2017 House of Delegates
Report of the New Business Review Committee

Committee Members

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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: Phillip Lawrence
(Name)

January 4, 2017
(Date) APhA-Academy of Pharmacy Practice & Management
(Organization)

Subject: Equal Employment Opportunity for Pharmacists

Motion: Move that the 2017 APhA House of Delegates amend the 2012, 1989 Equal Opportunities for Pharmacists policy as follows:

2012, 1989 Equal Rights and Opportunities for Pharmacists, Pharmacy Technicians, and Student Pharmacists

APhA reaffirms its unequivocal support of equal opportunities for professional employment and advancement, compensation, and organizational leadership positions for all pharmacists regardless of and pharmacy personnel. In addition, APhA opposes discrimination against pharmacists, pharmacy technicians, or student pharmacists based on an individual’s gender, gender identity or expression, race, color, religion, national origin, age, disability, genetic information, sexual orientation, or any other category protected by federal or state law.

Background:
Currently, no national pharmacy organization includes anti-discrimination language pertaining to sexual orientation AND gender identity or expression in policy. The following organizations have official policies which include statements directed against discrimination or bias in the healthcare workforce and/or education: American Association of Medical Colleges, American Medical Association, the American College of Physicians, the American Academy of Family Physicians, the American Physical Therapy Association, the American Psychological Association, the American Public Health Association, and the American Academy of Pediatrics.
It is important that the revised policy wording include the broad but unique terms: sexual orientation, gender, gender identity and gender expression. Sexual orientation includes someone’s emotional, sexual, or romantic attractions to others. While gender refers to attitudes, feelings and behaviors that a culture associates with biological sex, gender identity involves someone’s “innermost concept of self as male, female, a blend of both, or neither.” It describes how people may refer to themselves and how they perceive themselves whether different or the same as the gender they were assigned at birth. Gender expression is the “external appearance of one’s gender identity, usually expressed through behavior, clothing, haircut, or voice,” regardless whether one or more of these conforms to socially defined characteristics of male or female.9

Although only 30.8% of pharmacy schools have public written statements that include both sexual orientation and gender identity,10 sex and gender minorities are represented in a wide variety of health professions and professional training programs.11 Non-inclusive learning environments in the health professions are linked to higher rates of depression and discomfort.12 Health professions students also cite “fear of discrimination” as one of the most common reasons to not disclose their sexual or gender minority status.13 In the overall lesbian, gay, bisexual, or transgender (LGBT) populations, two thirds have experienced discrimination in some form due to their sexual orientation or gender identity.14 Up to 28% of transgender people have experienced verbal harassment, a physical attack, or sexual assault at work, specifically.15 Other forms of mistreatment at work related to transgender status including but not limited to forced resignation or sharing of private information have been reported by 23% of transgender individuals. Members of the LGBT community in our pharmacies, clinics, colleges, hospitals, and other healthcare settings deserve respect and equal treatment. Part of that process is reaffirming a commitment to fight discrimination in our professional community.

References


**Current APhA Policy & Bylaws:**

**2012, 1989 Equal Employment Opportunity for Pharmacists**

APhA reaffirms its unequivocal support of equal opportunities for professional employment and advancement, compensation, and organizational leadership position for all pharmacists regardless of gender, race, color, religion, national origin, age, disability, genetic information, sexual orientation, or any other category protected by federal or state law.


**1979 Consideration of the Equal Rights Amendment (Under “Women in Pharmacy” Section)**

APhA supports efforts to assure equal rights of all persons.

(AmPharm NS19(7):60 June 1979) (Reviewed 2009) (Reviewed 2014)

**2012, 1991 Recruitment of a Diverse Population into Pharmacy**

1. APhA supports a vigorous long term program for the recruitment of a diverse population of student pharmacists into the pharmacy profession.

2. APhA encourages the development and regular updating of comprehensive recruitment materials, directed toward diversity and inclusion, that address such issues as pharmacy career opportunities, financial aid, and educational prerequisites, and that highlight professional diverse role models.

3. APhA encourages national, state, and local association; schools; students; and industry to create a network of pharmacists who would serve as role models for a diverse population of student pharmacists.

4. APhA supports the development of guidelines that assist schools of pharmacy in implementing diversity and inclusion initiatives into student pharmacist recruitment programs.


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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: __________ CDR Heather D. Hellwig, USN

(Name)

2/21/2017                    U.S. Navy
(Date)     (Organization)

Subject: Drug Disposal

Motion: Move to adopt the following policy statement,

1. APhA urges pharmacists to expand patient access to secure, convenient, and ecologically responsible drug disposal options, in accordance with the Drug Disposal Act, by implementing disposal programs they deem appropriate for their individual practice sites, patient care settings, and business models in order to reduce the amount of dispensed but unused prescription drug product available for diversion and misuse.

Background:

The National Survey of Drug Use and Health 2010\(^1\) concluded that friends and family are the primary sources of abused opioids. This study reported 55% of persons who reported non-medical use of pain relievers obtained their supply from a family member or friend. The Drug Enforcement Agency has hosted biannual Drug Take-Back events with spurious success. The Drug Disposal Act of 2010 amended the Controlled Substance Act to allow a subset of DEA pharmacy registrants to voluntarily register as authorized collection sites to increase access to secure and convenient disposal locations. Since then, numerous drug disposal options in addition to pharmacy-based receptacles have been made commercially available to end users including, but not limited to, reverse distribution mailing envelopes and drug deactivation and disposal pouches. APhA has endorsed the safe handling and disposal of medication, shared responsibility for the costs of implementing disposal programs, and pharmacists’ role in planning and coordinating disposal programs via previous policy statements. However, the profession has never endorsed a statement of the specific role of pharmacists in offering access to disposal programs, nor the specific types of programs that could be offered. To fill this void, some state officials have asked pharmacies to assist in the prevention and treatment of the opioid addiction crisis specifically by registering as collection sites and installing drug take-back receptacles.\(^2\) APhA is in a position to endorse the adoption of policy that advocates for pharmacies to develop and implement programs that best fit their specific environment from a variety of responsible disposal options aimed at increasing patient access to such services. The longer that APhA waits to endorse a variety of
intervention options supported by its own members, the more likely that additional requests and eventual mandates for the implementation of specific options will be submitted from outside the profession.

References:
2. December 28, 2016 letter from Secretary of Pennsylvania Department of Drug and Alcohol Programs Gary Tennis to Pennsylvania Pharmacists.

Current APhA Policy & Bylaws:
2013 Medication Take-Back/Disposal Programs
1. APhA encourages pharmacist involvement in the planning and coordination of medication take-back programs for the purpose of disposal.
2. APhA supports increasing public awareness regarding medication take-back programs for the purpose of disposal.
3. APhA urges public and private stakeholders, including local, state, and federal agencies, to coordinate and create uniform, standardized regulations, including issues related to liability and sustainable funding sources, for the proper and safe disposal of unused medications.
4. APhA recommends ongoing medication take-back and disposal programs.
(JAPhA 53(4): 365 July/August 2013)

2009 Medication Disposal
1. APhA encourages appropriate public and private partnerships to accept responsibility for the costs of implementing safe medication disposal programs for consumers. Furthermore, APhA urges DEA to permit the safe disposal of controlled substances by consumers.
2. APhA encourages provision of patient-appropriate quantities of medication supplies to minimize unused medications and unnecessary medication disposal.

1990 Proper Handling & Disposal of Hazardous Pharmaceuticals & Associated Supplies & Materials
1. APhA supports the proper handling and disposal of hazardous, pharmaceutical products and associated supplies and materials by health professionals and by patients to whom such products, supplies, and materials are provided.
2. APhA supports involvement with representatives from other health professional organizations, industry, and government to develop recommendations for the proper handling and disposal of hazardous pharmaceuticals and associated supplies and materials.
3. APhA supports the development of educational programs for health professionals and patients on the proper handling and disposal of hazardous pharmaceuticals and associated supplies and materials.

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: ______________ LCDR Patrick Harper _____________________
(Name)

02/21/2017                        ___ U.S. Public Health Service ___
(Date)                           (Organization)

Subject: On-Label Indication and Medication Safety

Motion: Move to adopt the following policy statement,

1. APhA encourages pharmacists including the indication on prescription labels, using vocabulary appropriate for
their unique practice sites and that addresses the needs of their specific patient populations, when such
information is included by the prescriber on the prescription order or can be otherwise clearly and accurately
discerned per the professional knowledge and judgement of the pharmacist.

2. APhA recognizes that the inclusion of on-label indications may not meet the wants and needs of every patient or
may not be appropriate in all patient care situations and further encourages pharmacists’ use of best judgement
in executing self- or patient-initiated exclusion of on-label indication.

Background:
The Principles of Practice for Pharmaceutical Care, published by the American Pharmacists Association in 1995,
supports the need to develop and implement a plan with the patient that “[assures] that the patient has a thorough
understanding of the disease and the therapy/medications prescribed in the plan” and is in line with a “patient’s
level of comprehension1.” Despite major statutory requirements such as the Omnibus Budget Reconciliation Act
(OBRA) of 1990 – which imposes pharmacist counseling obligations, prospective drug utilization reviews, and record-
keep rules first applied to Medicaid patients and now found in standard practice -- it is common to find many
patients still unsure of the purpose of their medications2. “Right indication” has been proposed as the “sixth right”
alongside the right patient, drug, dose, time, and route to improve patient safety and meet desired outcomes3.

Patient knowledge impacts adherence to therapy4. Ignorance or misunderstanding of the reason a medication was
prescribed has led to prescriber mistrust and refusal to take medication3,5. Not only do patients prefer a prescription
label with the indication, but as one of the patient’s best source of information about their medication, prescription container bottles with on-label indications provide opportunity to enhance patient care\(^6\). In recognition of this, the United States Pharmacopoeia (USP) published, in November 2012, USP General Chapter <17> on prescription container labeling, stating the label should include a “purpose for use” based on patient preference\(^9\). As recently as November 2016, the Institute for Safe Medication Practices (ISMP) published agreement that “indications are the missing link connecting patients to their prescribed drugs, and that electronic prescribing systems must incorporate drug indications\(^10\)”. Thus, USP and ISMP join many providers, patients, and other key stakeholders in support of the inclusion of indication on prescription labels.

References


Current APhA Policy & Bylaws:

2010, 2001 Prescription Order Requirements

1. APhA supports the use of technology to facilitate the transmission of prescription order information from the prescriber to the pharmacist of the patient’s choice at no additional cost to the pharmacy.

2. APhA supports the use of technology where appropriate standards for patient confidentiality and prescriber and pharmacist verification are established.

3. APhA supports the transmission of complete prescriber information on or with the prescription order that enables the pharmacist to readily identify and facilitate communication with the prescriber.

4. APhA supports the use of specific instructions with prescription orders. Use of potentially confusing terminology (such as “as directed”, unclear use of Latin phrases, confusing abbreviations, etc.) should be avoided.
5. APhA supports the inclusion of the diagnosis or indication for use for which the medication is ordered on or with the transmission of the prescription order by use of standard diagnosis codes or within the directions for use. APhA further supports the inclusion of patient-specific information on or with the prescription order where appropriate.

6. APhA supports public education about the benefits and risks of technological advances in pharmacy practice.

2012 Medication Verification

APhA encourages including a description of a medication’s appearance on the pharmacy label or receipt as a means of reducing medication errors and distribution of counterfeit medications.

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by:  Heather Free, on behalf of the 2017 Policy Review Committee

(Name)

2/22/2017

(Date)

District of Columbia Delegation

(Organization)

Subject:  Work Schedules

Motion:  We, the members of the Policy Review Committee, urge the 2017 House of Delegates to amend the following policy statement as follows:

2001 Work Schedules

1.  APhA supports a work environment in which innovative work schedules are available to pharmacists and encourages employers to allow meal breaks and rest periods.

2.  APhA encourages employers to offer benefit packages that provide dependent-care benefits, such as including, but not limited to, flexible spending accounts, voucher systems, referral services, on-site dependent care, and negotiated discounts for use of day care facilities, to improve workforce conditions.

Background:

The purpose of this amendment is to provide a list of benefits as an example for employers to include within their dependent-care benefit packages. The original language stated that all of the items listed and others not listed, were to always be included. Smaller pharmacies may not have the capability to adhere to how the original statement was written specifically the on-site dependent care or use of day care facilities. The amendment suggests the items listed as examples of dependent-care benefits to include rather than require their inclusion altogether.
Current APhA Policy & Bylaws:


The employment relationship between pharmacists and their employers must start with the principle that pharmacists have a professional, inherent right to practice in a manner which will engender self-respect in pursuit of their professional and economic objectives.

It is the policy of APhA to further the following basic employment standards:

1. Employers are obligated to respect the professional status, privileges, and responsibilities of employed pharmacists.

2. Employers are obligated to provide working conditions that enhance the ability of employed pharmacists to utilize their full professional capacity in providing patient care service to the public.

3. Employers are obligated to provide employed pharmacists opportunities to increase their professional knowledge and experience.

4. Employers are obligated to fairly compensate employed pharmacists commensurate with their duties and performances. Such compensation should include benefits generally available to other professionals including, but not limited to, vacation, sick leave, insurance plans, and retirement programs.

5. Employed pharmacists are obligated to use their best efforts to further the services offered to the public by their employers.

6. Employed pharmacists are obligated to unhesitatingly bring to the attention of their employers all matters which will assist the employers in maintaining professional standards and successful practices.

7. Employed pharmacists are obligated, when negotiating compensation, to consider not only prevailing economic conditions in their community, but also their economic position relative to other health care professionals.

8. Employed pharmacists are obligated to recognize that their responsibility includes not depriving the public of their patient care services by striking in support of their economic demands or those of others.

9. Both employers and employed pharmacists are obligated to reach and maintain definite understandings with regards to their respective economic rights and duties by resolving employment issues fairly, promptly, and in good faith.

It is the policy of APhA to support these basic employment standards by:

1. Encouraging and assisting state pharmacists associations and national specialty associations to establish broadly representative bodies to study the subject of professional and economic relations and to establish locally responsive guidelines to assist employers and employed pharmacists in developing satisfactory employment relationships.

2. Encouraging and assisting state pharmacists associations and national specialty associations to use their good offices, whenever invited, to resolve specific issues which may arise.

3. Assisting state pharmacists associations and national specialty associations to use their good offices, whenever invited, to resolve specific issues which may arise.

4. Assisting state pharmacists associations and national specialty associations to develop procedures for mediation or arbitration of disputes which may arise between employers and employed pharmacists so that pharmacists can call on their profession for such assistance when required.

5. Increasing its activities directed towards educating the profession about the mutual employment responsibilities of employers and employed pharmacists.
6. Developing benefits programs wherever possible to assist employers in providing employed pharmacists with economic security.

7. Continuously reminding pharmacists that the future development and status of pharmacy as a health profession rests in their willingness and ability to maintain control of their profession.


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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: __________ LCDR Garrette Martin-Yeboah __________
(Name)

2/24/17
(Date)

U.S. Public Health Service
(Organization)

Subject: Support for clinically-validated blood pressure measurement devices

Motion: Move that APhA adopt the following statements:

1. APhA supports the use of clinically validated blood pressure measurement devices.
2. APhA supports regulations and peer reviewed clinical validation testing for blood pressure measurement devices.
3. APhA promotes public awareness on accuracy of blood pressure measurement devices.
4. APhA promotes pharmacist involvement in blood pressure monitoring.

Background:

This background information is intended to provide a basis for APhA and other pharmacy organizations to consider joining with international hypertension organizations in calling on the private healthcare sector and governments worldwide to address the issue of inaccurate blood pressure (BP) devices and to advocate for accurate BP measurement to ensure proper patient diagnosis and treatment decisions.

Approximately 18-months ago, the APhA Foundation engaged with the American Medical Association (AMA), Association for the Advancement of Medical Instrumentation (AAMI), American Heart Association (AHA), American Society of Hypertension (ASH), and Canadian Hypertension Education Program (CHEP) to form the Coalition for Accurate Measurement of Blood Pressure (CAMBP) with the intent to develop a publicly available Validated Blood Pressure Device Listing (VDL). This VDL will provide consumers and healthcare professionals with a common point of reference for self-measured, clinical use, and ambulatory blood pressure measurement and is expected to be available through CAMBP efforts in November, 2017.
The APhA Foundation’s collaboration with AMA has been based on the three following tenets:

1. Our collective intent is to improve care for the patients who we serve, to improve availability of accurate and objective information for clinical decision making, and to enhance meaningful patient-centered, team-based care.
2. We agree that it is important to communicate effectively about the importance of relying upon standards to assure the public that blood pressure measurements are precise, accurate, and trustworthy.
3. We believe that one of the best ways forward is having medicine and pharmacy work together on a clear, concise, collaborative initiative that presents a united front about the necessity of obtaining and utilizing valid blood pressure measurements in our healthcare delivery system.

The 2016 Centers for Disease Control and Prevention (CDC) publication, *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists*, supported by APhA and AMA also emphasizes the importance of measuring blood pressure accurately.

**FDA 510(k) Clearance Issues**

First, it’s important to understand that the FDA classifies non-invasive BP devices as “low risk”, and are therefore “class II”, subject to the lesser standard of the FDA 510(k) pathway. This is different from the more rigorous FDA “PMA” pathway for “high risk” medical devices. The differences are described here: [http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194468.htm](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194468.htm)

The 510(k) pathway is fundamentally flawed due to poor US legislation, and there is very little staff within the FDA can do within the confines of US law to ensure the safety and efficacy of devices falling under the purview of the 510(k) program. Reference this 2011 congressional report by the Institutes of Medicine (IOM) that called for legislative action to correct the 510(k) issues in the interest of public health and safety: [http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years/510k%20Clearance%20Process%202011%20Report%20Brief.pdf](http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years/510k%20Clearance%20Process%202011%20Report%20Brief.pdf)

The IOM report outlines the myriad issues concerning the 510(k) program. Please review their comments carefully, including their conclusion:

*The committee concludes that the FDA 510(k) process lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices and, furthermore, that it cannot be transformed into one.*

From direct experience working with blood pressure device manufacturers, and within standards organizations, and from multiple meetings with the FDA on the specific topic of BP Devices, the following concerns exist about the 510(k) program:

1. **No Transparency:** The public has no access to fundamental information about device performance. The manufacturer has 2 options with their submissions – submit a “Summary” or a “Statement” about the performance testing. The “summaries” posted on the FDA website contain little to no useful data in assessing the quality of the validation study. The “Statement” contains less, and the manufacturers that used the “statement” option are supposed to provide data to individuals asking for such data in a timely manner. As Dr. Alpert discovered in his published survey of kiosk manufacturers such inquiries are generally met with silence. The public can make a freedom of information request of the FDA but this process takes years, and the manufacturer in this case STILL has great flexibility to redact data as they see fit – clearly not a solution.
2. **No Assurance of Independent Testing:** It is common for manufacturers to perform “in-house” clinical testing of BP devices on their employees, by their employees, in the employer setting, with employees drafting the data analysis and submitting the reporting to file, or to the FDA. This raises obvious conflict of interest issues and calls into question the legitimacy of such data. Further, there is no way for the public to know whether a device has been cleared based on independent tests data, or “in-house” test data.

3. **Unclear Standards Applied:** FDA representatives have informed the AAMI Standards committee that the AAMI standard is used as a “guideline” for reviewing data, but that it is at the discretion of the reviewer to make exceptions when applying the standard. It is also possible that other, less rigorous worldwide standards (such as the ESH protocol, which is not recognized by ISO) may be deemed acceptable to certain FDA reviewers.

4. **No Peer Review:** Clinical data are not peer reviewed by experts outside the FDA prior to pre-market approval, and it is unclear the quality of the training nor knowledge of FDA peer reviewers in the highly specialized domain of BP device validation.

5. **Substantial Equivalence (SE):** The SE ruling is the most commonly applied ruling in 510(k) pre-market clearances. Despite the complexities of device algorithms, cuff design variations, module hardware changes, software changes, etc, devices can be cleared with “no testing required” based on a manufacturer claim of substantial equivalence to a predicate device.

6. **Letter to File:** Many manufacturers release re-engineered BP device models under existing 510(k) numbers without making any submission to the FDA under the “letter to file” option. In these instances, there is clearly no supervision and enforcement/inspection is severely lacking.

7. **No Intended Use Enforcement:** In the case of BP Kiosks, many devices have been cleared for which the intended use is “general public”, yet the same clearance documents (and the required labelling) make it clear that the devices are not appropriate for large arms (approximately 45% of the US adult population). The 510(k) legislation mandates that if the labeling is accurate the device is legal, and essentially it is up to the public to ensure they are following the labeling instructions (with are generally not visible to the public). During one meeting between concerned citizens and the FDA, the FDA representative stated that they “can’t regulate against ignorance”. In this case the FDA is essentially clearing the way for off-label use of a BP device on a massive scale. The same is true with many other devices sold in the market that are intended for limited arm sizes.

8. **No Enforcement of False Claims:** Many device manufacturers tout their status as “FDA Approved”, which is a false claim implying a much higher standard of validity than the 510(k) ever intended with its industry-friendly premarket approval approach. Devices are not “approved”; they are cleared to be legally marketed. There is apparently no proactive program within the FDA to monitor and enforce such false manufacturer claims.

The multi-layered issues with the 510(k) program indicate the issues are intractable and that small “adjustments” will not reestablish public confidence in the 510(k) ability to ensure the “safe and effective” use of BP devices across the US. Short of a legislative overhaul of the 510(k) program, the best solution will be the implementation of transparent and open device review programs driven through clinical organizations such as the AMA, APhA, AHA, and others. No opaque and secretive device validation and review process will be sufficient to establish the trust of the clinical community. The device validation process must be exposed to the light of public scrutiny. The healthcare stakes are extremely high, and unfortunately the required reform cannot happen with the confines of existing government regulatory framework.
Blood Pressure Kiosk Issues

APhA posted a Facebook page story in May of 2016 (see link below) about a local news reporter investigating the accuracy of in-store blood pressure kiosks. Two of the pharmacists interviewed admitted that they devices were not clinically sound. It seems counter intuitive that APhA does not have a position or policy statement on the appropriate use of clinically validated BP measurement devices by pharmacists. http://www.ksby.com/story/31846334/ksby-news-investigates-how-accurate-are-in-store-or-at-home-blood-pressure-monitors

APhA should join with international hypertension organizations calling on the private healthcare sector and governments worldwide to address the issue of inaccurate blood pressure (BP) devices. Noting inadequate regulatory control and lack of published evidence for many devices, the authors of the “Position Statement” described below called for immediate action to ensure accurate patient diagnosis and treatment decisions.

Recent position statements on Public-Use Blood Pressure (BP) kiosks from both the American Society of Hypertension (ASH) (2015) and the World Hypertension League (WHL) (2016), warned healthcare providers against the use of clinically questionable, pharmacy-based blood pressure kiosks, many of which are not designed for patients with large arm sizes, and/or which have not been subject to peer-reviewed clinical validation testing. In addition, the FDA has issued a consumer alert, advising the public some BP Kiosk devices, while cleared by the FDA, fail to provide accurate results for many users. Both ASH and WHL indicated that accurate and reliable BP Kiosk options are commercially available, and stated that it is the responsibility of healthcare professionals to make informed and buying decisions in the best interests of their patients.

BP kiosks are located in over 25,000 US pharmacy locations, performing approximately one million BP tests every day. It is critical to the profession of pharmacy that the APhA provide strong leadership on this topic in the interest of patient safety and optimal patient care.

US hypertension leaders view insufficient regulatory oversight as a major impediment to improved blood pressure control rates. Because inaccurate measurement confounds the diagnosis and management of hypertension, it also undermines efforts to reduce incidences of stroke, heart attack, diabetes, and other cardiovascular conditions linked to hypertension.

According to the American Society for Hypertension:

“The Food and Drug Administration (FDA) published a consumer health information bulletin in 2014 referencing the shortcomings of many kiosks and the frequently inaccurate BP values obtained. The FDA recommended to the public that if a person had questions relating to BP kiosks that he/she should ask his/her doctor for advice.

Kiosks are free-standing units. The kiosk has a single-size cuff designed into the unit. The user does not have the opportunity to select a cuff of appropriate size for his/her arm. Blood pressure readings performed with a cuff that is too small for an arm may give erroneously high BP values.

Alpert et al summarized the current arm sizes of United States citizens and stated that the average United States male has an arm circumference of 34.1 cm. For most kiosks, the maximum arm circumference that can fit into the cuff is 33-34 cm. That means almost half of the United States population cannot expect to use those kiosks and obtain an accurate BP reading. In the United States alone, there are over a million kiosk readings done per day. The public health implications of this magnitude of incorrect BP readings being used for diagnosis and management of disease are of serious concern.

Clinicians are often faced with the decision as to whether the occasional in-office reading is an adequate basis for developing or modifying a treatment plan for hypertension or whether out-of-office readings can be reliably substituted to derive an optimized antihypertensive medication regimen. The kiosk approach to BP measurement presents a quandary to both patient and physician if it may not provide reliable information as when the kiosk has not undergone ANSI/AAMI/ISO validation and if an inappropriate size cuff is used, raising management questions.

Blood pressure measurement is not a recreational activity, it is a clinical service that has major implications on clinical decisions and health outcomes. Among other professional organizations recognizing the impact of accurate blood pressure management are the American Medical Association and the American Heart Association. They have joined together to
create Target:BP. This initiative is designed to raise awareness about the dangers of hypertension, and to provide resources to help patients effectively manage their blood pressure.

Dr. Mark Niebylski, CEO of the World Hypertension League (WHL) has stated, “There is a growing global consensus for improved BP device quality. New guidelines in the US call for self-measurement outside the office setting, but patients and providers are unsure what devices can be trusted. The WHL supports urgent regulatory action in the US, and internationally, to address this healthcare issue.”

Asked about the role of community pharmacy, Dr. Niebylski added, “Pharmacies have an enormous opportunity to support improved BP control in the US, and to coordinate care with primary care physicians. But as the FDA and multiple clinical organizations have pointed out, recreational and ‘gamification’ blood pressure kiosks are providing inaccurate readings to millions of Americans. This is unacceptable to the WHL, and the clinical community in general. We urge pharmacies to upgrade into clinically valid BP Kiosk devices so that they can become an integral part of the hypertension care team. This issue goes to the core of professional trust between physicians and pharmacists.”

Recreational kiosk companies (those with no clinical accuracy validation) have claimed that their devices generate ‘meaningful health data’. How can their blood pressure data be ‘meaningful’ when the FDA and multiple physician groups have issued warnings about their technology in order to protect patient health? Additionally, millions of pharmacy customers use recreational blood pressure kiosks ‘off-label’, meaning the cuff is not designed to properly accommodate their large arm size. The situation is dangerous to patients, damages the reputation of the pharmacy profession, and is contrary to the hard-fought efforts of pharmacists nationwide to earn healthcare provider status.

Per the ASH and WHL recommendations, this policy should recommend that pharmacies use blood pressure kiosks that a) have been validated through peer-reviewed clinical trials to be clinically accurate (in accordance with the existing ISO standards), and b) employ a cuff size proven to accommodate at least 95% of the US adult population. In order to maintain their position as trusted health care professionals, pharmacists should not support use of unproven, or “recreational” medical devices in their professional environment or place of business.

Ensuring high standards for blood pressure measurement across the pharmacy profession will increase the trustworthiness of the profession, and will support efforts to contract with payers or providers for hypertension-related clinical services.

In conclusion, kiosk BP values can be of use in the diagnosis and treatment of patients, especially for the diagnosis of hypertension. The physician and patient need to be aware of the validation status, not just FDA clearance, and be knowledgeable about proper cuff size effects on BP measurement accuracy. It is our hope that all kiosk BP manufacturers will undergo independent validation of their devices using AAMI recommendations, or another acceptable standard, to foster confidence in the ability of kiosks to provide BP readings accurate enough to be useful in clinical care management.”

References

Current APhA Policy & Bylaws:

2016 Point-of-Care Testing

1. APhA recognizes the value of pharmacist-provided, point-of-care testing and related clinical services, and it promotes the provision of those tests and services in accordance with the Joint Commission of Pharmacy Practitioners Pharmacists' Patient Care Process.

2. APhA advocates for laws, regulations, and policies that enable pharmacist-provided, point-of-care testing and related clinical services that are consistent with the pharmacists' role in team-based care.

3. APhA opposes laws, regulations, and policies that create barriers to the tests that have been waived by the Clinical Laboratory Improvement Amendments (CLIA) and that are administered and interpreted by pharmacists.

4. APhA encourages use of educational programming and resources to facilitate practice implementation of pharmacist-provided, point-of-care testing and related clinical services.

5. APhA supports patients taking active roles in the management of their health, including their ability to request and obtain pharmacist-provided, point-of-care tests and related clinical services.

6. APhA advocates for access to, coverage of, and payment for both pharmacist-provided, point-of-care tests and any related clinical services.

1991 Mission of Pharmacy

APhA affirms that the mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes.


2012, 2002, 1964 Health Education: Selection of Pharmacist

APhA supports education of consumers about the importance of selecting their personal pharmacist to assist them in the proper use of all medications and medical devices.


2002, 1984 Depiction of Pharmacists in Public Media

APhA supports the development of guidelines or standards to enhance the depiction of the pharmacy profession in all public media.

2013, 1995 Pharmacists’ Role in the Development and Implementation of Evidence-Based Clinical Guidelines

1. APhA advocates direct involvement of pharmacists in the development, evaluation, and implementation of evidence-based clinical guidelines. Well-designed guidelines promote an interdisciplinary team approach to patient care that utilizes pharmacists’ expertise in optimizing patient outcomes.

2. APhA believes that evidence-based clinical guidelines should promote optimal patient care built on the best available scientific data. These guidelines should be developed using an interdisciplinary approach and should be evaluated regularly to ensure that they reflect current practice standards.

3. APhA should promote educational programs, products, and services that facilitate the participation of pharmacists in the development, evaluation, and implementation of evidence-based practice guidelines in all practice settings.

4. APhA advocates the use by pharmacists, in all practice settings, of evidence-based practice guidelines for pharmaceutical care built on the best scientific data to optimize patient outcomes. These guidelines should be developed using an interdisciplinary approach and should be evaluated regularly to ensure that they reflect current practice standards.


**Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item Content.**

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Starlin Haydon-Greatting
(Name)

02/12/2017
(Date)

Illinois Delegation
(Organization)

Subject: Pharmacy Technician Education, Training, and Development

Motion: Move to adopt the following policy statements:

1. APhA supports the following minimum requirements for all new pharmacy technicians by the year 2027:
   (a) successful completion of a Pharmacy Technician Accreditation Commission (PTAC) accredited education and training program and
   (b) certification by the Pharmacy Technician Certification Board (PTCB).

2. APhA supports state board of pharmacy regulations that require pharmacy technicians to meet minimum standards of education, training, certification, and recertification. APhA also encourages state boards of pharmacy to develop a phase-in process for current pharmacy technicians.

3. APhA recognizes the important contribution and role of pharmacy technicians in assisting pharmacists and student pharmacists with the delivery of patient care.

4. APhA supports the development of resources and programs that promote the recruitment and retention of qualified pharmacy technicians.

5. APhA supports the development of continuing pharmacy education programs that enhance and support the continued professional development of pharmacy technicians.

6. APhA encourages the development of compensation models for pharmacy technicians that promote sustainable career opportunities.
Background:

The first two statements in this new policy are pulled from existing 2008 Pharmacy Technician Education and Training and are meant to update the language with current dates, the appropriate accreditation group, and also to include recertification. If this item is adopted then the original statements from 2008 will be addressed by the 2017-18 Policy Review Committee. The new statements 3, 4, 5, and 6 all address the important role of pharmacy technicians and complement existing policy language.

Pharmacy Technicians are an essential to the advancement of pharmacy practice. The role of pharmacy technician is one that requires education, training, and development to best assist in the delivery of patient care. For many years, APhA has supported the advancement of pharmacy technicians and their education, training, and development. As the profession moves and the role of the pharmacist evolves, so will the needs and requirements placed on pharmacy technicians.

Current APhA Policy & Bylaws:

2008 Pharmacy Technician Education and Training
1. APhA reaffirms the 2005/2001/1996 Control of Distribution System policy, which states that APhA supports pharmacists’ authority to control the distribution process and personnel involved and the responsibility for all completed medication orders, regardless of practice setting.
2. APhA supports nationally recognized standards and guidelines for the accreditation of pharmacy technician education and training programs.
3. APhA supports the continued growth of accredited education and training programs that develop qualified pharmacy technicians who will support pharmacists in ensuring patient safety and enhancing patient care.
4. APhA supports the following minimum requirements for all new pharmacy technicians by the year 2015:
   a. successful completion of an accredited education and training program and
   b. certification by the Pharmacy Technician Certification Board (PTCB).
5. APhA supports state board of pharmacy regulations that require pharmacy technicians to meet minimum standards of education, training, and certification. APhA also encourages state boards of pharmacy to develop a phase-in process for current pharmacy technicians.

2004, 1996 Technician Licensure and Registration
1. APhA recognizes the following definitions with regards to technician licensure and registration:
   a. Licensure: The process by which an agency of government grants permission an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected. Within pharmacy, a pharmacist is licensed by a State Board of Pharmacy.
   b. Registration: The process of making a list or being enrolled in an existing list.

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