



# 2016 Policy Topic Open Forum

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Speaker, House of Delegates

# Objectives

1. Briefly review the purpose of the House of Delegates
2. Provide short overview of the policy development process
3. Outline the 2015-2016 proposed policy topics
4. Briefly discuss next steps in the process

*Webinar scheduled for 60 minutes (10 minutes for introductions/overview,  
15 minutes per topic, and 5-10 minutes for final comments/questions)*

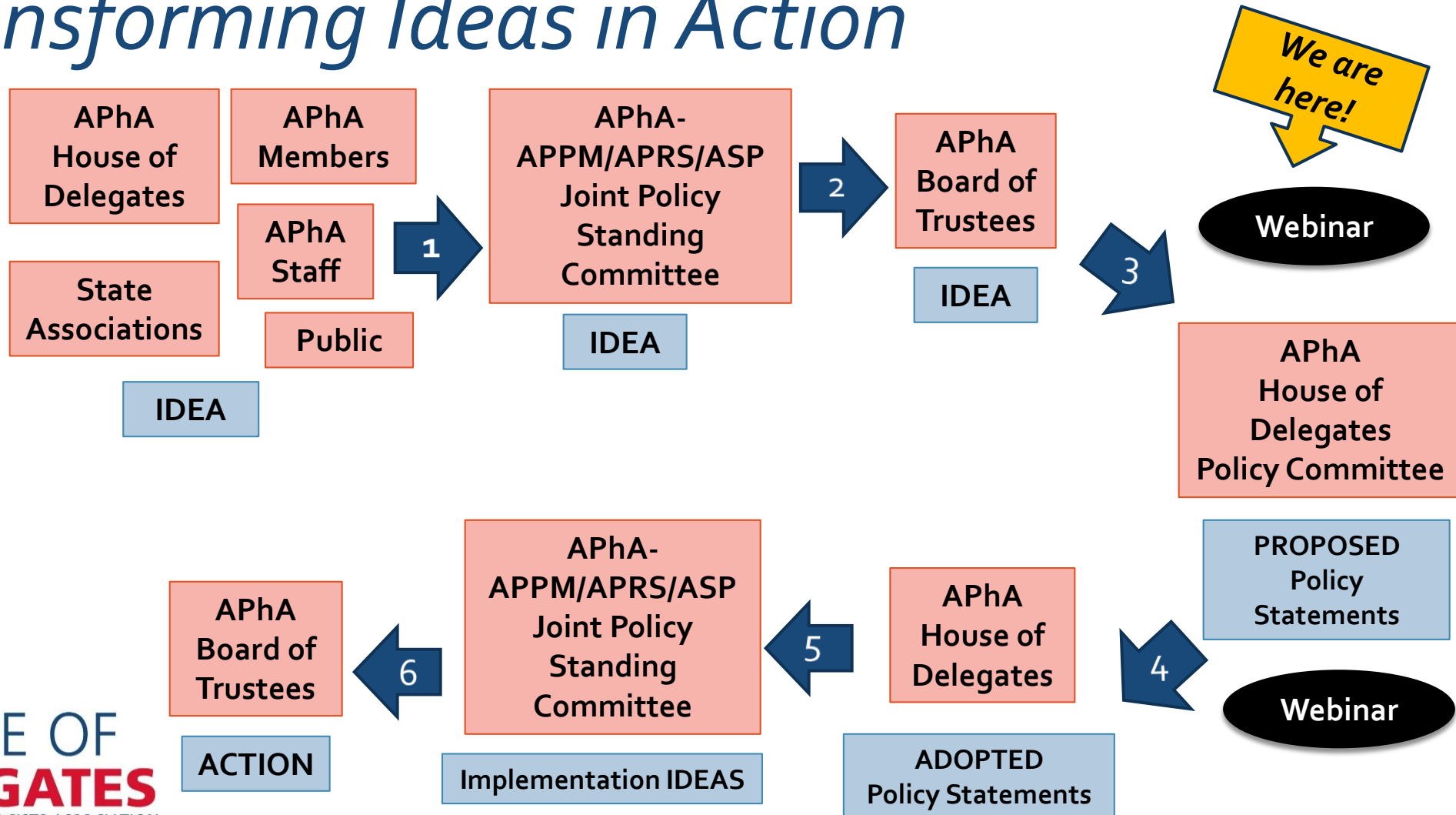
# For Your Information

- To request to speak during the webinar, click on the **raise hand** button. You will be placed in the queue and recognized by the moderator
- Provide written questions/comments in the **chat area** or send email to **HOD@aphanet.org**. Written comments may be limited due to time, but will be made available to the Policy Committee
- The moderator and APhA staff will clarify issues, but will not engage in debate
- Be courteous to your colleagues in your communications
- We want and need your perspective to help shape the direction of the proposed policy statements to be considered by the 2016 House

# Purpose of the House of Delegates

- House of Delegates
  - “serves as a legislative body in the development of association policy. It shall act on such policy recommendations as shall come before it and shall adopt rules or procedures for the conduct of its business.” (*from APhA Bylaws*)
- Association policy directs:
  - Advocacy activities
  - External communications
  - Advisory committees
  - Association activities
- Existing APhA policy can be found online at: [www.pharmacist.com/policy-manual](http://www.pharmacist.com/policy-manual)

# APhA Policy Development Process: *Transforming Ideas in Action*



# Policy Topics for 2016

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Biosimilar Drug Products

Point of Care and Rapid Diagnostic Testing

Medication Management Services

# Policy Topics for 2016

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**Biosimilar Product Selection/Substitution, Education and Training Needs related to Biotechnology and Biosimilar Products**

Point of Care and Rapid Diagnostic Testing

Medication Management Services

# Biosimilar Product Selection/Substitution by the Pharmacist, Education and Training Needs of Pharmacists Related to Biotechnology and Biosimilar Products

## Rationale

- Biosimilar drug products are a fast growing sector of the market and soon pharmacists will begin dispensing and counseling on these products
- The FDA is currently designing regulation that will impact naming, approval process, and other key areas related to biosimilar products
- States have varying legislation in place or introduced for consideration regarding the substitution of these products and how pharmacists should interact with biosimilar products
- Like any other medication, pharmacists should be able to adequately inform patients on these new products upon their release



# Biosimilar Product Selection/Substitution by the Pharmacist, Education and Training Needs of Pharmacists Related to Biotechnology and Biosimilar Products

## What issues(s) should this proposed policy topic address?

- The role of the pharmacist in product substitution/selection and what communication back to the provider should be in place
- Address different naming conventions currently proposed for biosimilar products
- Define necessary education for interaction with biosimilar products from a pharmacist and patient perspective

# Biosimilar Product Selection/Substitution by the Pharmacist, Education and Training Needs of Pharmacists Related to Biotechnology and Biosimilar Products

## What factors have contributed to the problem(s)?

- Multiple naming options have been used or proposed for use from the drug industry
- Lack of clear FDA guidance on the regulation of biosimilar products and process
- Unknown pharmacist role in substitution or selection between the parent drug and biosimilar products

# Biosimilar Product Selection/Substitution by the Pharmacist, Education and Training Needs of Pharmacists Related to Biotechnology and Biosimilar Products

## Why is this proposed policy topic necessary for the profession?

- Pharmacists will need to know their role regarding substitution or selection to provide adequate patient care
  - How are these products similar or dissimilar to generic pharmaceuticals in makeup and processes?
- Naming standardization will be important for pharmacists and patients to prevent confusion and potential medication errors
  - Legislators and decision makers are confused on terms
  - Concern with current naming recommendations and impact on pharmacovigilance
- Pharmacists and student pharmacists need to have knowledge on these drug products to provide proper counseling to patients and effective recommendations to other practitioners when more biosimilar drug products arrive to the market
  - What kind of, if any, notification or approval should be obtained from a prescriber

# Related APhA Policy

*2012, 2007*      *Biologic Drug Products*

1. APhA **encourages the development of safe, effective, and affordable therapeutically equivalent generic/biosimilar versions of biologic drug products**, including clinical trials that assess safety.
2. APhA **encourages the FDA to develop a scientifically based process** to approve therapeutically equivalent generic/biosimilar versions of biologic drug products.
3. APhA should **actively support legislation to hasten the development of an efficient regulatory process** to approve therapeutically equivalent generic versions of biologic drug products.
4. APhA **encourages the FDA to collaborate with drug supply chain and health care stakeholders** in identifying medications that meet the FDA definition of "medically necessary," preventing shortages of these medications, and developing patient care guidelines for managing shortages of these drugs.

# Related APhA Policy

1991 Biotechnology

2005, 1988 Pharmaceutical Biotechnology Products

# BIOSIMILAR PRODUCT SELECTION/SUBSTITUTION, EDUCATION AND TRAINING NEEDS RELATED TO BIOTECHNOLOGY AND BIOSIMILAR PRODUCTS

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**Opportunity for Discussion**

*"What other areas should the proposed policy statement address?"*

# What's your perspective?

1. Do you think pharmacists should be able to substitute biosimilar products like any other medication currently on the market?
2. Should pharmacists be required to obtain additional training to dispense and/or counsel patients receiving a biosimilar drug product?
3. Are you prepared to provide guidance to patients or other practitioners on biosimilar products?
4. What processes should pharmacists follow in regards to prescriber notification, etc?

# Policy Topics for 2016

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Biosimilar Product Selection/Substitution, Education and Training  
Needs related to Biotechnology and Biosimilar Products

**Point of Care and Rapid Diagnostic Testing**

Medication Management Services



# Point of Care and Rapid Diagnostic Testing

## Rationale

- Increasing opportunities for pharmacists to assume expanding roles in the provision of health and wellness services
- Provision of point of care and rapid diagnostic testing services is currently limited due to variability and ambiguity in state legislation and regulation
- Current legislation HR 592 and S 314 focus on the pharmacists ability to provide patient care services, many of which involve point of care testing

# Point of Care and Rapid Diagnostic Testing

## What issues(s) would this proposed policy topic address?

- What defines a point of care or rapid diagnostic test – how do they interrelate?
  - Distinction between point of care and rapid diagnostic testing services
  - What role does this activity play in regards to team-based care?
- Variability among state legislation/regulation on these services
- Continuing education needs on newly implemented point of care tests
- Incorporation of point of care tests into education curriculum
- Reimbursement/compensation for the provision of these services

# Point of Care and Rapid Diagnostic Testing

## What factors have contributed to the problem(s)?

- Lack of consistency among the state legislation and regulation
- Reimbursement/compensation has always been a question
  - Who pays? (Insurance, patient, or someone else)
- Increased research using these types of services showing a positive patient outcome

# Point of Care and Rapid Diagnostic Testing

## Why is this proposed policy topic necessary for the profession?

- As pharmacists' care shifts toward primary and preventive care, POC testing will become a standard practice and tool in pharmacies
  - How does the use of these tools enhance or support pharmacists' role on the healthcare team and patient care outcomes?
- Federal and state legislation should be the same to allow for adequate opportunities to provide care and the use point of care and rapid diagnostic tests

# Related APhA Policy

## *2012, 2003      The Pharmacists Role in Laboratory Monitoring and Health Screening*

1. APhA **supports pharmacist involvement in appropriate laboratory testing and health screening**, including pharmacists directly conducting the activity, supervising such activity, ordering and interpreting such tests, and communicating such tests results.
2. APhA **supports revision of relevant laws and regulations** to facilitate pharmacist involvement in appropriate laboratory testing and health screening as essential components of patient care
3. APhA **encourages research to further demonstrate the value of pharmacist** involvement in laboratory testing and health screening services.
4. APhA **supports public and private sector compensation for pharmacist involvement** in laboratory testing and health screening services.
5. APhA **supports training and education of pharmacists and student pharmacists** to direct, perform, and interpret appropriate laboratory testing and health screening services. Such education and training should include proficiency testing, quality control, and quality assurance.
6. APhA **encourages collaboration and research with other health care providers** to ensure appropriate interpretation and use of laboratory monitoring and health screening results.

# Related APhA Policy

- 2011 The Role and Contributions of the Pharmacist in Public Health
- 2013, 2009, 1987 Sale of Home-use Diagnostic and Monitoring Products
- 1989 Pharmacy-based Screening and Monitoring Services
- 1981 Pharmacist Training in Medical Technology

# POINT OF CARE AND RAPID DIAGNOSTIC TESTING

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**Opportunity for Discussion**

*"What other areas should the proposed policy statement address?"*

# What's your perspective?

1. Does your state pharmacy practice act allow you to offer point of care or rapid diagnostic tests to your patients? What should the policy's aspirational vision be?
2. How do you view these tools helping you deliver patient care?
3. Does your practice setting (employer) allow you to offer these services?
4. Do you have enough training to offer point of care tests or other preventive health screenings?
5. Does your practice setting have the necessary equipment or layout to effectively offer these services?
6. Are patients requesting these services from you at a pharmacy setting?



# Policy Topics for 2016

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Biosimilar Product Selection/Substitution, Education and Training  
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Point of Care and Rapid Diagnostic Testing

**Medication Management Services**

# Medication Management Services

## Rationale

- Pharmacists have an expanding role in medication management opportunities
- The pharmacists patient care process has recently been released and provides the backbone for any service that a pharmacist provides
- Newer types of medication management such as medication synchronization or the appointment based model are gaining in popularity while medication therapy management continues to expand
- There is an inconsistency in the definitions used regarding many medication management services and this is causing confusion among pharmacists and other practitioners

# Medication Management Services

**What issues(s) would this proposed policy topic address?**

- Proper integration of the new pharmacists patient care process
- Lack of standardization in terminology
- Standardization in delivery of medication management services
- Awareness of implementation strategies for these services
- Limitations on the patients who qualify for these services through insurance companies

# Medication Management Services

## What factors have contributed to the problem(s)?

- Pharmacists' Patient Care Process is new and not yet fully understood
- Lack of general understanding of MTM due to multiple definitions and differing workflow models for pharmacists to learn
- Confusion between medication synchronization and appointment based model practices
- Perception that the administrative burden outweighs financial gains seen with practitioner participation

# Medication Management Services

## Why is this proposed policy topic necessary for the profession?

- The Pharmacists Patient Care Process should be known throughout the entire profession to standardize how pharmacists and student pharmacists practice
- MTM has been around for a while, but still needs some tweaks to achieve improved implementation
- Standardization of definitions and processes will allow improvement in comparable research to show positive patient outcomes through medication management services
- Expanded patient populations who qualify for medication management services through their insurance plans

# Related APhA Policy

## **2012** *Contemporary Pharmacy Practice*

1. APhA **asserts that pharmacists should have the authority and support to practice to the full extent** of their education, training, and experience in delivering patient care in all practice settings and activities.
2. APhA **supports continuing efforts** that lead to the establishment of a consistent and accurate perception by the public, lawmakers, regulators, and other health care professionals of the role and contemporary practice of pharmacists.
3. APhA **supports continued collaboration with stakeholders** to facilitate adoption of standardized practice acts, appropriate related laws, and regulations that reflect contemporary pharmacy practice.
4. APhA **supports the establishment of multistate pharmacist licensure agreements** to address the evolving needs of the pharmacy profession and pharmacist-provided patient care.
5. APhA **urges the development of consensus documents**, in collaboration with medical associations and other stakeholders that recognize and support pharmacists' roles in patient care as health care providers.
6. APhA **urges universal recognition of pharmacists as health care providers** and compensation based on the level of patient care provided using standardized and future health care payment models.

# Related APhA Policy

2011 Healthcare Reform

2008 Billing and Documentation of Medication Therapy Management (MTM) Services

2003, 1992 The Pharmacist's Role in Therapeutic Outcomes

1989 Pharmacy-based Screening and Monitoring Services

2013, 1978 Pharmacists Providing Health Care Services

# MEDICATION MANAGEMENT SERVICES

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**Opportunity for Discussion**

*"What other areas should the proposed policy statement address?"*



# What's your perspective?

1. Have you heard about the Pharmacist's Patient Care Process?
2. Have you implemented any medication management services such as MTM, medication synchronization, or the appointment based model in your practice?
3. How should or do these various services interrelate or support each other? Is there confusion among the profession, other practitioners, patients and decision makers?
4. What barriers have you experienced attempting to implement these services?

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# Next Steps

- Policy Committee Meeting
  - October 16-18, 2015
- Webinars to discuss proposed policy statements
  - January-February 2016 (prior to Annual Meeting)
- 2016 Policy Reference Committee Webinar event
  - February 2016

# **NEW:** Earn CPE Credit for HOD Webinars

## Biosimilar Drug Products

October 20, 2015

1:00pm to 2:00pm ET

## Point of Care and Rapid Diagnostic Testing

October 21, 2015

1:00pm to 2:00pm ET

Sign-up at [www.pharmacist.com/apha-house-delegates](http://www.pharmacist.com/apha-house-delegates) (available soon)

# House “keeping”

- Reminder: sign up as a delegate if you have not already done so
  - Contact your state pharmacy association, APhA Academy, or affiliated organization
- Plan to be at APhA2016



**Expanding Opportunities  
through Patient Care**

Annual Meeting & Exposition  
Baltimore, MD March 4-7



# Have a New Business Item?

- New business items due 30 days prior to first HOD session
  - February 3, 2016
- Forms available at: [New Business Item Link](#) or [pharmacist.com/resources](http://pharmacist.com/resources)
- Contact APhA staff with any questions ([hod@aphanet.org](mailto:hod@aphanet.org))

# Thank You!

**Contact HOD Staff**

**or**

**Submit additional comments/questions**

[HOD@aphanet.org](mailto:HOD@aphanet.org)

[pharmacist.com/apha-house-delegates](http://pharmacist.com/apha-house-delegates)