Objectives

1. Briefly review the purpose of the House of Delegates
2. Provide short overview of the policy development process
3. Outline the 2019-2020 proposed policy topics
4. Briefly discuss next steps in the process

Webinar scheduled for 60 minutes.
(10 minutes for intro/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 2020 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
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.
Policy Topics for 2020

Accountability of Pharmacists in Patient Care
Recognition of Pharmaceuticals as a National Strategic Asset
Specialty Pharmacy Scope, Services, and Limited Drug Distribution
Accountability of Pharmacists in Patient Care

Rationale

As the healthcare system shifts from volume to value-based reimbursement, there is a need to define the accountability of the pharmacist within value-based care practice models.

As part of a team-based care model, defining the pharmacist’s level of accountability could impact decision making responsibilities to a patient’s care plan, reimbursement opportunities, and exposure to increased liability due to expanded scope of practice.

What issues should this proposed policy topic address?

Defining a pharmacist’s accountability to ensure medications are used appropriately and patient care services are provided in the best interest of the patient, beyond what is defined by the Drug Enforcement Agency (DEA) related to controlled substances.

Articulate the role and accountability of pharmacists as part of team-based care in alignment with the Joint Commission of Pharmacy Practitioners (JCPP) Patient Care Process.

Consideration of how a pharmacist may be impacted through different payment models, exposure to increased liability due to increased accountability, and expanded decision-making opportunities as part of a healthcare team.
Accountability of Pharmacists in Patient Care

What factors have contributed to the problem(s)?

- Expanded scope of pharmacy practice and an expanded role of the pharmacist on healthcare teams
- Lack of clarity by the public and as to the role of the pharmacist in ensuring appropriate medication use and provision of patient care services.
- Value-based payment models attributing outcomes and to specific activities within a patient-centered healthcare team
- A continued shift within healthcare and pharmacy practice to focus on patient outcomes versus solely dispensing a product

Why is this proposed policy topic necessary for the profession?

- Statements on this topic will promote medication safety and clarify the pharmacist’s role in collaborative care decision making.
- There is a need to position the pharmacist to best utilize the medication knowledge and patient care service delivery as part of expanding value-based care models.
- Reimbursement for services provided within expanded payment and practice models will be impacted based on what care and service each practitioner is accountable to provide.
Related APhA Policies

- 2014 Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents
- 2011 Pharmacist’s Role in Health Care Reform
- 2009 Pharmacist’s Role in Patient Safety
- 2002 Professional Practice Regulation
- 1991 Mission of Pharmacy

ACCOUNTABILITY OF PHARMACISTS IN PATIENT CARE

Opportunity for Discussion
Accountability of Pharmacists in Patient Care

What is your perspective?
• What other areas should the proposed policy statement address?

• What are your concerns, questions, etc. about defining a pharmacist’s accountability within team-based care models?

• What gaps in existing APhA policy need to be addressed by this topic?

• How do you see the pharmacist's role in value-based care models expand over the next 3-10 years and do you see this topic as helping this expansion?

Policy Topics for 2020

Accountability of Pharmacists in Patient Care
Recognition of Pharmaceuticals as a National Strategic Asset
Specialty Pharmacy Scope, Services, and Limited Drug Distribution
Recognition of Pharmaceuticals as a National Strategic Asset

Rationale

Development of medications and other pharmaceutical products have shifted outside the United States where there is varying ability to provide proper oversight by the FDA when compared to the drug development processes within the United States.

The number of sites and companies developing active ingredient products used in the development of pharmaceuticals has increased and adherence to proper standards within these facilities are increasingly harder to inspect.

Maintenance of a supply of pharmaceuticals, deemed a national strategic asset, may ensure access to safe and unadulterated medications in a time of need.

Recognition of Pharmaceuticals as a National Strategic Asset

What issues should this proposed policy topic address?

Adherence to appropriate active product ingredient and drug development standards.

Highlighting potential National security risks associated with restrictions in product distribution between countries.

Drug shortages due to a failure in the medication supply chain from a failure to adhere to appropriate standards.
Recognition of Pharmaceuticals as a National Strategic Asset

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

- Drug shortages due to various issues continue to hinder access to appropriate medications.

- Adverse events have been reported for medications linked back to improper development standards.

- The development of medications by pharmaceutical industries has shifted outside of the borders of the United States and provides an increasing challenge for inspecting active product ingredient and final product development sites by regulatory agencies.

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

- A reliable supply of medications is essential for patients and public health.

- Drug shortages negatively impact public health and force adjustments to patient care plans.

- A pharmacist is unable to effectively or accurately do their job if a patient doesn’t have access to a medication or does not trust that a medication will be safe and effective.
Related APhA Policies

2012  *Drug Supply Shortages and Patient Care*
2004  *Protecting the Integrity of the Medication Supply*
1989  *Impact of Drug Distribution Systems on Integrity and Stability of Drug Products*
2004, 1970  *Licensure/Registration of Drug Manufacturers*

**RECOGNITION OF PHARMACEUTICALS AS A NATIONAL STRATEGIC ASSET**

*Opportunity for Discussion*
Recognition of Pharmaceuticals as a National Strategic Asset

What is your perspective?

- What other areas should the proposed policy statement address?
- Do you think APhA’s existing policy covers the issues discussed in the background information provided?
- What experience have you had with patient questions on the safety of medications or specific ingredients in medications?
- What concerns, if any, do you have with the development of medications outside of the United States?

Policy Topics for 2020

Accountability of Pharmacists in Patient Care
Recognition of Pharmaceuticals as a National Strategic Asset
Specialty Pharmacy Scope, Services, and Limited Drug Distribution
Specialty Pharmacy Scope, Services, and Limited Drug Distribution

Rationale

Silos in healthcare inhibit a patient’s ability to get access to proper services.

The pharmacy profession exists in a silo as it relates to referring patients for services. This includes other providers referring patients to pharmacists and pharmacists referring patients to other pharmacists.

Technology is one barrier to allowing referrals amongst pharmacists, but the current culture of the healthcare community would need to change to accept a new referral system that incorporates pharmacists and the services they can provide.

What issues should this proposed policy topic address?

Definition of specialty pharmacy / pharmacist
The flow of information to providers and patients regarding specialty medications.
Access to specialty medications .
Patient safety should always be a priority and review of existing APhA policy regarding patient safety and related to specialty medications should be completed.
Consider addressing education needs more broadly as opposed to a product specific format (i.e. REMs)
Specialty Pharmacy Scope, Services, and Limited Drug Distribution

What factors have contributed to the problem(s)?

- The cost and complexity of new medication therapies that fall under the specialty medication umbrella.
- Increased development of specialty medication products in the pipeline.
- Limited drug distribution networks impede patient access to medications.
- Imprecise usage of terminology and a lack of standardization of overall terminology have led to confusion in this area.

Why is this proposed policy topic necessary for the profession?

- Limited drug distribution and siloed access to specialty medications affects patient outcomes due to fragmentation of care.

- Future drug development is trending toward an increase in specialty products.

- Confusion within the profession of pharmacy as to which pharmacies can access specialty medications and where to refer patients to when in need of one of these medications.
Related APhA Policies

1994  Product Licensing Agreements and Restricted Distribution
1978  Post-Marketing Requirements (Restricted Distribution)
2004, 1966  Distribution Programs: Circumvention of the Pharmacist
2004, 1968  Manufacturers’ Pricing Policies
1985  Pharmaceutical Pricing
1985  Reduction of Federal Laws and Regulations (Paperwork Burden)

SPECIALTY PHARMACY SCOPE, SERVICES, AND LIMITED DRUG DISTRIBUTION

Opportunity for Discussion
**Specialty Pharmacy Scope, Services, and Limited Drug Distribution**

**What is your perspective?**

- What other areas should the proposed policy statement address?
- What experience have you had with varying definitions of specialty medications in your practice setting?
- How have patients been able to access specialty medications in your practice setting?
- What areas of education, if any, do you believe are still needed for pharmacists related to specialty medications?
- Should practice setting matter when dispensing and counseling on specialty medications?
Next Steps

Policy Committee Meeting
• **October 18-20, 2019**

Webinars to discuss proposed policy statements
• **January 15\(^{th}\) and 22\(^{nd}\) in 2020**

Policy Review Committee Webinar
• **January 29\(^{th}\) and February 5\(^{th}\) in 2020**

New Business Review Committee Webinar
• **February 26\(^{th}\) and March 4\(^{th}\) in 2020**

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 APhA2020!
• [www.aphameeting.org](http://www.aphameeting.org)
Have a New Business Item?

New business items due **30 days prior** to first HOD session
- February 19, 2020

Forms available at:
- New Business Item Link or https://www.pharmacist.com/HODresources
  - *The New Business Item Form will download as a word document*

Contact APhA staff with any questions (hod@aphanet.org)

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**THANK YOU!**

Contact HOD Staff or submit additional questions/comments!
- HOD@aphanet.org
- pharmacist.com/apha-house-delegates