

2019 House of Delegates Report of the New Business Review Committee

Committee Members

Liza Chapman, Chair Jason Gaines Andrew Gentles Megan O'Connor April Shaughnessy Rebecca Jones Sorrell William Wynn

Ex Officio
Michael D. Hogue, Speaker of the House
Joey Mattingly, Speaker-elect of the House



Item No: I

Date received: 1/9/19

Time received: 9:13 AM (EST)

American Pharmacists AssociationHouse of Delegates – Seattle, Washington

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Jennifer Lamberts, Chair-elect, Basic Sciences Section, on behalf of APhA-APRS (Name)

January 9, 2019 (Date)

APhA Academy of Pharmaceutical Research and Science (APhA-APRS)

(Organization)

Subject: Gluten Content and Labeling in Medications

Motion:

Move to MODIFY language of policy passed during the 2018 APhA House of Delegates,

1. APhA supports labeling of all prescription and over the counter medications that drug products as well as dietary supplement products, to indicates the presence of gluten.

Move to ADOPT the following policy statement,

2. APhA encourages the development of analytical methods that can accurately detect lower levels of gluten than the current standard (20 ppm), and for the establishment of evidence based gluten-free standards for the labeling of foods, excipients, dietary supplements, prescription and over the counter drug products.

Background:

Report from the 2018-19 APhA-APRS Gluten Working Group

- Chair: Walt Chambliss (Oxford, MS)
- Members: Robert A. Mangione (Queens, NY), William McLaughlin Germantown, TN), Steve Plogsted (Columbus, OH), Abu Serajuddin (Queens, NY), Carmela Silvestri (Flemington, NJ)
- Ex-officio: Ed Bednarczyk (APhA-APRS Executive Council Liaison to Work Group Buffalo, NY) ,
 Jennifer Lamberts (APhA-APRS Basic Science Section Chair-elect Big Rapids, MI)

• Staff: Margaret Tomecki (Academy Staff Liaison)

Background

Eight policy statements related to gluten were introduced as New Business Items by the New Jersey Pharmacists Association at the 2018 APhA Annual Meeting. The following four statements were adopted by the APhA House of Delegates (HOD):

- 1. APhA supports labeling of all prescription and over the counter medications that indicates the presence of gluten.
- 2. APhA encourages manufacturers to formulate drug products without use of wheat, barley, rye or their derivatives whenever possible.
- 3. APhA supports additional research on the effects of gluten intolerance and celiac malabsorption, particularly as it related to medication absorption.
- 4. APhA supports pharmacist education regarding celiac disease and non-celiac gluten sensitivity.

The following four statements were referred to APhA-APRS for review by the APhA HOD:

- 1. APhA supports required gluten status verification for all plant derived excipients used in the manufacture of medications to assure that no cross-contamination has occurred, and in the absence of this verification, that batch testing of medication products be required to determine if they are free of detectable gluten.
- 2. APhA encourages the FDA to require post manufacturing testing of gluten content in oral drug products, and making quantitative information on gluten content easily accessible to health professionals.
- 3. APhA encourages USP to develop assays that can accurately detect trace levels of gluten in finished drug products and set appropriate standards.
- 4. APhA supports a mechanism for third party payers to acknowledge the need for, and accept responsibility for providing access to, medications with no detectable gluten when medically necessary.

The APhA-APRS Gluten Working Group was formed to review the four referred statements and make a recommendation to the APhA House of Delegates. The Working Group also reviewed the policy statements that were approved by the APhA HOD. The Working Group met by conference calls over a 3-month period to discuss the state of the science, how the industry and the FDA were addressing the issue, and patient care needs. Several documents were reviewed and discussed including review articles, the December 2017 FDA Draft Guidance on "Gluten in Drug Products and Associated Labeling Recommendations" (the "FDA Guidance") and responses from industry to the FDA Guidance. A previously conducted literature search on analytical methods for detecting gluten was updated.

Key Learnings

- The limit of detection of the existing analytical method (an ELISA method) is about 5 ppm with a 3-to 5-fold variation in the data. The limit of detection for the method is appropriate for testing food and dietary supplement products because the FDA requirement for "gluten-free" is 20 ppm or less. However, much lower levels of gluten (e.g. 1 ppm) in foods, dietary supplements and drug products could result in negative pharmacological and physiological effects.
- Because the "gluten free" standard for food is ≤ 20 ppm, many patients are unintentionally, and at times unknowingly, consuming dietary gluten in food, which is labeled "gluten free".
- The FDA Guidance states that gluten is not likely to be a significant issue in drug products because excipients known to contain gluten (wheat, barley and rye) are rarely, if ever, used; and any cross-

contamination from other grain based excipients (e.g. corn starch) would result in very small (non-detectible) quantities of gluten in a drug product.

- The International Pharmaceutical Excipient Council (IPEC) Americas recommends labeling of excipients/drug products as "contains gluten" rather than "gluten-free". The FDA recommends labeling: "Contains no ingredient made from a gluten-containing grain (wheat, barely or rye)".
- The social science issues (e.g. patients not taking a drug product because it is not labeled "gluten-free") are as important as hard science issues.
- Labeling for the presence of gluten in drug products and dietary supplements should address both unit dose and daily dose quantities since acute and chronic exposure can cause different pharmacological problems. This issue should be kept in mind when a more sensitive analytical method is developed.

Work Group Recommendations

- A. Policy statements adopted by the 2018 HOD
- 1. Statement #1. Consider revising to the following to be more inclusive:

APhA supports labeling of all prescription and over the counter drug *products* as well as *dietary supplement products*, to indicate the presence of gluten.

- 2. Statement #2 no changes.
- 3. Statement #3 no changes.
- 4. Statement #4 no changes.
- B. Policy statements deferred by the 2018 HOD
- 1. Statement #1 not be adopted due to the lack of an appropriate analytical method.
- 2. Statement #2 not be adopted due to the lack of an appropriate analytical method.
- 3. Statement #3 consider a revised statement:

APhA encourages the development of analytical methods that can accurately detect lower levels of gluten than the current standard (20 ppm), and for the establishment of evidence based gluten-free standards for the labeling of foods, excipients, dietary supplements, prescription and over the counter drug products.

4. Statement #4 – not be adopted due to the lack of an appropriate analytical method.

Current APhA Policy & Bylaws:

Gluten Content and Labeling in Medications

2018

- 1. APhA supports labeling of all prescription and over the counter medications that indicates the presence of gluten.
- 2. APhA encourages manufacturers to formulate drug products without use of wheat, barley, rye or their derivatives whenever possible.

3. APhA supports additional research on the effects of gluten intolerance and celiac malabsorption, particularly as it relates to medication absorption.4. APhA supports pharmacist education regarding celiac disease and non-celiac gluten sensitivity.	
(JAPhA 58(4):356 July/August 2018)	
w Business Items are due to the Speaker of the House by February 20, 2019 (30 days prior to the start of the firs use session). Consideration of urgent items can be presented with a suspension of the House Rules at the session ere New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email apphanet.org.	



Item No.: 2

Date received: 1/9/19 Time received: 9:13 AM

American Pharmacists Association House of Delegates – Seattle, Washington

NEW BUSINESS

(To be submitted and introduced by Delegates only)
Introduced by: Denise Clayton, Member-at-Lage Officer, on behalf of the APhA-APPM
(Name)

January 9, 2019 APhA Academy of Pharmacy Practice and Management (APhA-APPM)

(Date) (Organization)

Motion: I move to MODIFY the existing policy items,

2006, 2003 Unit-of-Use Packaging

Subject: Unit-of-Use Packaging

- 1. APhA encourages the continued supports development, distribution, and use of unit-of-use packaging as the pharmaceutical industry standard to enhance patient safety, patient adherence, drug distribution efficiencies, and Drug Supply Chain Security Act (DSCSA) regulation compliance, and efficiencies in drug distribution in the event of a recall and reduce the potential for counterfeiting.
- 2. APhA shall encourages collaboration with the pharmaceutical industry, third-party payers, and appropriate federal agencies to effect the changes necessary for the adoption of unit-of-use packaging as the industry standard.
- 3. APhA encourages supports the enactment of legislation and regulations to permit pharmacists to modify prescribed quantities to correspond with commercially available unit-of-use packages.

Topic: <u>Drug Product Packaging</u>

(JAPhA NS43(5:)Suppl.1:S57 September/October 2003) (JAPhA NS46(5):562 September/October 2006) (Reviewed 2007)(Reviewed 2012)(Reviewed 2013)(Reviewed 2018)

Background:

APhA House of Delegates has requested the APhA-APPM Policy Committee to review existing unit-of-use policy statements and introduce a new business item to sunset previous outdated language. and The needs of contemporary pharmacy practice are rapidly changing. The text below shows the recommended changes and how they affect the existing policy language. New policy language is shown as underlined text and deleted language is shown struck through.

Current APhA Policy & Bylaws:

2012 Counterfeit Medication and Unit-of-Use Packaging

APhA encourages the continued development, distribution, and use of unit-of-use packaging as the industry standard to enhance patient safety, patient adherence, and efficiencies in drug distribution, and to reduce potential for counterfeiting.

Topic: Drug Product Packaging

(JAPhA NS52(4) 458 July/August 2012)(Reviewed 2013)(Reviewed 2017)

2012, 2004, 1992 Drug Product Packaging

- 1. APhA supports the role of the pharmacist to select appropriate drug product packaging.
- APhA supports the pharmaceutical industry's performance of compatibility and stability testing of drug
 products in officially defined containers to assist pharmacist selection of appropriate drug product
 packaging.
- 3. APhA supports the value of unit-of-use packaging to enhance patient care, but recognizes that product and patient needs may preclude its use.
- 4. APhA encourages the pharmaceutical industry to ensure that all unit-of-use packaging will accommodate a standard pharmacy label.

Topic: Drug Product Packaging

(Am Pharm NS32(6):515 June 1992) (JAPhA NS44(5): 551 September/October 2004) (Reviewed 2006) (Reviewed 2007) (JAPhA NS52(4) 458 July/August 2012) (Reviewed 2013) (Reviewed 2017)

New Business Items are due to the Speaker of the House by **February 20, 2019** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at <a href="https://house.ncb/ho



Item No.: 3

Date received: 2/13/19

Time received: 4:44 PM (EST)

American Pharmacists AssociationHouse of Delegates – Seattle, Washington

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: <u>Kimberly Croley, PharmD, FAPhA on behalf of APhA-APPM Delegation</u>
(Name)

February 11, 2019 (Date)

<u>APhA Academy of Pharmacy Practice and Management (APhA-APPM)</u>
(Organization)

Subject: Pharmacist and Pharmacy Personnel Well-being

Motion: Move that APhA adopt the following policy statements:

- I. APhA calls for pharmacist employers to develop policies and resources to support pharmacist's and pharmacy personnel's ability to retreat or withdraw from patient and consumer interactions which threaten their safety or well-being.
- 2. APhA encourages the development of educational programs and resources by the Association and employers to empower pharmacists and pharmacy personnel regarding appropriate response to situations they perceive to threaten their safety or well-being.
- 3. APhA calls for education of the public regarding optimizing their interactions with pharmacists and pharmacy personnel.

Background:

As the recognized most accessible health care professional and staff, pharmacists and pharmacy personnel are often faced with situations they perceive to threaten their safety or well-being.

Interactions with patients, consumers, caregivers, and others may sometimes escalate to this point and

pharmacists and pharmacy personnel should have the right to make the appropriate response to these

situations as they deem necessary, and not fear disciplinary action from their employer, board of

pharmacy or other entity. Pharmacists have reported in social media and other communications being

physically attacked or verbally abused by drug seekers or individuals frustrated with the health care

system. As pharmacists are health care professionals they deserve the right to be respected and have

appropriate interactions with the public - in some situations, "the consumer is always right" is

inappropriate and pharmacists seek the authority to defuse and exit from situations that negatively impact

their safety and well-being.

Patients, consumers, and others benefit greatly from the pharmacist and their personnel's expertise

often in the absence of filling a prescription or recommending a product in response to a particular

question raised about a health or medication matter. Pharmacists and their pharmacy personnel desire to

address everyone's requests and meet their needs as much as possible; however, laws, regulations, and

other restrictions sometimes prohibit the pharmacist and their personnel from being able to do so. A

public education campaign and other efforts to educate the public on the importance of making the most

out of every interaction with their pharmacist and pharmacy personnel should include information about

the laws and regulations that govern and sometimes restrict a pharmacist and their technical personnel's

ability to address the patient or consumer's, etc., request. It should also include information on the

pharmacist and pharmacy personnel's right to step away from confrontational situations or situations they

perceive to be threatening.

References:

A cross-sectional study of psychological distress, burnout, and the associated risk factors in hospital

pharmacists in Japan

Yuji Higuchi, Masatoshi Inagaki, Toshihiro Koyama, Yoshihisa Kitamura, Toshiaki Sendo, Maiko Fujimori, Yosuke

Uchitomi and Norihito Yamada

BMC Public Health. 2016; 16: 534.

Published online 2016 Jul 8. doi: 10.1186/s12889-016-3208-5

Factors Associated With Health-Related Quality of Life of Student Pharmacists

Nalin Payakachat, PhD, Paul O. Gubbins, PharmD,* Denise Ragland, PharmD, Schwanda K. Flowers, PharmD,

and Cindy D. Stowe, PharmD

Am | Pharm Educ. 2014 Feb 12; 78(1): 7.

doi: 10.5688/ajpe7817

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Burnout, associated comorbidities and coping strategies in French community pharmacies—BOP study: A nationwide cross-sectional study

David Balayssac,* Bruno Pereira, Julie Virot, Aurore Collin, David Alapini, Damien Cuny, Jean-Marc Gagnaire, Nicolas Authier, and Brigitte Vennat

PLoS One. 2017; 12(8): e0182956.

Published online 2017 Aug 11. doi: 10.1371/journal.pone.0182956

Factors Associated With Burnout Among US Hospital Clinical Pharmacy Practitioners: Results of a Nationwide Pilot Survey

G. Morgan Jones, Neil A. Roe, Les Louden, and Crystal R. Tubbs Hosp Pharm. 2017 Dec; 52(11): 742–751.

Published online 2017 Sep 27. doi: 10.1177/0018578717732339

Burnout among pharmacists.

Lahoz MRI, Mason HL.

Am Pharm. 1990 Aug; NS30(8):28-32.

Healthcare Staff Wellbeing, Burnout, and Patient Safety: A Systematic Review.

Hall LH, Johnson J, Watt I, Tsipa A, O'Connor DB. PLoS One. 2016 Jul 8;11(7):e0159015. doi: 10.1371/journal.pone.0159015. eCollection 2016.

Current APhA Policy & Bylaws:

Pharmacist Workplace Environment and Patient Safety 2018

- I. APhA supports staffing models that promote safe provision of patient care services and access to medications.
- 2. APhA encourages the adoption of patient centered quality and performance measures that align with safe delivery of patient care services and opposes the setting and use of operational quotas or time-oriented metrics that negatively impact patient care and safety.
- 3. APhA denounces any policies or practices of third party administrators, processors, and payers that contribute to a workplace environment, which negatively impacts patient safety. APhA calls upon public and private policy makers to establish provider payment policies that support the safe provision of medications and delivery of effective patient care.
- 4. APhA urges pharmacy practice employers to establish collaborative mechanisms that engage the pharmacist in charge of each practice, pharmacists, pharmacy technicians, and pharmacy staff in addressing workplace issues that may have an impact on patient safety.

- 5. APhA urges employers to collaborate with the pharmacy staff to regularly and systematically examine and resolve workplace issues that may negatively have an impact on patient safety.
- 6. APhA opposes retaliation against pharmacy staff for reporting workplace issues that may negatively impact patient safety

2012, 2007, 2001, 1995

Impact of the Pharmacists' Working Conditions on Public Safety

- 1. APhA recognizes that the quality of a pharmacist's work-life affects public safety and that a working environment conducive to providing effective patient care is essential.
- 2. APhA opposes the practice of imposing minimum numbers of prescriptions which pharmacists are to dispense in a given period of time. Further, APhA opposes employment practices that evaluate a pharmacist's performance on the basis of set quotas of work performed.
- 3. APhA opposes employment practices that limit a pharmacist's ability to provide effective patient care. (Am Pharm NS35(6):36 June 1995) (JAPhA NS4(5):Suppl. 1:58 September/October 2001) (Reviewed 2001) (JAPhA NS45(5):580 September-October 2007)(JAPhA NS52(4) 459 July/August 2012)(Reviewed 2017)

2001 Stress and Conflict in the Workplace

APhA encourages employers to provide pharmacists with the tools required to manage stress and conflict within the workplace. (JAPhA NS41(5):Suppl.1:S9 September/October, 2001) (Reviewed 2007)(Reviewed 2012)(Reviewed 2017)

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American Pharmacist Association
House of Delegates - Seattle, Washington

To be completed by the Office of the Secretary of the House of Delegates

Item No.: 4

Date received: 2/19/19

Time received: 9:20 AM (EST)

NEW BUSINESS

	(To be submitted	d and introduced by Delegates only)
Introduced by:	Jeff Neigh	
·	_	(Name)
19 Feb 19		Federal Caucus
(Date)		(Organization)

Subject: Qualification Standards for Pharmacists

Motion: Move that APhA adopt the following policy statements:

- I. APhA supports qualification standards for pharmacist designation that are consistent with licensure standards issued by the National Association of Boards of Pharmacy (NABP).
- 2. APhA opposes non-licensing agencies developing minimum qualifications to practice pharmacy that are inconsistent with licensure standards issued by the National Association of Boards of Pharmacy (NABP).

Background:

Title 5 U.S.C. 3308 permits the establishment of minimum educational requirements only when the U.S. Office of Personnel Management (OPM) has determined that the work cannot be performed by persons who do not possess the prescribed minimum education. In September 2017, OPM issued a new qualification standard for Pharmacist, GS-0660. The new standard lists the basic educational requirements as a Doctor of Pharmacy (PharmD). In setting this PharmD requirement, it appears that OPM has determined pharmacist work cannot be performed by persons without this degree. All states allow BS Pharm pharmacists to gain licensure and practice pharmacy within the state. That means that it is the opinion of all state legislatures that BS Pharm pharmacists can practice pharmacy safely and effectively within the state.

The BS Pharm degree was awarded up to 2005 and was recognized as the prerequisite to practice as a pharmacist. It is only since 2006 that the PharmD became the only entry-level degree awarded. From 1975-2005, there were over 158,000 BS Pharm degrees awarded. The minimum educational requirements set by OPM automatically disqualified over 158,000 BS Pharm degree pharmacists that have not subsequently gone on to obtain their PharmD degree from entering the federal government workforce. This is a discriminatory practice not seen in the non-federal sector. This educational requirement from OPM generates legal concerns and creates a monumental challenge in building and maintaining a sufficient pharmacist workforce in the Department of Defense in supporting our warfighting efforts and taking care of our veterans.

All efforts to engage with OPM to rescind this qualification standard have been unproductive.

The highlighted statements within the three current adopted policy topics (referenced below) specifically relate to this issue and the additional background information provided.

Current APhA Policy & Bylaws:

2002 National Framework for Practice Regulation

- 1. APhA supports state-based systems to regulate pharmacy and pharmacist practice.
- 2. APhA encourages states to provide pharmacy boards with the following: (a) adequate resources; (b) independent authority, including autonomy from other agencies; and (c) assistance in meeting their mission to protect the public health and safety of consumers.
- 3. APhA supports efforts of state boards of pharmacy to adopt uniform standards and definitions of pharmacy and pharmacist practice.
- 4. APhA encourages state boards of pharmacy to recognize and facilitate innovations in pharmacy and pharmacist practice.

(JAPhA NS2(5):Suppl. 1: 563 September/October 2002) (Reviewed 2007)(Reviewed 2008)(Reviewed 2013)(Reviewed 2015)

2001,1990 Regulatory Infringements on Professional Practice

- 1. APhA, in cooperation with other national pharmacy organizations, shall take a leadership role in the establishment and maintenance of standards of practice for existing and emerging areas in the profession of pharmacy.
- 2. APhA encourages a cooperative process in the development, enforcement, and review of rules and regulations by agencies that affect any aspect of pharmacy practice, and this process must utilize the expertise of affected pharmacist specialists and their organizations.
- 3. APhA supports the right of pharmacists to exercise professional judgment in the implementation of standards of practice in their practice settings.

(Am Pharm NS30(6):45 June 1990) (JAPhA NS4(5)Suppl.1:S7 September/October, 2001)(Reviewed 2007)(Reviewed 2012)(Reviewed 2017)

2004,1978 Roles in Health Care for Pharmacists

- 1. APhA shall develop and maintain new methods and procedures whereby pharmacists can increase their ability and expand their opportunities to provide health care services.
- 2. APhA supports legislative and judicial action that confirms pharmacists' professional rights to perform those functions consistent with APhA's definition of pharmacy practice and that are necessary to fulfill pharmacists' professional responsibilities to patients they serve.

(Am Pharm NS18(8):42 July 1978)(JAPhA NS44(5):551 September/October 2004)(Reviewed 2007)(Reviewed 2011)(Reviewed 2012)(Reviewed 2013)(Reviewed 2018)



Item No.: 5

Date received: 2/20/19

Time received: 1:35 PM (EST)

American Pharmacists AssociationHouse of Delegates – Seattle, Washington

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: <u>Jennifer Adams (ID) and Lorri Walmsley (AZ)</u>
(Name)

02/20/19	Idaho, Virginia, Arizona
(Date)	(Organization)

Subject: Collaborative Practice Agreements

Motion: Amend the APhA Pharmacy Practice policy - 1997 Collaborative Practice

Agreement to add the following 5 statements:

Collaborative Practice Agreements

- 2. APhA supports the establishment of collaborative practice agreements between one or multiple pharmacists and one or multiple prescribers.
- 3. APhA supports collaborative practice laws that are inclusive of patients lacking a primary care provider.
- 4. APhA opposes state laws that limit collaborative practice agreements to specific patients.
- 5. APhA supports state laws that allow for delegated pharmacist prescriptive authority.
- 6. APhA supports state collaborative practice laws that allow all licensed pharmacists, in all practice settings, to establish collaborative practice agreements with other healthcare professionals.

Background:

The intent of this New Business Item is not to modify the existing two policy statements but add additional relevant statements to this policy category. The current APhA policy statements under this policy category are:

1997 Collaborative Practice Agreements

- I. APhA supports the establishment of collaborative practice agreements between pharmacists and other health care professionals designed to optimize patient care outcomes.
- 2. APhA shall promote the establishment and dissemination of guidelines and information to pharmacists and other health care professionals to facilitate the development of collaborative practice agreements. (JAPhA NS37(4):459 July/August 1997) (Reviewed 2003)(Reviewed 2007)(Reviewed 2009)(Reviewed 2011)(Reviewed 2012)(Reviewed 2017)

These two statements would not be debated in the 2019 House of Delegates session per House Rule 4, which describes "Re-statements of existing policy are discouraged". As an additional note, each whole numbered statement needs to stand on its own, but we would request staff reorder the statements to reflect how they are ultimately listed in the policy manual with the 2nd existing policy statement becoming the last numbered item.

Collaborative practice agreements (CPAs) create a formal practice relationship between pharmacists and other health care practitioners, whereby the pharmacist assumes responsibility for specific patient care functions that are otherwise beyond their typical "scope of practice," but aligned with their education and training. These patient care services can include initiation and modification of drug therapy. The extent of the services authorized under the collaborative agreement depends on the state's statutory and regulatory provisions for collaborative practice authority, as well as the terms of the specific agreement between the pharmacist and other health care practitioners. State laws and regulations authorizing CPAs are highly variable. Some states specify the practitioners able to participate in CPAs, restrict the services that may be provided under a CPA, or include extensive logistical barriers that limit the utility of such agreements. In their 2015 paper, The Expanding Role of Pharmacists in a Transformed Health Care System, the National Governors Association (NGA), presented the following state policy considerations in regards to collaborative practice provisions:

- Enact broad collaborative practice provisions that allow for specific provider functions to be determined at the provider level rather than set in state statute or through regulation.
- Evaluate practice setting and drug therapy restrictions to determine whether pharmacists and providers face disincentives that unnecessarily discourage collaborative arrangements.
- Examine whether CPAs unnecessarily dictate disease or patient specificity.1

The National Alliance of State Pharmacy Associations' (NASPA's) Executive Committee directed staff to convene a workgroup to build upon the NGA policy considerations with additional specificity. The workgroup was charged with examining existing state CPA laws and regulations. The workgroup was tasked with developing recommendations for what elements of collaborative practice authority should appropriately be defined under state law and/or regulation, and what elements are best left to be determined between pharmacists and other practitioners when developing their specific collaborative practice arrangement. Using a modified Delphi method, the Collaborative Practice Workgroup conducted this work with two key questions in mind:

- Is this recommendation in the best interest of the patient receiving care under a collaborative agreement?
- Is this recommendation aligned with pharmacists' education and training?

WORKGROUP RECOMMENDATIONS

The workgroup took the approach that rapid innovation in education, training, technology, and evidence-based guidelines necessitate a collaborative practice framework that is flexible and facilitates innovation in care delivery. Thus the following statements include two levels of recommendations:

- 1. Elements of collaborative practice authority that should be codified in state law and/or state regulations; and
- 2. Elements that are more appropriately determined by the parties at the practice level who voluntarily enter into a CPA, and thus for which the laws and regulations should be silent.

The workgroup views both levels of recommendations as needed and synergistic. State law and/or regulations, if too restrictive, can impede innovative team-based care models.

The following is a report of the workgroup's collaborative practice recommendations to specify in laws and/or regulations:

- Any practitioner with prescriptive authority may collaborate with pharmacists using a CPA.
- CPAs may be between a single or multiple pharmacists and a single or multiple prescribers.
- CPAs may apply to a single patient, multiple patients, or patient populations as specified in the agreement.
- The initiation and modification of drug therapy may be authorized under a CPA with a prescriber
- All prescription drugs, including controlled substances, may be included within pharmacists' collaborative practice authority.
- CPAs should be maintained by the pharmacist(s) and collaborating prescriber(s) and be available upon request or inspection

The workgroup recommended that all other CPA considerations may be determined within the individual CPAs or state laws and/or regulations should be silent.

This report entitled – Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority. A Report of the Collaborative Practice Workgroup Convened by the National Alliance of State Pharmacy Association. The final report has been supported by the following organizations: American Association of Colleges of Pharmacy (AACP), American Pharmacists Association (APhA), College of Psychiatric and Neurologic Pharmacists (CPNP), and National Association of Chain Drug Stores (NACDS).

We believe the APhA Policy and Bylaws which passed the House of Delegates in 1997, should be updated to reflect the national recommendations put forth by pharmacist collaborative practice subject matter experts.

References:

- I. National Governors Association. The Expanding Role of Pharmacists in a Transformed Health Care System. Available from: http://www.nga.org/files/live/sites/NGA/files/pdf/2015/1501TheExpandingRoleOfPharmacists.pdf. (Accessed February 20, 2019).
- 2. NASPA. Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority. 2015. Available from: https://naspa.us/wp-content/uploads/2017/01/CPA-Workgroup-Report-FINAL.pdf (Accessed February 20, 2019).

Current APhA Policy & Bylaws:

1997 Collaborative Practice Agreements

- I. APhA supports the establishment of collaborative practice agreements between pharmacists and other health care professionals designed to optimize patient care outcomes.
- 2. APhA shall promote the establishment and dissemination of guidelines and information to pharmacists and other health care professionals to facilitate the development of collaborative practice agreements. (JAPhA NS37(4):459 July/August 1997) (Reviewed 2003)(Reviewed 2007)(Reviewed 2009)(Reviewed 2011)(Reviewed 2012)(Reviewed 2017)

2017 Patient Access to Pharmacist-Prescribed Medications

- I. APhA asserts that pharmacists' patient care services and related prescribing by pharmacists help improve patient access to care, patient outcomes, and community health, and they align with coordinated, team-based care.
- 2. APhA supports increased patient access to care through pharmacist prescriptive authority models.
- 3. APhA opposes requirements and restrictions that impede patient access to pharmacist-prescribed medications and related services.
- 4. APhA urges prescribing pharmacists to coordinate care with patients' other health care providers through appropriate documentation, communication, and referral.
- 5. APhA advocates that medications and services associated with prescribing by pharmacists must be covered and compensated in the same manner as for other prescribers.
- 6. APhA supports the right of patients to receive pharmacist-prescribed medications at the pharmacy of their choice. (JAPhA 57(4): 441 July/August 2017)

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Item No.: 6

Date received: 2/20/19

Time received: 3:43 PM (EST)

American Pharmacist Association House of Delegates - Seattle, Washington

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: ______ Lieutenant Timothy Laderach
(Name)

______ (Name)

______ United States Navy
(Date) (Organization)

Subject: Expanding Technician Roles: Tech-Check-Tech

Motion: Move that APhA adopt the following policy statements:

- 1. APhA encourages state boards of pharmacy to develop regulations endorsing expanded pharmacy technician roles, such as tech-check-tech programs, that allow both technicians and pharmacists to practice at the top of their training and license or certification.
- 2. APhA supports state boards of pharmacy regulations that standardize and set minimum didactic and experiential standards for technicians practicing in expanded roles.
- 3. APhA encourages the creation of standardized technician training and continuing education programs that support expanded pharmacy technician roles.

Background:

Pharmacy technicians are valued members of the healthcare team that enable pharmacists to perform their professional duties with increased ease and efficiency. Similarly, other health professions, such as radiologists and surgeons, employ technicians to allow the physicians the ability to operate at the top of their degrees and licenses in providing high quality patient care. However, the specific role of a pharmacy technician is difficult to define, as pharmacy is a profession that has a broad range of practice settings (e.g. community, institutional, long-term care, etc.). For example, the Bureau of Labor Statistics defines the role of pharmacy technician as, "help pharmacists dispense prescription medication to customers or health professionals¹." That definition doesn't nearly encompass all the responsibilities that pharmacy technicians possess even in the retail setting. The situation is further complicated by the lack of consistency across the United States in the regulations and professional standards of who can be a pharmacy technician. Whereas pharmacists are universally required to

complete an accredited PharmD program, pass a federal and state exam, and have a minimum number of experiential hours before granted licensure, pharmacy technicians have no such universal standard. In fact, according to a 2015 *Pharmacy Times* review, there were at that time some states that had no licensure requirements for pharmacy technicians and some others that only required that individuals register with the state board of pharmacy².

Perhaps the inconsistencies and sometimes limited regulation at the state level is what has led to a resistance to expanding technician roles at a national level. A 2009 NABP survey showed that 12 states allowed techcheck-tech programs in the institutional setting at that time. Currently, only one state, North Dakota, allows tech-check-tech in the community practice setting and one other allows tech-check-tech for long-term care medications (Iowa). According to Adams et. al., some states allow provisional agreements for tech-check-tech while still others take part in tech-check-tech because their state does not prohibit it⁴. Nevertheless, there is a growing number of articles that highlight the data from tech-check-tech programs as a promising window into the future of pharmacy.

It is no secret that obtaining provider status for pharmacists has been the focus of pharmacy advocacy in the 21st century. APhA's policy manual contains statements such as, "APhA supports changes to the Social Security Act to allow pharmacists to be recognized and paid as providers of patient care services," and "Pharmacists are health care providers who must be recognized and compensated by payers for their professional services." Yet, APhA's current policy on pharmacy technician education does not provide clear support for the advancement of technician roles. As stated above, the purpose of the pharmacy technician is to enable the pharmacist to perform their professional duties. As the role of the pharmacist expands to include provider functions, such as prescribing medications, patient evaluation and point of care testing, the role of the pharmacy technician must also evolve. The aforementioned data provided by tech-check-tech programs is already showing that technicians can be effective at product verification. The review by Adams and colleagues describes data showing technicians as accurate (and sometimes more accurate) at providing final product verification of unit dose distribution systems. It also describes research that shows that these tech-check-tech programs allow pharmacists to assume greater responsibilities in the realm of clinical services⁴. A later review describes tech-check-tech as providing ~19% decrease in pharmacist dispensing activity and ~19% increase in pharmacist time providing clinical services⁵.

Frost and Adams performed a comprehensive review of the available literature on tech-check-tech in the community setting. Their review found similar results in the community setting as has been known to occur in the institution setting with tech-check-tech programs: high accuracy.⁶ Given the increased need for the role of the pharmacy technician to expand, especially with the association's position on expanding the role of the pharmacist, it is only logical that APhA take an official stance on the expanded role of the pharmacy technician. The inconsistencies in technician certification are of concern, but APhA can look to existing state law as a guide as to what it should recommend in the way of education/certification. North Dakota, the only state to allow community tech-check-tech programs, uses the following language⁷:

61-02-07.1-12. Technicians checking technicians. Activities allowed by law to be performed within a licensed pharmacy by a registered pharmacy technician in the preparation of a prescription or order for dispensing or administration may be performed by one registered pharmacy technician and verified by another registered pharmacy technician working in the same licensed pharmacy, under the following conditions:

- 1. The licensed pharmacy where the work is being conducted has policies and procedures specifically describing the scope of the activities to be verified through this practice, included in the policy and procedure manual required under section 61-02-01-18.
 - a. Training for the specific activity is reflected in a written policy.
 - b. A record of the individuals trained is maintained in the pharmacy for two years.
- 2. The pharmacy has a continuous quality improvement system in place to periodically verify the accuracy of the final product, including:
- a. Recording any quality related events leading up to the final dispensing or administration of the drug prepared.
 - b. Recording any errors which actually reach the patient as a result of these activities.
 - c. Specific limits of acceptable quality related event levels before reassessment is required.
- d. Consideration must be made for high-risk medications on the institute for safe medication practices (ISMP) list and specific monitoring, review, and quality assurance parameters must be instituted if any of these products are included in the pharmacy's technicians-checking-technicians program.
- 3. Any error must trigger pharmacist review of the process. This review and subsequent recommendations must be documented.
- 4. The pharmacy has a system in place to review all quality related events and errors recorded and takes corrective action based on the information to reduce quality related events and eliminate errors reaching the patient.
- 5. As always, the pharmacist-in-charge and the permitholder are jointly responsible for the final product dispensed or released for administration from the pharmacy

The Department of Defense has had a system in place for decades that allows its pharmacy technicians the ability to check refills. This program requires that technicians be graduates of the military technician training program, have at least six months of direct pharmacy experience, complete didactic courses on the topics of 'medication errors' and 'prescription interpretation', and pass an examination. The technicians then must check at least 600 prescriptions under the supervision of a pharmacist who double-checks all prescriptions. Any errors made are addressed by the pharmacist with the technician and any more than one error is not allowed. Technicians must complete an annual assessment, including both CE requirements and a competency quality control review of 50 prescriptions by a pharmacist. This program has freed pharmacist time from checking refill prescriptions pharmacies, allowing them to focus on new prescriptions and more clinical responsibilities. It is recommended that APhA endorse this other similar programs that help expand technician responsibilities to help both technicians and pharmacists practice at the top of their training and license or certification.

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- 3. 2009 Survey of Pharmacy Law. Park Ridge, IL: National Association of Boards of Pharmacy; 2009:42–9.
- 4. Adams AJ, Martin SJ, Stolpe SF; Am J Health Syst Pharm. 2011;68(19):1824-1833.

- 5. Frost, T. P., & Adams, A. J. (2017). Tech-Check-Tech in Community Pharmacy Practice Settings. *Journal of Pharmacy Technology*, 33(2), 47–52.
- 6. N.D. Admin. Code §61-02-07.1-12.

Current APhA Policy & Bylaws:

2017 Pharmacy Technician Education, Training, and Development

- 1. APhA supports the following minimum requirements for all new pharmacy technicians: (a) Successful completion of an accredited or state-approved education and training program (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 encourages state boards of pharmacy to develop a phase-in process for current pharmacy technicians. APhA also encourages boards of pharmacy to delineate between pharmacy technicians and student pharmacists for the purposes of education, training, certification, and recertification.
- 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

(JAPhA 57(4): 442 July/August 2017)

New Business Items are due to the Speaker of the House by **February 20, 2019** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at https://doi.org/10.1001/journal.org/.



Item No.: 7

Date received: 2/20/19

Time received: I I:50 PM (EST)

American Pharmacists AssociationHouse of Delegates – Seattle, Washington

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: <u>Delegate Anita Jacobson, PharmD, on behalf of the Rhode Island Delegation</u>

<u>and APhA-APPM Alternate Delegate Jeffrey Bratberg, PharmD</u>

(Name)

2/20/2019	Rhode Island Pharmacists Association
(Date)	(Organization)

Subject: Patient-Centered Care of People Who Inject Drugs (PWID)

Motions: Move that APhA adopts the following policy statements:

- I. APhA encourages state legislatures and boards of pharmacy to revise laws and regulations to support the patient-centered care of People Who Inject Drugs (PWID).
- 2. To reduce the consequences of stigma associated with injection drug use, APhA supports the expansion of interprofessional harm reduction education in the curriculum of schools and colleges of pharmacy, post-graduate training, and continuing professional development programs.
- 3. APhA encourages pharmacists to initiate, sustain, and integrate evidence-based harm reduction principles and programs into their practice to optimize the health of People Who Inject Drugs (PWID).

- 4. APhA supports pharmacists' roles to provide and promote consistent, unrestricted, and immediate access to evidence-based, mortality and morbidity-reducing interventions to enhance the health of People Who Inject Drugs (PWID) and their communities, including: sterile syringes, needles, and other safe injection equipment, syringe disposal, fentanyl test strips, immunizations, condoms, wound care supplies, pre- and post-exposure prophylaxis medications for human immunodeficiency virus (HIV), point-of-care testing for HIV and hepatitis C virus (HCV), opioid overdose reversal medications, and medications for opioid use disorder.
- 5. APhA urges pharmacists to refer People Who Inject Drugs (PWID) to specialists in mental health, infectious diseases, and addiction treatment; to housing, vocational, harm reduction, and recovery support services; and to overdose prevention sites and syringe service programs.

Background:

The opioid overdose crisis is fueled by a four-fold increase in heroin overdoses, and a tripling of the death rate for synthetic opioids (ie. fentanyl). Illicitly-manufactured synthetic opioids such as fentanyl and fentanyl analogues are the main cause of the rapid increase in unintentional opioid overdose deaths nationwide! Importantly, heroin and fentanyl are most often used intravenously, requiring sterile syringe access to reduce injection-related morbidity and bloodborne pathogen transmission. **People Who Inject Drugs (**PWID) engage with every area of the healthcare system to seek care to improve their health. Each connection, whether in primary care, at a syringe service program, with an outreach worker, or at a community pharmacy, presents an opportunity to promote health, set goals to reduce risk, build rapport, reduce stigma, and mitigate harm caused by the opioid overdose crisis.

Injection drug use (IDU) increases the overall rate of death by over 11 times that of the general population, with drug overdose as the leading cause. IV drug use is associated with high utilization and cost of health services, higher than for HIV infection alone. PWID are four times more likely to need healthcare services, but are less likely to seek preventative care for chronic conditions as a marginalized population.² Pharmacists have essential public health responsibilities to serve vulnerable members of society and to triage, and connect them to the patient-centered care services and programs they deserve.

Some state and federal statutes and/or regulations limit, restrict, and/or criminalize the sale, possession, and distribution of harm reduction equipment, medications, and establishment of overdose prevention sites. Other states lack laws permitting point of care testing and pharmacist-delivered immunizations for hepatitis A and B. APhA has supported expansion of these practices, and should support additional policy changes that advance the role of pharmacists to reduce morbidity and mortality among PWID, including prescribing and/or administering medications for treating opioid use disorder, managing opioid withdrawal, and for pre-exposure or post-exposure prophylaxis for HIV, as well as provision of fentanyl test strips and support for overdose prevention sites as part of comprehensive opioid overdose prevention efforts.

Harm reduction is defined as "Any positive change." ³ Central elements of harm reduction are focused on acceptance of PWID who are individuals entitled to basic human rights, and provision of services/policies aimed at reducing negative consequences and stigma associated with injecting drugs. Stigma is the thought that leads to discriminatory actions or behaviors by members of society.

Drug use disorder is ranked as one of the most stigmatized conditions in the world, more than alcohol use disorder, homelessness, HIV infection, mental health conditions, or having a criminal record. Nearly all PWID experience at least one of these other conditions, and sometimes all of them. PWID face stigma from the public, their family, healthcare workers, and themselves, resulting in barriers to access employment, education, housing, as well as delaying evidence-based addiction and mental health treatment.^{4,5} To help reduce stigma, pharmacists should integrate harm reduction principles into all areas of education and practice.

Pharmacists have essential roles in interprofessional education, scholarship, and advocacy efforts focused on harm reduction. Interdisciplinary work with pharmacists can aid in mitigating this national public health emergency by expanding and de-stigmatizing evidence-based and progressive harm reduction interventions. Pharmacists generally have a positive attitude toward providing health promotion and harm reduction programs and express interest in increasing their role in this area.⁶ All practicing pharmacists can expand their recognized and trusted public health role as disease-state management specialists to universal screening and treatment of substance use disorder, increased harm reduction actions through increased syringe and naloxone access, and taking an active role in shaping policy.

These policies can take the form of company policies on unrestricted, nondiscriminatory provision of harm reduction services, encouraging stigma-reducing and sensitivity training to staff, and using rational business models and

approaches to providing a new service in the pharmacy. Pharmacies should educate and partner with local business leaders and owners, as well as law enforcement, to best describe the community benefits of providing harm reduction services.²

Many pharmacists are unaware of their state laws on syringe and needle sales, and add unnecessary and stigmatizing steps to a non-prescription syringe purchase interaction, from asking for identification, to limiting quantities sold, to claims that a requested syringe type is out of stock. These add to existing structural barriers to syringe access for a vulnerable and marginalized population that disproportionately and increasingly suffers injection-related harms from re-used and/or shared needles, from HIV and HCV infection and transmission to bacterial skin and heart infections. Even when syringes are available, if safe injection materials aren't also provided, these pose similar threats to the health of the user. Clear evidence indicates that syringe sales not only do not increase crime around pharmacies,⁷ but pharmacy-based syringe and needle programs are effective for reducing risk behaviors among PWID.⁸

Pharmacists have reported that the lack of syringe disposal is a barrier to selling syringes, even though discarded syringes pose no risk.9 In interviews with PWID who purchase sterile syringes and needles from pharmacies, they most often request information regarding syringe disposal. As a growing number of pharmacies offer public medication disposal, public syringe disposal is a natural low-cost intervention that a small percentage of pharmacies already provide that should be expanded based on the reported needs of PWID.

Fentanyl test strips (FTS) are a relatively new harm reduction tool, where drugs that may be contaminated with fentanyl are qualitatively tested for the presence of fentanyl before injecting. Not only have PWID found the practice to be acceptable, ¹¹ FTS used by syringe service program participants reduced non-fatal opioid overdoses and resulted in positive changes in drug use behaviors when samples turned positive for fentanyl. ¹²

There are currently several outbreaks of hepatitis A infection and transmission among PWID and homeless people in the US, prompting changes in CDC recommendations for hepatitis A immunization to include these populations.¹³ Injection drug use has remained of the major risk factors for hepatitis B infection and transmission, as well as morbidity and mortality. PWID should be screened for their immunization history and be offered the hepatitis B vaccine series. Recent primary care recommendations also include tetanus and pneumococcal immunization, as indicated.¹⁴ Pharmacists are essential, accessible immunization providers and should integrate immunization delivery into comprehensive harm reduction efforts.

8-12% of new HIV infections occur in PWID as a result of injecting in conjunction with high-risk sexual practices, pre-exposure prophylaxis with tenofovir/emtricitabine dramatically reduces risk HIV transmission.¹⁴ Pharmacists can provide of pre- and post-exposure prophylaxis medications for human immunodeficiency virus (HIV) and point-of-care testing for HIV and hepatitis C virus (HCV), and condoms to protect PWID and their contacts from transmission of HIV and HCV using these prevention and screening tools.^{15,16}

Acknowledgements: We are indebted to Nicole Schwab, PharmD '19, who researched and assembled the statements and background while on an elective public health advanced pharmacy practice experience with Dr. Bratberg.

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Current APhA Policy & Bylaws:

2012, 2005, 1992 The Role of Pharmacists in Public Health Awareness

- I. APhA recognizes the unique role and accessibility of pharmacist in public health.
- 2. APhA encourages pharmacists to provide services, education, and information on public health issues.
- 3. APhA encourages the development of public health programs for use by pharmacists and student pharmacists.
- 4. APhA should provide necessary information and materials for student pharmacists and pharmacists to carry out their role in disseminating public health information.
- 5. APhA encourages organizations to include pharmacists and student pharmacists in the development of public health programs.

(Am Pharm NS32(6):515 June 1992) (Reviewed 2005) (Reviewed 2009)(Reviewed 2010) (JAPhA NS52(4) 460 July/August 2012)(Reviewed 2017)

2005, 1993 HIV Testing

- I. APhA opposes mandatory HIV testing of pharmacists, student pharmacists, and pharmacy personnel.
- 2. APhA supports voluntary and confidential HIV testing of pharmacists, student pharmacists, and pharmacy personnel, to facilitate early detection and disease intervention.
- 3. APhA supports training designed to foster compliance with infection control procedures outlined in current Centers for Disease Control and Prevention (CDC) guidelines for universal precautions and OSHA standards for blood-borne pathogens.
- 4. APhA encourages the development of support networks to assist HIV-positive health care professionals and students. (Am Pharm NS33(7):54 July 1993) (JAPhA NS45(5):556 September/October 2005) (Reviewed 2009)(Reviewed 2014)

1996 HIV Testing in Pregnant Women

APhA encourages pharmacists to provide pharmaceutical care to women, including education about the availability and benefits of HIV testing in pregnancy to decrease the risk of HIV transmission to unborn children, APhA encourages pharmacists to provide education about the availability and benefits of HIV testing in pregnancy. (Am Pharm NS36(6):395 June 1996) (Reviewed 2005) (Reviewed 2009)(Reviewed 2014)

2005, 1993 HIV/AIDS Education

- I. APhA encourages pharmacists and student pharmacists to become more knowledgeable about HIV/AIDS.
- 2. APhA supports the development of cooperative efforts among health care organizations and agencies to facilitate the collection, evaluation, and distribution of information on HIV/AIDS.
- 3. APhA supports the development of educational programs for pharmacists and student pharmacists that would enable them to assume a service role in the prevention and treatment of HIV/AIDS.

(Am Pharm NS33(7):54 July 1993) (JAPhA NS45(5):556 September/October 2005) (Reviewed 2009)(Reviewed 2014)

2005, 1990 Needle/Syringe Exchange Programs in the Prevention of the Spread of Human Immunodeficiency Virus (HIV) and Other Infections

- I. APhA supports distribution of educational materials on the risks of sharing needles/syringes with respect to the spread of human immunodeficiency virus (HIV) and other blood-borne infectious diseases.
- 2. APhA supports the objective gathering and analysis of data and information about the effectiveness of pilot needle/syringe exchange programs in preventing the spread of HIV and other blood-borne infectious diseases.
- 3. APhA supports needle/syringe exchange programs when part of a comprehensive approach in the prevention of the spread of HIV and other blood-borne infections.

(Am Pharm NS30(6):45 June 1990) (JAPhA NS45(5):556 September/October 2005) (Reviewed 2009)(Reviewed 2014)

1999 Sale of Sterile Syringes

APhA encourages state legislatures and boards of pharmacy to revise laws and regulations to permit the unrestricted sale or distribution of sterile syringes and needles by or with the knowledge of a pharmacist in an effort to decrease the transmission of blood-borne diseases.

(JAPhA 39(4): 447 July/August 1999)(Reviewed 2003)(Reviewed 2006)(Reviewed 2008)(Reviewed 2009)(Reviewed 2014)

2001 Syringe Disposal

APhA supports collaboration with other interested health care organizations, public and environmental health groups, waste management groups, syringe manufacturers, health insurers, and patient advocacy groups to develop and promote safer systems and procedures for the disposal of used needles and syringes by patients outside of health care facilities. (JAPhA NS41(5): Suppl.1:S9 September/October 2001)(Reviewed 2007)(Reviewed 2012)(Reviewed 2017)

2005, 2003, 1996 Pharmacists' Role in Immunizations

- I. APhA encourages pharmacists to take an active role in achieving the goals of the Healthy People program regarding immunizations through: (a) advocacy, (b) contracting with other health care professionals, or (c) pharmacists administering vaccines to vulnerable patients.
- 2. APhA encourages the availability of all vaccines to all pharmacies in order to meet public health needs.
- 3. APhA supports the compensation of pharmacists for the administration of immunizations and the reimbursement for vaccine distribution.
- 4. APhA should facilitate the development of programs that educate pharmacists about their role in immunizations in public health.

(JAPhA NS36(6):395 June 1996) (JAPhA NS43(5):Suppl. 1:S57 September/October 2003) (JAPhA NS45(5):556 September/October 2005)(Reviewed 2007)(Reviewed 2009)(Reviewed 2012)(Reviewed 2014)

1987 Encouraging Availability and Use of Vaccines

- I. APhA encourages the continued availability of vaccines to meet public health needs.
- 2. APhA supports the development of programs that educate the public about the role of immunizations in public health.
- 3. APhA supports the reimbursement by public and private third-party payers for immunizations.

(Am Pharm NS27(6):424 June 1987) (Reviewed 2005)(Reviewed 2009)(Reviewed 2012)(Reviewed 2014)

2018 Efforts to Reduce the Stigma Associated with Mental Health Disorders or Diseases

- I. APhA encourages all stakeholders to develop and adopt evidence-based approaches to educate the public and all health care professionals to reduce the stigma associated with mental health diagnoses.
- 2. APhA supports the increased utilization of pharmacists and student pharmacists with appropriate training to actively participate in the care of patients with mental health diagnoses as members of interprofessional health care teams in all practice settings.
- 3. APhA supports the expansion of mental health education and training in the curriculum of all schools and colleges of pharmacy, post-graduate training, and within continuing professional development programs.
- 4. APhA supports the development of education and resources to address health care professional resiliency and burnout.

(JAPhA 58(4): 356 July/August 2018)

2004, 1965 Mental Health Programs

APhA supports pharmacists' participation in the development and implementation of all aspects of mental health programs so that the special needs and problems of the mentally ill can be effectively met. (JAPhA NS5:274 May 1965) (JAPhA NS44(5):551 September/October 2004)(Reviewed 2010)(Reviewed 2011)

2016, 2003, 1987 Substance Use Disorder Education

APhA supports comprehensive substance use disorder education, prevention, treatment, and recovery programs.

2016 Substance Use Disorder

- I. APhA supports legislative, regulatory, and private sector efforts that include pharmacists' input and that will balance patient-consumers' need for access to medications for legitimate medical purposes with the need to prevent the diversion, misuse, and abuse of medications.
- 2. APhA supports consumer sales limits of nonprescription drug products, such as methamphetamine precursors, that may be illegally converted into drugs for illicit use.
- 3. APhA encourages education of all personnel involved in the distribution chain of nonprescription products so they understand the potential for certain products, such as methamphetamine precursors, to be illegally converted into drugs for illicit use. APhA supports patient-consumer education of consequences of methamphetamine use, misuse, and abuse.
- 4. APhA supports public and private initiatives to fund treatment and prevention of substance use disorders.
- 5. APhA supports stringent enforcement of criminal laws against individuals who engage in drug trafficking. (JAPhA 56(4); 369 July/August 2016)

2016 Opioid Overdose Prevention

- I. APhA supports access to third-party (non-patient recipient) prescriptions for opioid reversal agents that are furnished by pharmacists.
- 2. APhA affirms that third-party (non-patient recipient) prescriptions should be reimbursed by public and private payers. (JAPhA 56(4); 370 July/August 2016)

2014 Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents

- I. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.
- 2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.
- 3. APhA supports pharmacists' access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.
- 4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.
- 5. APhA supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.

(JAPhA 54(4) July/August 2014)(Reviewed 2015)(Reviewed 2018)

2016 Medication-Assisted Treatment

APhA supports expanding access to Medication Assisted Treatment (MAT), including but not limited to pharmacist-administered injection services for treatment and maintenance of substance use disorders that are based on a valid prescription.

. (JAPhA 56(4); 370 July/August 2016) (JAPhA 56(4); 370 July/August 2016)

2005, 1998 Administration of Medications

I. APhA recognizes and supports pharmacist administration of prescription and non-prescription drugs as a component of pharmacy practice.

- 2. APhA supports the development of educational programs and practice guidelines for student pharmacists and practitioners for the administration of prescription and non-prescription drugs.
- 3. APhA supports pharmacist compensation for administration of prescription and non-prescription drugs and services related to such administration.
- 4. APhA urges adoption of state laws and regulations authorizing pharmacist administration of prescription and non-prescription drugs.

(JAPhA 38(4): 417 July/August 1998) (JAPhA NS45(5):559 September/October 2005) (Reviewed 2006)(Reviewed 2011)(Reviewed 2012)(Reviewed 2017)

2016 Point-of-Care Testing

- I. 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.

(JPhA 56(4); 369 July/August 2016)(Reviewed 2018)

2013 Pharmacists Providing Primary Care Services

APhA advocates for the recognition and utilization of pharmacists as providers to address gaps in primary care. (JAPhA 53(4): 365 July/August 2013)(Reviewing 2018)

2017 Patient Access to Pharmacist-Prescribed Medications

- I. APhA asserts that pharmacists' patient care services and related prescribing by pharmacists help improve patient access to care, patient outcomes, and community health, and they align with coordinated, team-based care.
- 2. APhA supports increased patient access to care through pharmacist prescriptive authority models.
- 3. APhA opposes requirements and restrictions that impede patient access to pharmacist-prescribed medications and related services.
- 4. APhA urges prescribing pharmacists to coordinate care with patients' other health care providers through appropriate documentation, communication, and referral.
- 5. APhA advocates that medications and services associated with prescribing by pharmacists must be covered and compensated in the same manner as for other prescribers.
- 6. APhA supports the right of patients to receive pharmacist-prescribed medications at the pharmacy of their choice. (JAPhA 57(4): 441 July/August 2017)

2005, 1972 Prevention and Control of Sexual Transmitted Infections

- I. APhA calls upon all producers of prophylactic devices to include in or on their packaging adequate instructions for use so as to better ensure the effectiveness of the devices in the prevention of sexually transmitted infections.
- 2. APhA urges pharmacists to make more readily available to the public educational materials, prophylactic devices, and adequate instructions for use in combating sexually transmitted infections.

(JAPhA NS12:304 June 1972) (JAPhA NS45(5):557 September/October 2005) (Reviewed 2009)(Reviewed 2014)

2003 Drug Addiction/Chemical Dependency Education

APhA urges pharmacists and pharmacy students to become educated in the recognition and treatment of drug addiction and chemical dependency.

(JAPhA NS43(5):Suppl. 1:S57 September/October 2003) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

1982 Innovative Approaches to Combating Pharmacy Crime

- I. APhA encourages federal government agencies to provide mechanisms for supporting experimental, drug-dependence, treatment programs based on principles of maintenance and/or detoxification.
- 2. APhA supports the development of a comprehensive educational program on drug use and misuse, starting with children in primary grades (kindergarten-Grade 5).

(Am Pharm NS22(7):32 July 1982) (Reviewed 2003) (Reviewed 2006) (Reviewed 2010) (Reviewed 2015)

2009 Disparities in Healthcare

APhA supports elimination of disparities in health care delivery. (JAPhA NS49(4):493 July/August 2009)(Reviewed 2013)(Reviewed 2018)

2006 Cultural Health Beliefs and Medication Use

- I. APhA supports culturally sensitive outreach efforts to increase mutual understanding of the risks and other issues of using prescription medications without a prescription order or using unapproved products.
- 2. APhA supports expanding culturally competent health care services in all communities.

(JAPhA NS46(5):561 September/October 2006) (Reviewed 2009)(Reviewed 2014)

2005 Patient Safety

- I. Patient safety is influenced by patients, caregivers, health care providers, and health care systems. APhA recognizes that improving patient safety requires a comprehensive, continuous, and collaborative approach to health care.
- 2. APhA should promote public and provider awareness of and encourage participation in patient safety initiatives.
- 3. APhA supports research on a more effective, proactive, and integrated health care system focused on improving patient safety. APhA encourages implementation of appropriate recommendations from that research.

(JAPhA NS45(5):554 September/October 2005) (Reviewed 2009)(Reviewed 2011)(Reviewed 2016)

New Business Items are due to the Speaker of the House by **February 20, 2019** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at ^{4,5}.



Item No: 8

Date received: 3/11/19

Time received: 10:26 AM (EST)

American Pharmacists AssociationHouse of Delegates – Seattle, Washington

NEW BUSINESS

(To be submitted and introduced by Delegates only)

(To be submitted and introduced by Delegates only)						
Introduced b	y: Nimit Jin	dal, APhA-ASP National President				
		(Name)				
	<u>March 7, 2019</u> (Date)	APhA – Academy of Student Pharmacists (Organization)				
•	Creating Safe Work and Pharmacists and Pharma	d Learning Environments for Student Pharmacists,				

Motion:

- I. APhA strongly believes that all pharmacists, student pharmacists and pharmacy technicians should be safe in their work and learning environments and be free from firearm-related violence.
- 2. APhA strongly recommends that schools and colleges of pharmacy, residency programs, and employers should develop programs to increase readiness in the event of an active shooter.
- 3. APhA strongly believes pharmacists and student pharmacists should be trained to recognize and refer patients at high risk of violence to themselves or others.
- 4. APhA encourages pharmacists, student pharmacists and pharmacy technicians who are victims of firearm-related violence to seek the help of counselors and other trained mental health professionals.

Background:

The numbers of firearm-related injuries and fatalities have increasingly become a public health problem¹, with the Centers for Disease Control and Prevention's WONDER database² demonstrating over 600,000 firearm-related deaths in from 1999 to 2017. In 2017 alone, nearly 40,000 individuals were killed due to firearms. Firearm-related incidents are non-discriminatory in terms of environmental impact, with a 2011 study³ finding that both rural and urban areas are impacted by firearm-related violence. Firearm-related violence is expensive in another key way as well: medical costs for firearm injuries total more than \$70 billion in direct medical care and loss of productivity.⁴ The passing of a pharmacy resident at Mercy⁵ Hospital and Medical Center, Dayna Less, further creates a necessary and timely opportunity for the American Pharmacists Association-Academy of Student Pharmacists to initiate an informed, multifaceted conversation about firearm-related safety in places of work and learning.

Firearm in common parlance refers to any portable gun. More specifically, firearms that are regulated by the National Firearms Act⁶ (NFA) include the following: "(I) a shotgun having a barrel or barrels of less than 18 inches in length; (2) a weapon made from a shotgun if such weapon as modified has an overall length of less than 26 inches or a barrel or barrels of less than 18 inches in length; (3) a rifle having a barrel or barrels of less than 16 inches in length; (4) a weapon made from a rifle if such weapon as modified has an overall length of less than 26 inches or a barrel or barrels of less than 16 inches in length; (5) any other weapon, as defined in subsection (e); (6) a machinegun; (7) any silencer (as defined in section 921 of title 18, United States Code); and (8) a destructive device."

Active shooter preparedness programs are not new in educational and work settings. Existing guidelines, such as the one from the Washington Office of Superintendent of Public Instruction⁷, outlines readiness programs and resources available for K-I2 programs. The Readiness and Emergency Management for Schools program (REMS)⁷ also outlines recommended steps for response to an active shooter, such as respond immediately, run, and hide. The Joint Commission⁹ similarly issued recommendations in 2014 regarding planning for active shooter situations in healthcare facilities. Hospital-based violence intervention programs have begun to work on reducing firearm violence-related recidivism rates as well. A 2016 study¹⁸ pinpoints three components of an effective institution-based strategy: addressing risks associated with violent injury, introducing services at the time of acute injury and hospital care, and providing culturally competent case management. With all these best practice recommendations published and programs being built, there is still room for improvement. A survey from the Education Week Research Center¹⁰ found that one in five school law enforcement officers does not feel their respective schools are prepared to handle an active shooter situation. Furthermore, not every school and college of pharmacy has a published active shooter protocol or related training – such as the protocol at Presbyterian College School of Pharmacy¹¹ and drills conducted at Samford University²⁴ – readily available to student pharmacists, pharmacists, and pharmacy technicians.

A 2013 report from the American Psychological Association (APA)¹² defines the following groups at high risk for firearm-related violence: domestic violence offenders, persons convicted of violent misdemeanor crimes, and individuals with mental illness who have been adjudicated as being a threat to themselves or to others. Note that the APA does not categorize all individuals who have been diagnosed with a mental health condition or exhibiting behaviors such as suicidal ideation as being dangerous. However, there is an emphasis in recommendations in all age groups to develop interventions or programs – such as those involving psychologists – to promote emotional and mental health. Carter and colleagues in 201513 found that youth in emergency departments with at least one prior incident of firearm-related assault are at higher risk for subsequent firearm-related violence; the authors advocate for interventions including those addressing substance use and mental health needs. American Association of Colleges of Pharmacy (AACP) Curricular Guidelines for Pharmacy (Substance Abuse and Addictive Disease)¹⁴ promote foundational and elective curricular opportunities to help student pharmacists be able to identify "characteristics of addiction and related disorders and patterns of abuse and dependence... to allow pharmacists to assist in early identification and assistance where appropriate," as well as be well-educated about "methods of prevention, intervention, referral, withdrawal, treatment, and recovery support." While the AACP recommends at least four hours of training be focused on "the identification, intervention, and treatment of addiction and related disorders," a 2017 survey of pharmacists 15 regarding perceived readiness of mental health-related medication issues indicates a greater need for training in this area. It is important to continue to identify and develop opportunities to expand learning for mental health and substance abuse - such as in curricula in schools and colleges of pharmacy, continuing education programs, and post-graduate residency and fellowship programs – for student pharmacists and pharmacists. A 2015 study¹⁶ by O'Reilly and colleagues demonstrated that pharmacists "are capable of performing screening and risk assessment services for depression in primary care... and

community pharmacies." Additionally, there has been support – such as by the National Community Pharmacists Association – for pharmacists to be trained in existing programs such as the Mental Health First Aid program¹⁷, thus enabling pharmacists "to identify when an individual is experiencing a mental health issue or crisis, and to start the intervention process, which includes referring out to help."

Firearm-related violence is a traumatic experience. The American Psychological Association¹⁹ points to a number of possible reactions of those involved in a firearm-related incident: post-traumatic stress, depression, anxiety, substance abuse. The Substance Abuse and Mental Health Services Administration (SAMHSA)²⁰ further categorizes three stages of healing after a firearm-related incident: acute phase – denial, shock, disbelief; intermediate phase – fear, anger, anxiety, depression, trouble sleeping; long-term phase (months afterward) – solidification of behavioral health reactions into mental health or substance use disorders. A 2008 study at Northern Illinois University²¹ completed after a mass shooting on the campus found that 12% of survivors reported PTSD, higher than the average incidence of PTSD among trauma survivors. A later study in 2018²² similarly found that armed robberies increased posttraumatic stress in victims. With the potential for developing sequelae post-firearm-related incident, there is a large need for continued promotion of trained mental health professionals available to help student pharmacists, pharmacists, and pharmacy technicians access evidence-based pharmacological treatments and psychosocial interventions²³ – such as exposure-based interventions and cognitive-based therapies – that have been proven effective for conditions such as PTSD.

Firearm-related violence is devastating – physically, psychologically, financially – regardless of the scope or environment. Many healthcare professional associations have taken a stand on proactive and reactive recommendations to reduce the harmful impacts of firearm-related violence. APhA-ASP aims to accomplish these same goals ultimately to improve the safety of pharmacists, student pharmacists and pharmacy personnel.

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Current APhA Policy & Bylaws:

**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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