

# Open Forum on New Business Items

Missy Duke

Chair, New Business Review
Committee

Michael D. Hogue

Speaker, APhA House of Delegates

### Webinar Information

- Dial-in and use access code and audio pin on your control panel to limit audio issues and background noise during the webinar
- Submit your comments/questions during the webinar using the chat box on your control panel or email <a href="https://example.com/HOD@aphanet.org">HOD@aphanet.org</a>
- Select "raise hand" button to request to speak and you will be recognized by the moderator as time permits
- This webinar is being recorded for future access on the House of Delegates webpage, <a href="https://www.pharmacist.com/apha-house-delegates">www.pharmacist.com/apha-house-delegates</a>
- Note: all comments/questions received will be considered by the New Business Review Committee



### Webinar Information

- Webinar scheduled for 90 minutes
  - 10 minutes for overview
  - 70 minutes for NBI Review & Discussion
  - •10 minutes for closing information

 Moderators will clarify issues, but will not engage in debate



### **New Business Review Committee**

Missy Duke, Chair

Phoenix, AZ

Amber L. Briggs

Soldotna, AK

**Kisha Gant** 

Slidell, LA

**Joey Mattingly** 

Baltimore, MD

**Haniff Sealy** 

Gallup, NM

**Larry Selkow** 

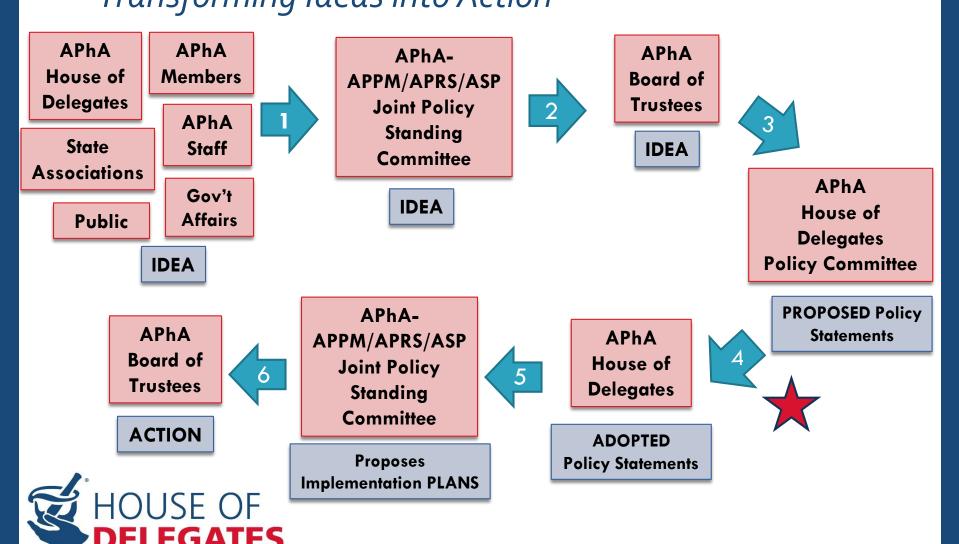
Palm Springs, CA

**Emily Willard** 

Cincinnati, OH



# Policy Process Roadmap Transforming Ideas into Action



# **Current Policy Information**

- Policy Manual
  - Online searchable database:
    - <a href="http://www.pharmacist.com/policy-manual">http://www.pharmacist.com/policy-manual</a>
  - Online PDF version:
    - <a href="http://pharmacist.com/sites/default/files/files/16898%20CURRENT%20ADOPTED%20POLICY%20MANUAL%20-%20FINAL.pdf">http://pharmacist.com/sites/default/files/files/16898%20CURRENT%20ADOPTED%20POLICY%20MANUAL%20-%20FINAL.pdf</a>



### American Pharmacists Association Antitrust Statement

The American Pharmacists Association complies with all Federal and State Antitrust laws, rules and regulations. Therefore:

- 1) Meetings will follow a formal, pre-approved agenda which will be provided to each attendee. Participants at meetings should adhere strictly to the agenda. Subjects not included on the agenda should generally not be considered at the meeting.
- 2) The agenda will be specific and will prohibit discussions or recommendations regarding topics that may cause antitrust problems, such as prices or price levels. In addition, no discussion is permitted of any elements of a company's operations which might influence price such as:
  - a) Cost of operations, supplies, labor or services;
  - b) Allowance for discounts;
  - c) Terms of sale including credit arrangements; and,
  - d) Profit margins and mark ups, provided this limitation shall not extend to discussions of methods of operation, maintenance, and similar matters in which cost or efficiency is merely incidental.
- 3) It is a violation of Antitrust laws to agree not to compete, therefore, discussions of division of territories or customers or limitations on the nature of business carried on or products sold are not permitted.
- 4) Boycotts in any form are unlawful. Discussion relating to boycotts is prohibited, including discussions about blacklisting or unfavorable reports about particular companies including their financial situation.
- 5) Whenever discussion borders on an area of antitrust sensitivity, the Association's representative should request that the discussion be stopped and ask that the request be made a part of the minutes of the meeting being attended. If others continue such discussion, the webinar will be terminated.



# 2018 House of Delegates New Business Item Process

- Submission
  - Deadline has passed (February 14, 2018)
  - Urgent matters may be considered
- Webinars / Open Hearing
  - Obtain initial feedback for committee
    - Two webinars (2/28 and 3/7)
    - Engage HOD Community Discussion
    - Open Hearing Saturday, March 17, 1:00 to 2:30pm in Room 209A
- New Business Review Committee Meeting
  - Activity at Annual Meeting
- Debate / decisions on New Business Items at APhA2018



### 2018 Potential Recommendations

- Adoption
- Rejection
- Referral
- Adoption as amended by Committee
- No action



### **New Business Review Committee**

- •8 New Business Items
  - Subject / Motion
  - Current related APhA Policy & Bylaws
  - Brief Summary of background
  - Discussion / Feedback



Pharmacy Schools' Curriculum and Contemporary Pharmacy Practice

Introduced by: Delegate Michael Carulli, on behalf of the APhA Policy Review Committee

**Motion:** I move, on behalf of the Policy Review Committee, that the following item be ADOPTED to replace existing APhA Policy.

# 2005, 1990 Pharmacy Schools' Curriculum and Contemporary Pharmacy Needs

1. APhA supports continuous quality improvement processes at the national and school/college level to identify differences between contemporary pharmacy practice and curriculum offerings, and to provide information and resources to encourage maintenance of up-to-date curricula.



Pharmacy Schools' Curriculum and Contemporary Pharmacy Practice
Introduced by: Delegate Michael Carulli, on behalf of the APhA Policy Review Committee

#### **Highlighted Modifications:**

I. APhA supports continuous quality improvement processes at the national and school/college level to identify will work with schools and colleges of pharmacy and pharmacy organizations to address differences between contemporary pharmacy practice and curriculum offerings, and to provide information and resources to encourage maintenance of up-to-date curricula.

#### **Background Summary:**

- The needs of contemporary pharmacy practice are rapidly changing
- The suggested wording revision calls for schools and colleges to implement CQI processes, which regularly asses the needs of contemporary pharmacy practice.
- Additionally, the committee felt this policy should support APhA providing information and resources to the individual schools to assist them in making changes and updates to their curricula.

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Time for Discussion

#### Revisions to the Medication and Medical Device Classification System

Introduced by: Delegate Laura Joglekar, on behalf of the APhA Policy Review Committee

**Motion:** I move, on behalf of the Policy Review Committee, that the following item be ADOPTED to replace existing APhA Policy.

#### 2013 Revisions to the Medication and Medical Device Classification System

- 1. APhA supports the Food and Drug Administration's (FDA's) efforts to revise the drug and medical device classification paradigms for prescription and nonprescription medications and medical devices to allow greater access to certain medications and medical devices under conditions of safe use while maintaining patients' relationships with their pharmacists and other health care providers.
- **2.** APhA supports the implementation or modification of state laws to facilitate pharmacists' implementation and provision of services related to a revised drug and medical device classification system.
- 4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications and medical devices under FDA's approved conditions of safe use.
- **5.** APhA urges manufacturers, FDA, and other stakeholders to include pharmacists' input in the development and adoption of technology and standardized processes for services related to medications and medical devices under FDA's defined conditions of safe use.
- **6.** APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications and medical devices under FDA's approved conditions of safe use.
- **7.** APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA's defined conditions of safe use within health benefit coverage.



Revisions to the Medication and Medical Device Classification System

Introduced by: Delegate Laura Joglekar, on behalf of the APhA Policy Review Committee

#### **Background Summary:**

- In certain practice settings pharmacists are qualified to provide clinical intervention as well as input in development of medications as well as medical devices
- Over the past few years, FDA has been partnering with key stakeholders regarding medical device requirements and it is pertinent that APhA continues to support pharmacists who help shape FDA's policies.
- The recommended changes add medical devices to statements 1, 2, 4, 5, 6, 7 and would not remove any existing language.



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Time for Discussion

#### **Direct and Indirect Remuneration Fees**

Introduced by: Delegates Betsy Elswick and L. Douglas Ried, on behalf of the Texas Delegation

**Motion:** Move to adopt the following policy statements:

- 1. APhA supports legislation that would prohibit retroactive direct and indirect remuneration (DIR) fees on pharmacies.
- 2. APhA supports prospective, transparent disclosure to pharmacies, employers and consumers, of all fee structures, performance-based network payments and penalties, and network participation requirements for any pharmacy benefit administrator.
- 3. APhA opposes percentage-based or flat-rate, plan-based performance assessments in lieu of assessments based on a pharmacy's performance on pharmacy specific quality metrics.

#### **Direct and Indirect Remuneration Fees**

Introduced by: Delegates Betsy Elswick and L. Douglas Ried, on behalf of the Texas Delegation

#### Related to:

2017 Pharmacy Performance Networks (Current policy)

1. APhA supports performance networks that improve patient care and health outcomes, reduce costs, use pharmacists as an integral part of the health care team, and include evidence-based quality measures.

2. APhA urges collaboration between pharmacists and payers to develop distinct, transparent, fair, and equitable payment strategies for achieving performance measures associated with providing pharmacists' patient care services that are separate from the reimbursement methods used for product fulfillment.

3. APhA advocates for prospective notification of evidence-based quality measures that will be used by a performance network to assess provider and practice performance. Furthermore, updates on provider and practice performance against these measures should be provided in a timely and regular manner.

4. APhA supports pharmacists' professional autonomy to determine processes that improve performance on evidence-based quality measures.



#### **Direct and Indirect Remuneration Fees**

Introduced by: Delegates Betsy Elswick and L. Douglas Ried, on behalf of the Texas Delegation

#### **Background Summary:**

- Relatively recently, Part D plan sponsors and Pharmacy Benefit Managers (PBMs) have begun to extract DIR (Direct and Indirect Remuneration) fees from pharmacies.
- At present, nearly all pharmacy DIR fees are clawed back retroactively months later rather than deducted from claims on a real-time basis, which impacts operations of a pharmacy.
- The original purpose of DIRs as intended by the CMS was to lower the drug cost to the "true cost", such as including manufacturer rebates.



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Time for Discussion

#### Efforts to Reduce Mental Health Stigma

Introduced by: Delegate Mary Elizabeth Bradley, on behalf of the APhA-ASP Delegation

**Motion:** Move that APhA adopt the following policy statements:

- 1. APhA encourages all stakeholders to develop and adopt evidence-based approaches in order to educate the public and reduce mental health stigma. This may include, but is not limited to, depression, bipolar disorder, schizophrenia, anxiety, and other disorders and conditions.
- 2. APhA supports the increased utilization of pharmacists and student pharmacists with appropriate training to actively participate in psychiatric interprofessional health care teams in all practice settings.
- 3. APhA supports the inclusion and expansion of mental health education and training in the curriculum of all schools and colleges of pharmacy and post-graduate opportunities.



#### Efforts to Reduce Mental Health Stigma

Introduced by: Delegate Mary Elizabeth Bradley, on behalf of the APhA-ASP Delegation

Related to:

2004, 1965 Mental Health Programs (Current Policy)

APhA supports pharmacists' participation in the development and implementation of all aspects of mental health programs so that the special needs and problems on the mentally ill can be effectively met.

#### **Background Summary:**

- As the prevalence of mental disorders continues to increase worldwide, the mental health community remains an underserved and undertreated population.
- As the pharmacotherapy experts, pharmacists' knowledge and skills can be leveraged to increase access to mental health services in both the inpatient and outpatient settings.



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Time for Discussion

#### Pharmacist's Permissive Language Related to Medication Cost

Introduced by: Delegates Betsy Elswick and L. Douglas Ried, on behalf of the Texas Delegation

**Motion:** Move to adopt the following statement:

APhA opposes language included in contractual agreements between pharmacy benefits manager (PBM) and pharmacy that prohibit or limit a pharmacist's ability to communicate information to patients pertaining to the cost of and access to medications.



#### Pharmacist's Permissive Language Related to Medication Cost

Introduced by: Delegates Betsy Elswick and L. Douglas Ried, on behalf of the Texas Delegation

Related to:

2013, 2001, 1994 Pharmacist-Patient-Prescriber-Payer Responsibilities in Appropriate Drug Use (Current policy)

#### **Background Summary:**

- Pharmacists increasingly cite concerns about contractual agreements that prohibit them about speaking to their patients about the out-of-pocket cost of a drug versus a health carrier's reimbursement rates.
- While APhA has policy related to the access to and affordability of medications to patients, policy does not exist related to so-called "gag orders" that restrict the pharmacist from voluntarily communicating cost information with the patient or purchaser of prescription medications.



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Time for Discussion

**Gluten Content and Labeling in Medications** 

Introduced by: Delegate Carmela Silvestri, on behalf of the New Jersey Delegation

**Motion:** Move to adopt the following policy statements:

- 1. APhA supports labeling of all prescription and over the counter medications that indicates the presence or absence of gluten (protein associated with wheat, barley, rye or their derivatives) regardless of whether the addition of these substances is intentional or inadvertent.
- 2. 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.
- 3. 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.
- 4. APhA encourages USP to develop assays that can accurately detect trace levels of gluten in finished drug products and set appropriate standards
- 5. APhA encourages manufacturers to formulate drug products without use of wheat, barley, rye or their derivatives whenever possible.
- 6. 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.
- 7. APhA supports additional research on the effects of gluten intolerance and celiac malabsorption, particularly as it relates to medication absorption.
- 8. APhA supports pharmacist education regarding celiac disease and non-celiac gluten sensitivity.



#### Gluten Content and Labeling in Medications

Introduced by: Delegate Carmela Silvestri, on behalf of the New Jersey Delegation

Related to:

2004, 1970 Disclosure of Ingredients in Drug Products (Current policy)

APhA supports legislation or regulation to require a full disclosure of therapeutically inactive, as well as active ingredients of all drug products.



#### Gluten Content and Labeling in Medications

Introduced by: Delegate Carmela Silvestri, on behalf of the New Jersey Delegation

#### **Background Summary:**

- Several studies have been done to estimate the time required by pharmacists in determining the gluten status in medications in order to protect patients from exposure.
- The celiac community is riddled with anecdotal stories of patients who report being left to check with manufacturers on their own to verify gluten status of their medications.
- Standards were set back in 2014 on gluten content by the FDA and now it is possible to be even more precise when measuring this content using new Elisa tests.
- Encouraging manufacturers to eliminate these excipients in their products moving forward would be helpful, but full disclosure of any contact with any known gluten source is essential for patient safety.
- Pharmacists need to be aware of celiac disease and gluten sensitivity in order to guide patients to verified gluten- free products and assist in limiting inadvertent exposure.



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Time for Discussion

#### Pharmacist's Electronic Referral Tracking

Introduced by: Delegate LT William Christopher Charles, on behalf of the USPHS Delegation

**Motion:** Move that APhA adopt the following policy statements:

- 1. APhA supports the development of electronic systems that enhance and simplify the ability of pharmacists in all practice settings to receive, send, and track referrals between all members of the health care team irrespective of the health care system, model, or network the patient participates in.
- 2. APhA supports the interoperability and integration of referral tracking systems with electronic health records so patients can receive the benefit of optimally coordinated care from all members of the health care team.



#### Pharmacist's Electronic Referral Tracking

Introduced by: Delegate LT William Christopher Charles, on behalf of the USPHS Delegation

#### Related to:

2017 Patient Access to Pharmacist-Prescribed Medications (Current Policy)

2015 Interoperability of Communications Among Health Care Providers to Improve Quality of Patient Care (Current Policy)

2014 Care Transitions (Current Policy)

2009 Health Information Technology (Current Policy)

2006 Continuity of Care (Current Policy)



#### Pharmacist's Electronic Referral Tracking

Introduced by: Delegate LT William Christopher Charles, on behalf of the USPHS Delegation

#### **Background Summary:**

- A piece that is missing in current APhA policy is a statement focused specifically on the enhancement of referrals within such a system.
- Medical Home Models, Value-Based Payment structures, and Performance Networks are examples of initiatives that have been launched to expand on a referral structure.
- APhA should advocate for the development of electronic systems that improve all aspects of the referral interface between other providers and pharmacists.
- Improving the flow of referral information will enhance pharmacists' ability to implement collaborative practice agreements for the care of our patients.



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Time for Discussion

#### Pharmacist's Role in Chronic Disease Prevention

Introduced by: Delegate LT Kinbo Le, on behalf of the USPHS Delegation

**Motion:** Move that APhA adopt the following policy statements:

- 1. APhA advocates for the recognition and utilization of pharmacists as providers to address chronic disease prevention.
- 2. APhA advocates for pharmacy campaigns focused on increased community wellness awareness and health benefit knowledge in areas such as healthy eating and physical exercise.
- 3. APhA encourages the development of pharmacy curriculum and continuing education on the topics of chronic disease prevention and health promotion through improvements in modifiable risk factors.



#### Pharmacist's Role in Chronic Disease Prevention

Introduced by: Delegate LT Kinbo Le, on behalf of the USPHS Delegation

#### Related to:

2013 Pharmacists Providing Primary Care Services (Current Policy)

2013 Ensuring Access to Pharmacists' Services (Current Policy)

2012, 1981 Pharmacist Training in Nutrition (Current Policy)

2012, 2005, 1992 The Role of Pharmacists in Public Health Awareness (Current Policy)

2012 Contemporary Pharmacy Practice (Current Policy)

2011 The Role and Contributions of the Pharmacist in Public Health (Current Policy)

2004, 1978 Roles in Health Care for Pharmacist (Current Policy)



#### Pharmacist's Role in Chronic Disease Prevention

Introduced by: Delegate LT Kinbo Le, on behalf of the USPHS Delegation

#### **Background Summary:**

- Existing APhA policy does not provide focused activities on prevention of chronic disease states.
- Pharmacist management of patients with diabetes has show positive results through medication adherence, patient education, and lifestyle modifications.
- Given that greater than 93% of Americans live within 5 miles of a community pharmacy), it seems sensible to further engage pharmacists in preventative patient lifestyle interventions nutrition intake, physical activity, and weight control to turn the tide on the diabetes and obesity epidemic.



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Time for Discussion

### **New Business Review Committee**

- New Business Item #1 Pharmacy Schools' Curriculum and Contemporary Pharmacy Practice
- New Business Item #2 Revisions to the Medication and Medical Device Classification System
- New Business Item #3 **Direct and Indirect Remuneration Fees**
- New Business Item #4 Efforts to Reduce Mental Health Stigma
- New Business Item #5 **Pharmacist's Permissive Language Related to Medication Cost**
- New Business Item #6 Gluten Content and Labeling in Medications
- New Business Item #7 Pharmacist's Electronic Referral Tracking
- New Business Item #8 Pharmacist's Role in Chronic Disease
  Prevention



Time for Discussion

# House Keeping

#### Additional NBIs

 Consideration of additional and "urgent" NBIs require suspension of House Rules

#### House Committee Reports

• Available at <u>www.pharmacist.com/apha-house-delegates</u>

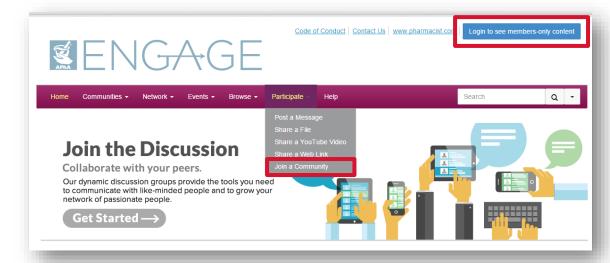
#### Delegate Reference Materials

- Electronic version available on HOD webpage and sent out soon
- Paper copies will be mailed out
- A limited number will be available on-site



# Continue the Conversation Visit APhA Engage

- APhA Engage makes joining the conversation easy!
  - 1. Visit <u>engage.pharmacist.com</u>
  - 2. Login using your APhA username and password
  - 3. Click "Participate" then "Join a Community"
  - 4. Find the "HOD" communities
  - 5. Click "Join" and follow the prompts on your screen





# 2018 House of Delegates

**House of Delegates First Session** 

Friday, March 16, 3:00 to 5:00pm

**Policy Committee Open Hearing** 

Sunday, March 18, 1:00 to 3:00pm

New Business Review Committee Open Hearing

Saturday, March 17, 1:00 to 2:30pm

**House of Delegates Final Session** 

Monday, March 19, 1:30 to 4:30pm



# Who Will be the Next Speaker-Elect?

- •Applications due March 15<sup>th</sup>, 2018
  - <a href="https://apha.secure-platform.com/a/solicitations/home/127">https://apha.secure-platform.com/a/solicitations/home/127</a>

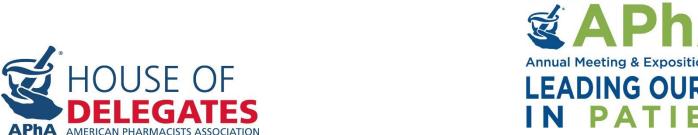
•Please contact House of Delegates at HOD@aphanet.org





# Ideas for Future Policy Topics

- Are there topics we should consider for the 2019 House of Delegates?
  - These are topics needing more development than through the new business process
  - •Tell us now or send to <a href="HOD@aphanet.org">HOD@aphanet.org</a>







# Open Forum on New Business Items

Thank you for your time and attention!

<u>www.pharmacist.com/apha-house-delegates</u> <u>HOD@aphanet.orq</u>