Open Forum on 2016 Proposed Policy Statements

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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 HOD@aphanet.org.
- Select “raise hand” button to request to speak and you will be recognized by the moderator as time permits.
- Note: all comments/questions received will be considered by the Policy Reference Committee.
- This webinar is being recorded for future access on the House of Delegates webpage, www.pharmacist.com/apha-house-delegates.
Webinar Information

• Webinar scheduled for 90 minutes
  • 15 minutes for overview
  • 20 minutes per topic
  • 15 minutes for questions/general information

• Moderators will clarify issues, but will not engage in debate
Policy Committee

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Iowa City, IA

Krystalyn Weaver
Richmond, VA
Policy Process Roadmap
Transforming Ideas into Action

1. APhA House of Delegates
   - State Associations
   - Public
   - APhA Members
   - APhA Staff
   - Gov’t Affairs

2. APhA-APPM/APRS/ASP Joint Policy Standing Committee

3. APhA Board of Trustees
   - IDEA

4. APhA House of Delegates
   - PROPOSED Policy Statements

5. APhA House of Delegates
   - ADOPTED Policy Statements

6. APhA Board of Trustees
   - ACTION

Proposes Implementation PLANS

APhA AMERICAN PHARMACISTS ASSOCIATION

HOUSE OF DELEGATES
Current Policy Information

- Policy Manual
  - Online searchable database:
  - Online PDF version:
2016 Policy Topics

Biologic, Biosimilar, and Interchangeable Biologic Drug Products

Point-of-Care Testing

Medication Optimization Services
Biologic, Biosimilar, and Interchangeable Biologic Drug Products (5 statements)

1. APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products.
   [Refer to Summary of Discussion Items 1, 2.]

2. APhA urges the Food and Drug Administration (FDA) to expedite the development of standards and pathways to evaluate the interchangeability of biologic products.
   [Refer to Summary of Discussion Items 3, 4, 5.]
Biologic, Biosimilar, and Interchangeable Biologic Drug Products (5 statements)

3. APhA recognizes the Food and Drug Administration’s (FDA) Purple Book as the authority on biologic product interchangeability within the United States and discourages development of nonconforming domestic interchangeability lists.

   [Refer to Summary of Discussion Items 6, 7, 8.]
Biologic, Biosimilar, and Interchangeable Biologic Drug Products (5 statements)

4. APhA opposes interchangeable biologic product substitution processes that require authorization, recordkeeping, or reporting beyond generic product substitution processes.

   [Refer to Summary of Discussion Items 8, 9.]

5. APhA encourages scientific justification for extrapolation of indications for biologic products to ensure patient safety and optimal therapeutic outcomes.

   [Refer to Summary of Discussion Items 10, 11.]
Related Existing 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 should initiate educational programs for pharmacists and other health care professionals concerning the determination of therapeutic equivalence of generic/biosimilar versions of biologic drug products.

**1991 Biotechnology**
- APhA encourages the development of appropriate educational materials and guidelines to assist pharmacists in addressing the ethical issues associated with the appropriate use of biotechnology-based products.

**2005, 1988 Pharmaceutical Biotechnology Products**
- APhA recognizes the urgent need for education and training of pharmacists and student pharmacists relative to the therapeutic and diagnostic use of pharmaceutical biotechnology products. APhA, therefore, supports the continuing development and implementation of such education and training.

- APhA supports state substitution laws which emphasize the pharmacists’ professional responsibility for determining, on the basis of available evidence, including professional literature, clinical studies, drug recalls, manufacturer reputation and other pertinent factors, that the drug products they dispense are therapeutically effective.
Biologic, Biosimilar, and Interchangeable Biologic Drug Products

Time for Discussion
Biologic, Biosimilar, and Interchangeable Biologic Drug Products

1. APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products.

2. APhA urges the Food and Drug Administration (FDA) to expedite the development of standards and pathways to evaluate the interchangeability of biologic products.

3. APhA recognizes the Food and Drug Administration’s (FDA) Purple Book as the authority on biologic product interchangeability within the United States and discourages development of nonconforming domestic interchangeability lists.

4. APhA opposes interchangeable biologic product substitution processes that require authorization, recordkeeping, or reporting beyond generic product substitution processes.

5. APhA encourages scientific justification for extrapolation of indications for biologic products to ensure patient safety and optimal therapeutic outcomes.
Point-of-Care Testing
Point-of-Care Testing (6 statements)

1. APhA recognizes the value of pharmacist-provided point-of-care testing and related clinical services and promotes the provision of these tests and services in accordance with the Joint Commission of Pharmacy Practitioners Pharmacists’ Patient Care Process.
   [Refer to Summary of Discussion Items 3, 4, 5.]

2. APhA supports laws, regulations, and policies that enable pharmacists to order, perform, interpret, and act on the results of point-of-care testing consistent with their role in team-based care.
   [Refer to Summary of Discussion Items 3, 4, 5, 6, 7, 8, 9, 10.]
Point-of-Care Testing (6 statements)

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

   [Refer to Summary of Discussion Items 11, 12.]

4. APhA encourages use of education programs and resources to facilitate practice implementation of point-of-care testing and related clinical services.

   [Refer to Summary of Discussion Items 13, 14.]
Point-of-Care Testing (6 statements)

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

[Refer to Summary of Discussion Item 15.]

6. APhA supports access to, coverage of, and payment for both point-of-care tests and related clinical services provided by pharmacists.

[Refer to Summary of Discussion Items 16, 17.]
Related Existing Policy

- APhA supports the need to protect the health of the American people through proper instruction in the safe and effective use of the more complex home-use diagnostic and monitoring products.
- APhA supports the promotion of the pharmacist as a widely available and qualified health care professional to advise patients in the use of home-use diagnostic and monitoring products.

2012, 2013 The Pharmacist’s Role in Laboratory Monitoring and Health Screening
- 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 test results.
- 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.
- APhA encourages research to further demonstrate the value of pharmacist involvement in laboratory testing and health screening services.
- APhA supports public and private sector compensation for pharmacist involvement in laboratory testing and health screening services.
- 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.
- APhA encourages collaboration and research with other health care providers to ensure appropriate interpretation and use of laboratory monitoring and health screening results.

2011 The Role and Contributions of the Pharmacist in Public Health
- In concert with the American Public Health Association’s (APHA) 2006 policy statement, “The Role of the Pharmacist in Public Health,” APhA encourages collaboration with APHA and other public health organizations to increase pharmacists’ participation in initiatives designed to meet global, national, regional, state, local, and community health goals.

1981 Pharmacist Training in Medical Technology
- APhA supports the education and training of pharmacists in the ordering and interpretation of laboratory tests as they may relate to the usage, dosing, and administration of drugs.
- APhA opposes requiring certification of pharmacists as medical technologists for the practice of pharmacy.

1989 Pharmacy-based Screening and Monitoring Services
- APhA supports projects that demonstrate and evaluate various pharmacy-based screening and monitoring services.
Point-of-Care Testing

Time for Discussion
Point-of-Care Testing

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

2. APhA supports laws, regulations, and policies that enable pharmacists to order, perform, interpret, and act on the results of point-of-care testing consistent with their role in team-based care.

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

4. APhA encourages use of education programs and resources to facilitate practice implementation of point-of-care testing and related clinical services.

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

6. APhA supports access to, coverage of, and payment for both point-of-care tests and related clinical services provided by pharmacists.
Medication Optimization Services within the Patient Care Process
Medication Optimization Services within the Patient Care Process (6 statements)

1. APhA asserts that pharmacist-directed “medication optimization services” encompass patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access.

   [Refer to Summary of Discussion Items 1, 2, 3.]

2. APhA calls for the interprofessional development and adoption of a framework to describe the spectrum of medication optimization services.

   [Refer to Summary of Discussion Items 4, 5, 6, 7, 8.]
Medication Optimization Services within the Patient Care Process (6 statements)

3. APhA calls for pharmacists and student pharmacists to provide medication optimization services in accordance with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process in any practice setting.
   [Refer to Summary of Discussion Items 8, 9, 10.]

4. APhA supports technologies and standards for multidirectional data exchange related to medication optimization services that facilitate timely communication among pharmacists, patients, other health care providers, pharmacies, health systems, and payers.
   [Refer to Summary of Discussion Item 11.]
Medication Optimization Services within the Patient Care Process (6 statements)

5. APhA encourages health care providers, including pharmacists, to refer patients for pharmacist-provided medication optimization services, as appropriate.

   [Refer to Summary of Discussion Item 12.]

6. APhA supports coverage of and payment for pharmacist-provided patient care services, including medication optimization services within traditional and value-based payment systems in accordance with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacist’s Patient Care Process.

   [Refer to Summary of Discussion Items 8, 13.]
Related Existing Policy

2012 Contemporary Pharmacy Practice
• 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.
• 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.
• APhA supports continued collaboration with stakeholders to facilitate adoption of standardized practice acts, appropriate related laws, and regulations that reflect contemporary pharmacy practice.
• APhA supports the establishment of multistate pharmacist licensure agreements to address the evolving needs of the pharmacy profession and pharmacist-provided patient care.
• 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.
• 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.

2011 Pharmacist’s Role in Healthcare Reform
• APhA affirms that pharmacists are the medication experts whose accessibility uniquely positions them to increase access to and improve quality of health care while decreasing overall costs.
• APhA asserts that pharmacists must be recognized as the essential and accountable patient care provider on the health care team responsible for optimizing outcomes through medication therapy management (MTM).
• APhA asserts the following: (a) Medication Therapy Management Services: Definition and Program Criteria is the standard definition of MTM that must be recognized by all stakeholders. (b) Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model, as adopted by the profession of pharmacy, shall serve as the foundational MTM service model.
• APhA asserts that pharmacists must be included as essential patient care provider and compensated as such in every health care model, including but not limited to, the medical home and accountable care organizations.
• APhA actively promotes the outcomes-based studies, pilot programs, demonstration projects, and other activities that document and reconfirm pharmacists’ impact on patient health and well-being, process of care delivery, and overall health care costs.

2008 Billing and Documentation of Medication Therapy Management (MTM) Services
• 1. APhA encourages the development and use of a system for billing of MTM services that:
   (a) includes a standardized data set for transmission of billing claims;
   (b) utilizes a standardized process that is consistent with claim billing by other healthcare providers;
   (c) utilizes a billing platform that is accepted by the Centers for Medicare and Medicaid Services (CMS) and is compliant with the Health Insurance Portability and Accountability Act (HIPAA)
• 2. APhA supports the pharmacist’s or pharmacy’s choice of a documentation system that allows for transmission of any MTM billing claim and interfaces with the billing platform used by the insurer or payer.
• 4. APhA supports efforts to further develop CPT codes for billing of pharmacists’ services, through the work of the Pharmacist Services Technical Advisory Coalition (PSTAC).

2003, 1992 The Pharmacist’s Role in Therapeutic Outcomes
• APhA affirms that achieving optimal therapeutic outcomes for each patient is a shared responsibility of the health care team.
• APhA recognizes that a primary responsibility of the pharmacist in achieving optimal therapeutic outcomes is to take an active role in the development and implementation of a therapeutic plan and in the appropriate monitoring of each patient.

2013, 1978 Pharmacists Providing Health Care Services
• APhA supports the study and development of new methods and procedures whereby pharmacists can increase their ability and expand their opportunities to provide health care services to patients.
Medication Optimization Services within the Patient Care Process

Time for Discussion
Medication Optimization Services within the Patient Care Process

1. APhA asserts that pharmacist-directed “medication optimization services” encompass patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access.

2. APhA calls for the interprofessional development and adoption of a framework to describe the spectrum of medication optimization services.

3. APhA calls for pharmacists and student pharmacists to provide medication optimization services in accordance with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process in any practice setting.

4. APhA supports technologies and standards for multidirectional data exchange related to medication optimization services that facilitate timely communication among pharmacists, patients, other health care providers, pharmacies, health systems, and payers.

5. APhA encourages health care providers, including pharmacists, to refer patients for pharmacist-provided medication optimization services, as appropriate.

6. APhA supports coverage of and payment for pharmacist-provided patient care services, including medication optimization services within traditional and value-based payment systems in accordance with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacist’s Patient Care Process.
General Discussion

Biologic, Biosimilar, and Interchangeable Biologic Drug Products

Point-of-Care Testing

Medication Optimization Services within the Patient Care Process
House Keeping

• **New Business Items are due** February 3, 2016
• House Committee reports available at [www.pharmacist.com/apha-house-delegates](http://www.pharmacist.com/apha-house-delegates)
• Contact your state association or recognized national organization to secure your Delegate seat
  • **All Delegate materials will be sent electronically this year unless you request a hard copy at this link:** [https://fs3.formsite.com/apha/form249/index.html](https://fs3.formsite.com/apha/form249/index.html)
  • *A limited number* of Delegate books will be available onsite

• **Policy Review Committee Webinars**
  February 3, 6:00 – 7:30pm (ET)
  February 10, 12:00-1:30pm (ET)

• **New Business Item Webinars**
  February 17, 12:00 – 1:30pm (ET)
  February 24, 7:00 – 8:30pm (ET)
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  4. Find one of the three the “HOD Issue” communities
  5. Click “Join” and follow the prompts on your screen
2016 House of Delegates

**House of Delegates First Session**
Friday, March 4, 3:00 to 5:00pm

**Policy Committee Open Hearing**
Sunday, March 6, 1:00 to 3:00pm

**New Business Review Committee Open Hearing**
Saturday, March 5, 1:00 to 2:30pm

**House of Delegates Final Session**
Monday, March 7, 1:30 to 4:30pm

**APHa2016**
Expanding Opportunities through Patient Care
Annual Meeting & Exposition
Baltimore, MD March 4–7
Ideas for Future Policy Topics

• Are there topics we should consider for the 2017 House of Delegates?
  • These are topics needing more development than through the new business process
  • Tell us now or send to HOD@aphanet.org
Open Forum on 2016 Proposed Policy Topics

Thank you for your time and attention!

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HOD@aphanet.org