment: The intent of the policy was to focus on how to improve employee engagement and workforce resiliency and not advocate for creation of benchmarking or productivity metrics that are addressed in ASHP Policy 0901, Workload Monitoring and Reporting. We also recommend that the bullets following "support the following principles" be incorporated into the background/rationale, as they are important points to consider, but are not needed in the actual policy statement. We also recognized that as for-profit organizations are expanding and other organizations are looking for cost savings, there is a need to create a minimum staffing ratio, similar to what nursing has. We would recommend that ASHP create a Task Force or develop a White Paper around safe staffing ratios, future guidance on the use of productivities metrics, and value-based care. The Section of Pharmacy Informatics & Technology supports the proposed amendment. We suggest adding language that calls out telehealth practices as indicated below. The policy does identify using technology available, we feel this language is more explicit.
No amendments have been proposed for this policy recommendation.

To recognize that violence in the U.S. is a public health crisis; further,

To affirm that the pharmacy workforce has important roles in a comprehensive public health and medical approach to violence prevention, including leadership roles in their communities and workplaces; further,

To encourage members of the pharmacy workforce to seek out opportunities to engage in violence prevention efforts in their communities and workplaces; further,

To promote collaboration between the pharmacy workforce and community and healthcare organizations in violence prevention efforts; further,

To foster education, training, and the development of resources to prepare the pharmacy workforce for their roles in violence prevention; further,

To support research and dissemination of information on the effectiveness of pharmacy-focused violence-prevention strategies.