MEMORANDUM

TO: Delegates and Alternate Delegates to the APhA House of Delegates
FROM: Joey Mattingly, Speaker of the APhA House of Delegates
RE: Delegate Reference Materials and Important Information

Congratulations on your appointment as a Delegate or Alternate Delegate to the APhA House! I appreciate your willingness to serve the profession and your interest in the policy development process. Within this booklet, you will find schedules, background information, and reports to help you prepare for your important role in the House. Extra copies of this booklet will not be available, so please remember to bring this information with you.

Included within your Delegate Reference Materials, you will find:

- APhA House of Delegates Schedule At A Glance;
- 2019-2020 APhA Policy Committee Report; and
- 2019-2020 APhA New Business Items received to date.

**Policy-Related Webinars Available**
If you were unavailable to participate in any of the committee-related webinars, I encourage you to visit [http://pharmacist.com/learn-about-0](http://pharmacist.com/learn-about-0) to view an archived version of the webinars related to the policy topics, policy committee report, or the policy review committee report. These webinars will present you with additional background information related to the subjects and provide insight into the questions raised by your fellow Delegates.

To provide an overview of the New Business Items to be discussed in this year’s House, I will host two **New Business Item Webinar sessions** (one of which was held on February 26) the next is scheduled **March 4 from 6:00-7:30pm**. If you find that you are unable to participate in one of the live webinars, an archived version will be available online soon after. These webinars will aid you in learning more about the items submitted prior to the Annual Meeting and provides you an opportunity to prepare for the Open hearing and House discussions. You must register to participate in the webinars, register at [http://pharmacist.com/learn-about-0](http://pharmacist.com/learn-about-0).

If you are new to the House of Delegates, or if you just desire a refresher course on the rules and procedures of the APhA House, I encourage you to view the **Delegate Orientation Webinar recording**.

**Onsite Delegate Registration – Maryland Ballroom C Registration Desk**
Registration for the First Session will open from **12:00pm-3:00pm on Friday, March 20, 2020**. Delegate registration will be located at the **Gaylord National Resort & Convention Center**. Registration for the Final session will be available in the same location, from **11:00am-1:30pm on Monday, March 23, 2020**. There is no need to check-in with the House of Delegates prior to these registration times.
Delegates **ONLY** are required to complete the following steps below prior to each House session:

**Step 1** – Report to the Delegate registration area outside of the **Maryland Ballroom A-D**. Please remember to bring your delegate reference materials and your name badge with you to registration. Please allocate sufficient time to check in prior to the start time of the House.

**Step 2** – Scan your name badge, pick up your Delegate ribbon (if needed), and pick up your electronic voter keypad from APhA staff. Note: you must return the keypad to staff at the conclusion of each House session.

Delegates who have not pre-registered will be required to sign a waiver agreeing to pay a replacement fee if the voter keypad is not returned to APhA staff. **Also, Alternate Delegates are not required to register or check-in unless asked to substitute for a Delegate. When registering in place of a Delegate, Alternate Delegates will follow the same check-in procedures as a Delegate.**

**House of Delegates Office Hours**
If you have specific questions regarding the policy development process or general House procedures, I encourage you to schedule an appointment to speak with me or the House Parliamentarian during the Annual Meeting. See your Schedule At-A-Glance for House of Delegates Office Hours or contact APhA staff at [hod@aphanet.org](mailto:hod@aphanet.org) for further information.

**Planning for the 2021 House**
It’s never too early to plan ahead! In mid-April, APhA will begin the policy development process for 2020. With that in mind, I encourage you to begin thinking about the potential policy topics that should be addressed by the House of Delegates. Within this booklet, you will find a call for potential policy topics. I encourage you to bring your completed form to the meeting, or submit the form electronically by early **March 30, 2020** at [http://fs3.formsite.com/apha/form220/index.html](http://fs3.formsite.com/apha/form220/index.html).

On a related note, there are a number of opportunities for you to serve APhA on one of the House of Delegates committees. If you are interested in serving during the 2020-2021 policy development process, I encourage you to complete the committee volunteer interest form by **April 17, 2020** at [http://fs3.formsite.com/apha/form217/index.html](http://fs3.formsite.com/apha/form217/index.html).

Thank you again for your interest and service to the 2020 House of Delegates! I look forward to seeing you at the National Harbor! If you have any questions about House activities, please visit [http://www.pharmacist.com/apha-house-delegates](http://www.pharmacist.com/apha-house-delegates) or contact APhA staff at [hod@aphanet.org](mailto:hod@aphanet.org).

Sincerely,

![Joey Mattingly, PharmD, PhD](signature)

**Joey Mattingly, PharmD, PhD**
**APhA Speaker of the House of Delegates**

![Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA](signature)

**Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA**
**Secretary, APhA House of Delegates**
**APhA Executive Vice President & Chief Executive Officer**

**Staff Liaisons:**
- Mitchel Rothholz, RPh, MBA, Chief Strategy Officer
- Brian Wall, PharmD, Associate Director, Governance
- Wendy Gaitwood, Project Manager, Executive Office & Governance

**Online:** [http://www.pharmacist.com/apha-house-delegates](http://www.pharmacist.com/apha-house-delegates)  **Email:** [hod@aphanet.org](mailto:hod@aphanet.org)
# House of Delegates Schedule at a Glance

## Friday, March 20

<table>
<thead>
<tr>
<th>Time</th>
<th>Location</th>
<th>Event</th>
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<tbody>
<tr>
<td>12:00 pm – 2:45 pm</td>
<td>Maryland Ballroom C</td>
<td>Delegate Registration</td>
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<tr>
<td>1:00 pm – 2:15 pm</td>
<td>Magnolia 1</td>
<td>APhA-APPM Delegate Caucus</td>
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<tr>
<td>1:00 pm – 2:15 pm</td>
<td>Magnolia 3</td>
<td>APhA-APRS Delegate Caucus</td>
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<tr>
<td>2:45 pm – 5:15 pm</td>
<td>Maryland Ballroom A-D</td>
<td>House of Delegates – First Session   (Be seated by 2:30 pm)</td>
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## Saturday, March 21

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<tr>
<td>1:00 pm – 2:30 pm</td>
<td>Potomac 3-4</td>
<td>New Business Review Committee Open Hearing</td>
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## Sunday, March 22

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<tr>
<th>Time</th>
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<th>Event</th>
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<tr>
<td>11:30 am - 12:30 pm</td>
<td>Potomac 5</td>
<td>Bringing the Code of Ethics to Life: Conditions, State Boards, and Moral Distress – A Townhall Discussion</td>
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<tr>
<td>1:00 pm – 3:00 pm</td>
<td>Potomac 3-4</td>
<td>Policy Committee Open Hearing</td>
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## Monday, March 23

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<td>Potomac 1-2</td>
<td>APhA-APPM Delegate Caucus</td>
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<td>9:00 am – 11:30 am</td>
<td>Potomac 3-4</td>
<td>APhA-APRS Delegate Caucus</td>
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<tr>
<td>11:00 am – 1:30 pm</td>
<td>Maryland Ballroom C Registration Desk</td>
<td>Delegate Registration</td>
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<tr>
<td>1:30 pm – 4:30 pm</td>
<td>Maryland Ballroom A-D</td>
<td>House of Delegates – Final Session   (Be seated by 1:15 pm)</td>
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## House of Delegates Office Hours

<table>
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<tr>
<td>Maryland Ballroom C</td>
<td>Thursday, March 19 3:00 pm – 6:00 pm</td>
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<td>Friday, March 20 7:30 am – 3:00 pm</td>
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<td>Saturday, March 21 8:00 am – 3:00 pm</td>
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<tr>
<td></td>
<td>Sunday, March 22 8:00 am – 3:00 pm</td>
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<tr>
<td></td>
<td>Monday, March 23 7:30 am – 1:00 pm</td>
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</tbody>
</table>
## FRIDAY, MARCH 20 • House of Delegates – First Session

**Agenda**

1. Call to Order
2. Review of Voting Procedures
3. Credentials Report*
4. Adoption of Agenda and Rules*
5. Introduction of Head Table
6. Report of the Speaker, APhA House of Delegates
7. APhA House Rules Review Committee Report*
8. New Business Procedure
9. Report of the Committee on Nominations*
10. Speaker-elect Candidate Introductions
11. APhA Policy Review Committee Report – (Received)
12. APhA Policy Review Committee Report Considerations*
13. APhA Policy Committee Report (Received)
14. APhA Policy Committee Report Considerations*
15. Recognition of APhA and Academy Officers
16. Meet the Candidates for the 2020 APhA Board of Trustees Election
17. Housekeeping Announcements
18. Adjournment of the First House Session

## MONDAY, MARCH 23 • House of Delegates – Final Session

**Agenda**

1. Call to Order
2. Review of Voting Procedures
3. Credentials Report*
4. Adoption of Agenda*
5. Consideration of Unfinished Business
   a. APhA Policy Committee Report*
   b. APhA Policy Review Committee Report*
6. Speaker-elect Candidate Speeches
7. Speaker-elect Election*
8. Consideration of New Business*
9. Announcement of Election Results
10. Installation of the 2020-2021 Speaker-elect
11. Installation of the APhA Board of Trustees
12. Installation of the 2020-2021 APhA President
13. Recommendations from APhA Members
14. Closing Announcements
15. Adjournment of the 2020 APhA House of Delegates

*Please note: (*) asterisk indicates potential opportunities to cast votes.
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<thead>
<tr>
<th>Delegation</th>
<th>Delegates</th>
<th>Alt. Delegates</th>
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<tr>
<td>AACP (Delegates-2 Out of 2)</td>
<td>Anne Lin</td>
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<td>Lynette Bradley-Baker</td>
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<td>Tessa Hastings</td>
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<td>Yifei Liu</td>
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* The numbers reflect the allotted delegates per delegation, not the actual listed delegates.
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<th>Delegates</th>
<th>Alt. Delegates</th>
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<td>APhA-ASP (Delegates-28 Out of 28)</td>
<td>Alvin Leung, Amanda Hammond, Andrea McDonald, Andrew Stephens, Ashley Dike, Asim Ali, Augustine Bui, Claire Schumann, Cortni Hicks, David Giang, Eduardo Rizo, Eric Dobberpuhl, Ian Floresta, Jaemie Myers, Jaspreet Bhullar, Justin Bladecki, Kaveh Oloumi, Kayla Lucas, Kristina Fritsch, Laura Sosinski, Lauren Dickerson, Laurie Plewinski, Michael Behal, Samantha Tomberlin, Stanley Dowell, Sydney Tu, Tessa Schnelle, Zachary Hitchcock</td>
<td>Christian Isch, Dominique Taylor, Elizabeth Wandling, Heather Garr, Jessica Gierka, John Roberts, Judy Chan, Martin Bailey, Megan Byrne, Miranda Craft, Morgan Olhausen, Sidrah Alam</td>
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<td>Arnold Clayman, Lisa Morris</td>
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<td>Brianna Palowitch, Chad Worz</td>
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<td>ASHP (Delegates-1 Out of 1)</td>
<td>Georgia Luchen</td>
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<td>Clifford Young, Elizabeth Johnson, Ethan Huynh, George Yasutake, Jennifer Courtney, Kathleen Besinque, Khanh-Long Thai, Mike Pavlovich, Richard Dang, Steven Gray, Veronica Bandy</td>
<td>Noelle Lee, Sarah McBane</td>
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<td>Karen Hoang, Philip Hritcko, Valentino Caruso</td>
<td>Julie Dopheide, Sarah Melton</td>
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<td>CPNP (Delegates-2 Out of 2)</td>
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<td>Kevin Musto, Kimberly Robbins</td>
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<td>William Harbester</td>
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<td>DISTRICT OF COLUMBIA (Delegates-2 Out of 2)</td>
<td>Tamara McCants, Terri Moore</td>
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<td>FLORIDA (Delegates-7 Out of 7)</td>
<td>Angola Garcia, Barbara Beadle, David Mackarey, Joseph Scuro</td>
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* The numbers reflect the allotted delegates per delegation, not the actual listed delegates.
FORMER SPEAKERS (Delegates-15 Out of 15)
Adele Pietrantoni
Bethany Boyd
Betty Jean Harris
Craig Pedersen
Elizabeth Valentine
Hazel Pipkin
Leonard Camp
Lucinda Maine
Michael Mone
Michael Smith
Pamela Whitmire
Susan Bartlemay
Valerie Prince
William Riffe
Wilma Wong

GEORGIA (Delegates-5 Out of 5)
Christopher Thurmond
David Carver
Johnathan Hamrick
Joshua Kinsey
Liza Chapman

GUAM (Delegates-0 Out of 2)

HAWAII (Delegates-2 Out of 3)
Jarred Prudencio
Marcella Chock

HOPA (Delegates-2 Out of 2)
Bethany Sibbitt
David Deremer

HOPA (Alt. Delegates)
Jacky Olin

IDAHO (Delegates-3 Out of 3)
Donald Smith
Jennifer Adams
Nicole Chopski

IDAHO (Alt. Delegates)
Ryan Fuchs

ILLINOIS (Delegates-6 Out of 6)
Cynthia Russell
Emily Wetherolt
Garth Reynolds
Laura Licari
Miranda Wilhelm
Starlin Haydon-Greating

ILLINOIS (Alt. Delegates)
Henry Gould

INDIANA (Delegates-4 Out of 4)
Broxton Davis
Chelsea Baker
Mark Bunton
Tamara Fox

INDIANA (Alt. Delegates)

IOWA (Delegates-4 Out of 4)
Lynn Thoma
Meagan Williams
IOWA (Alt. Delegates)
Cheryl Clarke
Connie Connolly
Diane Reist
Steve Firman

KANSAS (Delegates-3 Out of 3)
Carl Benton
Emily Prohaska
Robert Emerson

KANSAS (Alt. Delegates)
Jessica Bates

KENTUCKY (Delegates-4 Out of 4)
Catherine Hanna
Chris Harlow
Don Kupper
Kimberly Croley

KENTUCKY (Alt. Delegates)
Martika Martin

LOUISIANA (Delegates-3 Out of 3)
Beverly Walker
Peggy Van
William Kirchain

LOUISIANA (Alt. Delegates)
Robert Toups

MAINE (Delegates-2 Out of 2)
Daniel Mickool
Kenneth McCall

MAINE (Alt. Delegates)
Peter Holland

MARYLAND (Delegates-5 Out of 5)
Erin South
Hoai-An Truong
James Dvorsky
Lauren Haggerty
Matthew Shimoda

MARYLAND (Alt. Delegates)
Kerry Cormier
Seth Weinstock

MASSACHUSETTS (Delegates-2 Out of 2)
Kim Tanzer
Trisha LaPointe

MICHIGAN (Delegates-4 Out of 5)
Charles Mollien
Dianne Malburg
Larry Wagenknecht
Mark Bomia

MINNESOTA (Alt. Delegates)

MINNESOTA (Alt. Delegates)

MISSISSIPPI (Delegates-3 Out of 3)
David Allen
Lauren Bloodworth
Olivia Strain

MISSISSIPPI (Alt. Delegates)
Leigh Ann Ross

MISSOURI (Delegates-4 Out of 4)
Anne Eisenbeis
John Pieper
Michaela Newell
Sarah Oprinovich

MISSOURI (Alt. Delegates)
Francisco Franco

MONTANA (Delegates-2 Out of 2)
Lyndee Fogel
Monica Orsborn

NAVY (Delegates-2 Out of 2)
Christina Bravos
Michael Cunningham

NAVY (Alt. Delegates)
Osaze Uwadia

NCPA (Delegates-2 Out of 2)

NEBRASKA (Delegates-3 Out of 3)
Aakash Gandhi
Carmela Silvestri
Elise Barry
Javier Rodriguez
Lucio Volino

NEW HAMPSHIRE (Delegates-2 Out of 2)

NEW JERSEY (Delegates-5 Out of 5)

NEW MEXICO (Delegates-3 Out of 3)

Aakash Gandhi
Carmela Silvestri
Elise Barry
Javier Rodriguez
Lucio Volino

NEW MEXICO (Alt. Delegates)
April Cross

* The numbers reflect the allotted delegates per delegation, not the actual listed delegates.
NEW MEXICO (Alt. Delegates)
Donald Godwin

NEW YORK (Delegates-7 Out of 7)
Brian Richardson
Christopher Daly
Karl Fiebelkorn
Karl Williams
Roxanne Richardson
Steven Moore
Vibhuti Arya

NORTH CAROLINA (Delegates-3 Out of 5)
Evan Colmenares
Macary Marciniak
Ouita Davis Gatton

NORTH DAKOTA (Alt. Delegates)
Elizabeth Skoy

NPhA (Delegates-2 Out of 2)
Frank North
Lakesha Butler

NRPhA (Delegates-1 Out of 1)
Thomas Hanson

OHIO (Delegates-7 Out of 7)
Brigid Groves
Dana Wilkerson
E Murphy
Jeff Steckman
Jessica Hinson
Kelli Barnes
Mitchell Howard

OHIO (Alt. Delegates)
Juanita Draime

OKLAHOMA (Delegates-3 Out of 3)
Eric Johnson
Katherine O'Neal
Krista Brooks

OREGON (Delegates-3 Out of 3)
Huy Hoang
Jill McClellan
Kiomyi Lehman

OREGON (Alt. Delegates)
Kevin Russell

PENNNSYLVANIA (Delegates-7 Out of 7)
Bethany Abrahams
Charles Kray
Daniel Hussar
Karleen Melody
Melinda Williams
Patricia Melissen
Thomas Franko

PENNNSYLVANIA (Alt. Delegates)
Julie Gerhart-Rothholz

PHS (Delegates-2 Out of 2)
Nicholas Palm
Susan Janeczko

PUERTO RICO (Delegates-2 Out of 3)
Giselle Rivera
Milagros Morales

RHODE ISLAND (Delegates-2 Out of 2)
Kenny Correia
Matthew Lacroix

SOUTH CAROLINA (Delegates-3 Out of 3)
David Shirley
John Brumfield
Ron Guida

SOUTH CAROLINA (Alt. Delegates)
Linda Reid

SPEAKER APPOINTED (Delegates-14 Out of 20)
Alicia Guthrie
Alison Knutson
Betsy Elswick
Christopher Kotschevar
Dominic Solimando
Farah Towfic
Heather Free
Heather Hellwig
Jonathan Vincent
Larry Selkow
Loren Kirk
Marsha Gilbreath
Nicole Guist
Wendy Mobley-Bukstein

TENNESSEE (Delegates-5 Out of 5)
Chelsea Renfro
Denise Barker
Lucy Adkins
McKenzie Calhoun
R. Taylor Reed

TEXAS (Delegates-8 Out of 8)
Carol Reagan
Carole Hardin-Oliver
Laura Beall
M. Lynn Crisman
Mark Comfort
Mary Klein
May Woo
Raj Chhadua

TEXAS (Alt. Delegates)
Kimberly Cauthon

UTAH (Delegates-2 Out of 2)
Diane Ogborn
Golden Berrett

VERMONT (Delegates-2 Out of 2)
Brittany Allen
Lauren Bode

VETERANS ADMIN (Delegates-2 Out of 2)
Heather Ourth
John Santell

VETERANS ADMIN (Alt. Delegates)
Anthony Morreale
Ronald Nosek

VIRGINIA (Delegates-5 Out of 5)
Adrian Wilson
Alexis Page
Krystalyn Weaver
Leigh Hester
Sharon Gatewood

WASHINGTON (Delegates-4 Out of 4)
C A Leon Alzola
Collin Conway
Julie Akers
Sara McElroy

WASHINGTON (Alt. Delegates)
Jennifer Arnold

WEST VIRGINIA (Delegates-3 Out of 3)
Karen Reed
Krista Capehart
Michael Lemasters

WISCONSIN (Delegates-2 Out of 3)
Karen MacKinnon
Stacy Doyle

WYOMING (Delegates-1 Out of 1)
Reshmi Singh

WYOMING (Alt. Delegates)
Antoinette Brown

* The numbers reflect the allotted delegates per delegation, not the actual listed delegates.
## American Pharmacists Association House of Delegates

**FIRST SESSION**

**Friday, March 20, 2020**

**2:45PM – 5:15PM**

### SEATING CHART

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<th>Speaker of the House</th>
<th>1</th>
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<th>31</th>
<th>MO-4</th>
<th>MS-3</th>
<th>46</th>
<th>PA-7+</th>
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<td>GU-2</td>
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<td>MN-4+</td>
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<td>OR-3*</td>
<td>PR-3*</td>
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<td>APhA-APRS-7</td>
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<td>Army, Air Force, Navy</td>
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<td>APhA-ASP-7</td>
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<td>APhA-APRS-7 (S)</td>
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<td>APhA-APRS-7</td>
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</table>

### KEY

+ = Seat reserved for State Pharmacy Association Executive (Non-voting)

* = Seat reserved for State Pharmacy Association Executive (Voting)

(S) = APhA Staff Member
## Seating Chart by Delegation Name

| Alabama – Table 1 | Montana – Table 23 | AAPS – Table 9 |
| Alaska – Table 2  | Nebraska – Table 32 | AACP – Table 9 |
| Arizona – Table 2  | Nevada – Table 34  | ACA – Table 9 |
| Arkansas – Table 1 | New Hampshire – Table 22 | ACCP – Table 9 |
| California – Tables 3 & 4 | New Jersey – Table 33 | AIHP – Table 24 |
| Colorado – Table 6 | New Mexico – Table 32 | AMCP – Table 24 |
| Connecticut – Table 5 | New York – Table 36 | ASHP – Table 24 |
| Delaware – Table 5 | North Carolina – Table 35 | ASCP – Table 24 |
| District of Columbia – Table 4 | North Dakota – Table 35 | ASPL – Table 54 |
| Florida – Table 8 | Ohio – Table 37 | CPNP – Table 54 |
| Georgia – Table 7 | Oklahoma – Table 34 | HOPA – Table 54 |
| Guam – Table 7 | Oregon – Table 38 | NCPA – Table 53 |
| Hawaii – Table 6 | Pennsylvania – Table 46 | APC – Table 53 |
| Idaho – Table 16 | Puerto Rico – Table 38 | National Pharmaceutical Assn. – Table 53 |
| Illinois – Table 18 | Rhode Island – Table 47 | National Pharmacists Assn. – Table 53 |
| Indiana – Table 17 | South Carolina – Table 48 | Air Force – Table 57 |
| Iowa – Table 16 | South Dakota – Table 38 | Army – Table 57 |
| Kansas – Table 19 | Tennessee – Table 49 | Navy – Table 57 |
| Kentucky – Table 19 | Texas – Tables 49 & 50 | PHS – Table 56 |
| Louisiana – Table 21 | Utah – Table 48 | USP – Table 54 |
| Maine – Table 17 | Vermont – Table 52 | Veterans Administration – Table 56 |
| Maryland – Table 20 | Virginia – Table 47 | APhA-APPM – Tables 10, 11, 12 & 13 |
| Massachusetts – Table 21 | Washington – Table 51 | APhA-APRS – Tables 41, 42, 43 & 44 |
| Michigan – Table 22 | West Virginia - 51 | APhA-ASP – Tables 25, 26, 27 & 28 |
| Minnesota – Table 23 | Wisconsin – Table 52 | APhA Board of Trustee – Tables 58, 59, & 60 |
| Mississippi – Table 31 | Wyoming – Table 52 | APhA Former Presidents – Tables 14, & 15 |
| Missouri – Table 31 | | APhA Former Speakers – Tables 29, 30, & 45 |
| Speaker Appointed – Tables 39, 40 & 55 | | |
# American Pharmacists Association House of Delegates

**FINAL SESSION**  
**Monday, March 23, 2020**  
**1:30PM – 4:30PM**

**SEATING CHART**

<table>
<thead>
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<th>FL-7+</th>
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<tr>
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</tbody>
</table>

**KEY**

+ = Seat reserved for State Pharmacy Association Executive (Non-voting)  
* = Seat reserved for State Pharmacy Association Executive (Voting)  
(S) = APhA Staff Member
SEATING CHART BY DELEGATION NAME

<table>
<thead>
<tr>
<th>Alabama – Table 8</th>
<th>Montana – Table 16</th>
<th>AAPS – Table 9</th>
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<tr>
<td>Alaska – Table 7</td>
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<tr>
<td>Hawaii – Table 3</td>
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Speaker Appointed – Tables 39, 40 & 55
**General Information**

**for Delegates**

| DUTIES OF THE HOUSE OF DELEGATES | The APhA House of Delegates performs a major role in developing policy for the Association. With Delegates representing all segments of the profession, the House serves as a forum for discussion of key issues and articulation of positions reflecting input from a broad cross-section of pharmacy.

The APhA House of Delegates is charged by the APhA Bylaws to serve as a legislative body in the development of Association policy. Policies adopted by the House guide the Association and its Board of Trustees in matters relating to educational, professional, scientific, and public health policy. These policies help to establish the role of the profession and its relationship with other elements of the contemporary health care system and set the objectives and future agenda of APhA in the continuous evolution of health care. |
| COMPOSITION OF THE HOUSE OF DELEGATES | The approximately 400-member APhA House of Delegates is composed of delegates representing state pharmacy associations, recognized national and federal organizations, APhA’s Academies and Board of Trustees, former APhA Presidents, and former Speakers of the APhA House. Each state-affiliated organization appoints two Delegates, plus one additional Delegate for each 200 APhA Members residing in the state.

Recognized national organizations and recognized Federal organizations appoint two Delegates each. Each of the Association’s three Academies appoints 28 Delegates. Every member of the current APhA Board is a Delegate. Every Delegate must be an APhA member.

Delegates are appointed to serve a term of one year, June 1-May 31 of the following year. As a result, the appointment date for submitting delegates is June 1.

In 2013, APhA amended its Bylaws (Article IV, Section 2) to increase member engagement in the Association’s policy development process of the House of Delegates; delegations that have one or more seats unfilled during both House sessions for 3 consecutive years, shall have those seats removed from their delegate allocation. While the initial delegate allocations outlined in the APhA Bylaws will always stand, the actual number of delegate seats for each delegation may vary from year-to-year based on this change to the Bylaws (Article VI, Section 2, G). |
| CERTIFICATION OF DElegates | Organizations will be able to certify Alternate Delegates as Delegates upon notification to the Secretary of the APhA House of Delegates as late as 1:00PM on, Monday the day of the last House session. No Alternate Delegates will be seated after the Final Session of the House commences. The Secretary will announce the number of Delegates in attendance and whether a quorum has been reached based on the electronic system or roll call cards. Delegates who arrive after the quorum announcement should check in with APhA staff at the registration table. |
| OFFICERS OF THE HOUSE OF DELEGATES | The APhA Bylaws provide that the officers of the APhA House of Delegates shall be the Speaker, the Speaker-elect, and the Secretary. The Speaker and Speaker-elect are elected by the House. The Bylaws provide that the Executive Vice President of APhA shall serve as Secretary. The position of Speaker spans three years: the first year as Speaker-elect (a non-Trustee position) and the subsequent two years as Speaker and Trustee. Elections for Speaker-elect are held on even-numbered years. The Speaker, Speaker-elect, and the Secretary of the House are members of the APhA House of Delegates and, as such, may claim the floor and are entitled to vote. |
**DELEGATE ORIENTATION**

Delegates and Alternate Delegates who are new to the policy process or want a refresher course on the rules and procedures of the APhA House of Delegates may review a posted webinar on the House website. For more in-depth information on the role of the Delegate review the “Delegate Toolkit” located at [http://pharmacist.com/apha-delegate-toolkit](http://pharmacist.com/apha-delegate-toolkit).

**APhA HOUSE RULES REVIEW COMMITTEE**

The House Rules Review Committee is charged to review and establish rules and procedures for the conduct of business at each House session.

The Committee meets via conference call at least twice a year:

- Within 30 days after the conclusion of the Final Session of the House, to review and approve language of adopted House policy and to discuss observations of House operations for potential improvement.
- To review and approve the House of Delegates Schedule, make recommendations regarding the proceedings of the House, and to issue a Final Report to the APhA House of Delegates.

The Committee is comprised of 6 APhA members from diverse pharmacy practice backgrounds and is appointed prior to the beginning of the First Session of the House. The Committee’s term concludes prior to the First Session of the House the following year.

**APhA POLICY COMMITTEE**

The Policy Committee is charged with analyzing specific topics assigned by the Board of Trustees and proposing policy on those topics for consideration by the House of Delegates.

- Committee members meet in Washington, DC, to develop policy statements.
- Committee members prepare a report of policy recommendations for presentation to the APhA House of Delegates.
- The Committee is comprised of 7-10 APhA members from diverse pharmacy practice backgrounds.

**APhA POLICY REFERENCE COMMITTEE**

The APhA Policy Reference Committee is charged with providing greater participation in the policy development process and ensuring objective consideration of APhA member comments.

- Committee members listen to Delegate comments during the First Session of the House of Delegates and during the Policy Committee Open Hearing at the APhA Annual Meeting. Following the Open Hearing, Committee members meet in an executive session to review comments and propose modifications to the original Policy Committee report language. The Committee then issues its final report during the Final Session of the House of Delegates.
- The Committee is comprised of the Chair of the Policy Committee, two other members of the Policy Committee, and three or four new members.

**APhA POLICY REVIEW COMMITTEE**

The APhA Policy Review Committee is charged to ensure that adopted policy is relevant and reflects the opinion of the contemporary pharmacy community.

- The Committee meets via conference call to determine whether adopted policy statements should be amended, retained, archived, or rescinded. The Committee can propose New Business Items for those statements needing an amendment.
  - The Committee reviews adopted policy statements according to the schedule outlined in the House of Delegates Rules of Procedure.
  - The Committee reviews adopted policy related to the policy topics assigned to APhA’s Policy Committee.
- The Policy Review Committee is comprised of 7-10 APhA members from diverse pharmacy practice backgrounds.

**APhA NEW BUSINESS REVIEW COMMITTEE**

The New Business Review Committee is charged to review proposed policy submitted by Delegates and recommend action on those items.

- Committee members participate in the New Business Review Committee Open Hearing at the Annual Meeting and meet in an executive session to finalize their report to the House.
- The Committee is comprised of 7 APhA members from diverse pharmacy practice backgrounds.
| HOUSE OF DELEGATES COMMITTEE ON NOMINATIONS | The House of Delegates Committee on Nominations is charged to nominate candidates for the office of Speaker-elect of the House of Delegates each even-numbered year.  
- The Committee is appointed by the immediate former (non-incumbent) Speaker of the House and is comprised of 5 members.  
- The Committee only slates 2 candidates, but additional nominations may be made from the floor of the House. Candidates for Speaker-elect must be current Delegates to the APhA House.  
- The Committee presents its report, including the slate of candidates, during the First Session of the House. Each candidate is given 2 minutes to introduce him/herself to the Delegates.  
- At the Final Session of the APhA House, each candidate is given 3 minutes to address the APhA House. The election for the office of Speaker-elect is conducted electronically at the Final Session of the APhA House of Delegates. |
| COMMITTEE OF CANVASSERS | The Committee of Canvassers is charged to observe the administration of the electronic voting process for the election of Speaker-elect during the Final Session of the APhA House. APhA members are appointed each even-numbered year to perform the responsibilities of this position. |
| SUBMISSION OF NEW BUSINESS ITEMS | Items of New Business must be submitted to the Speaker of the House no later than 30 days before the start of the First Session of the House of Delegates.  
An urgent item can be considered, without a suspension of the House rules, if presented to the Speaker, with necessary background information, at least 24 hours prior to the beginning of the first session of the House. Urgent items are defined as matters, which due to the nature of their content must be considered by the House outside of normal policy procedures. The submission of urgent new business items will be determined at the discretion of House leadership. |
| DISTRIBUTION OF MATERIALS IN THE HOUSE OF DELEGATES | Materials may only be distributed in the APhA House of Delegates with the approval of the Secretary of the APhA House of Delegates. Individuals seeking to distribute material in the APhA House must submit a sample to the APhA House of Delegates Office prior to the start of the House Session. Materials to be distributed must relate to subjects and activities that are proposed for House action or information. |
| HOUSE OF DELEGATES RULES OF ORDER | The rules contained in Robert’s Rules of Order Newly Revised govern the deliberations of the APhA House of Delegates in all cases in which they are applicable and not in conflict with special APhA House Rules or Bylaws. The Speaker of the APhA House appoints a Parliamentarian whose principal duty is to advise the Speaker. It is proper for the Parliamentarian to state his opinion to the APhA House of Delegates only when requested to do so by the Speaker. A parliamentary procedure reference guide is provided with the Delegate materials. |
| ACCESS TO THE FLOOR OF THE HOUSE OF DELEGATES | Each Delegate has the right to speak and vote on every issue before the APhA House of Delegates. The Speaker shall announce at the opening session of each House meeting the procedure he/she will follow in recognizing requests from the floor. During the APhA House sessions, the procedure for seeking recognition by the Speaker will be for the Delegate to approach a floor microphone and, when recognized by the Speaker, to state his/her name and delegation affiliation. Only Delegates or individuals recognized by the Speaker shall have access to the microphone. |
| AVAILABILITY OF REPORTS | The final report of the APhA Policy Committee will be sent electronically to members and hard copies can be obtained at the House of Delegates Office beginning at 8:00AM on Monday. The final report of the APhA New Business Review Committee will also be sent electronically to members and hard copies can be obtained at the House of Delegates Office beginning 8:00AM on Sunday. |
| VOTING PROCEDURES | Voting will occur via voice vote or by electronic tabulation. For action on Association policy and items of New Business, votes will be cast using voice votes. If the Speaker is unable to determine the outcome of the voice vote, or a Delegate calls for a vote count, the electronic voting system will be used. Actual vote numbers will be utilized versus percentages to determine vote outcomes. Voting for the election of Speaker-elect will occur using the electronic voting system. |
American Pharmacists Association
House of Delegates
Rules of Procedure
Updated March 2019

The following information reflects the final language adopted by the 2019 APhA House of Delegates.

Rule 1 Delegate Appointment
All delegates, except APhA Membership Organization delegates, shall be appointed no later than June 1 of each year and will continue to function in that role until May 31 of the following year. APhA Membership Organizations have the flexibility to appoint their delegates based upon their existing processes with a delegate appointment deadline of no later than August 1 or these seats will also be subject to Speaker appointment as described in Rule 2 of the APhA House Rules of Procedure. APhA’s student Academy delegates must be appointed no later than November 30.

Rule 2 Unfilled Delegate Seats
Unfilled delegate seats of any delegation as defined by APhA Bylaws Article VI, Section 2, Subsection G, shall become inactive if unfilled during both House sessions for 3 consecutive years. This historical information shall be reported annually to the House Rules Review Committee and the APhA Board of Trustees, in addition to being made available to the representative of any delegation being impacted. Delegates shall be notified 60 days prior to the inactivation of delegate seats and may petition the Secretary of the House for reappointment of any inactive seats.

Rule 3 Speaker Appointment of Unfilled Delegate Seats
Per APhA Bylaws Article VI, Section 2-subsection A.i, the Speaker may appoint delegates to unfilled delegate seats of Affiliated State Organizations (ASO). The Speaker will give preference to appointing delegates who served the delegation in previous House sessions. The Speaker must select an individual who resides or works within the state represented by the ASO which they will represent in the House. This process also applies to delegations who have an inactive delegate seat per APhA Bylaws Article VI, Section 2, subsection G. The Speaker will make a reasonable attempt to notify the ASO executive staff of the Speaker appointment. In the event the ASO has a preferred individual to serve in the House after the Speaker has made the appointment, then the ASO’s choice will take precedence if it is received not less than 30 days prior to the first House session. All individuals appointed under this rule will be seated with their ASO’s delegation, irrespective of whether the ASO or the Speaker appointed them into the seat.

Rule 4 Delegates and Voting
At the first session of a meeting of the House of Delegates, the Secretary shall report the number of accredited delegates who shall then compose the House of Delegates. Each delegate shall be entitled to one (1) vote. No delegate shall act as proxy of another delegate nor as delegate for more than one (1) association or organization. A member registered as an alternate may, upon proper clearance by the Credentials Committee, be transferred from alternate to delegate at any time during the continuance of business meetings.

Rule 5 Delegate Identification
Each delegate is required to wear a delegate ribbon attached to the convention name badge while seated in a session of the House of Delegates.
**Rule 6  Consideration of Committee Reports**
The House shall receive and consider the recommendations of each Association Policy Committee on each whole-number section of a Policy Committee report during the first session of the APhA House of Delegates at each Association Annual Meeting. The Committee chair will recommend adoption of policy statements and preside over the debate. Action on the report will be governed by Robert’s Rules of Order (current edition).

Debate in the first session of the House will be time limited. If the Speaker, the Committee chair, or any delegates feel additional debate on the policy statement is warranted, the item may be carried over to an open hearing at which the Policy Reference Committee will preside. The remaining items requiring action will be brought back to the final session of the House of Delegates for action. The Policy Reference Committee may recommend adoption, referral, rejection, or amendments to the original Policy Committee report. Action requires a majority vote.

**Rule 7  Privilege of the Floor**
Only delegates may introduce business on the floor of the House of Delegates. Any individual that is duly recognized by the Speaker and/or the House may have the privilege of the floor in order to address the delegates during a session of the House of Delegates. Any individual may present testimony during an open hearing.

**Rule 8  Nomination and Election of Speaker-elect**
The House of Delegates Committee on Nominations shall consist of five delegates, including the Chair, and shall be appointed by the Immediate Past (nonincumbent) Speaker of the House of Delegates, and that Committee shall meet preceding the first session of the House of Delegates at the Association Annual Meeting to select candidates for the office of Speaker-elect of the House of Delegates.

Elections for Speaker-elect will occur every even-numbered year. Only two candidates for the office of Speaker-elect of the House of Delegates shall be nominated by the Committee on Nominations, and this report shall be presented at the first session of the House of Delegates. No member of the Committee on Nominations shall be nominated by that Committee. All candidates examined by the Committee shall be notified of the results as soon as possible after the nominees have been selected by the Committee on Nominations.

Nominations may then be made from the floor at the first session of the House of Delegates by any delegate immediately following the presentation of the Report of the Committee on Nominations. Candidates nominated from the floor must submit biographical data to the Secretary of the House not less than 24 hours prior to the start of the final session of the House of Delegates in order to qualify as a candidate.

All candidates must be an APhA Member as defined in Article III, Section 2, of the APhA Bylaws, and a seated delegate in the House of Delegates. Candidates will be introduced at the first session of the House of Delegates and permitted to speak to the House for no more than two (2) minutes. Candidates will then be permitted to address the House for a maximum of three (3) minutes at the second session prior to voting on the candidates by the House. Candidates shall be listed in alphabetical order on the ballot regardless of whether they were slated by the Committee on Nominations or nominated from the floor of the House. A majority vote of delegates present and voting is required for election. If no majority is obtained on the first ballot, a second ballot shall be cast for the two candidates who received the largest vote on the first ballot. If electronic voting mechanisms are available, then the election shall be conducted utilizing the technology, with the results not publicly displayed.

If a vacancy occurs in the office of Speaker, the vacancy process detailed in Article VI, Section 5, of the APhA Bylaws shall be followed.
Rule 9  Amendments to Resolutions
All amendments to Policy Committee recommendations or New Business Resolutions shall be submitted in writing to the Secretary on a form provided to Delegates. There are no secondary amendments or “friendly” amendments. The Speaker will rule any Delegates out of order who express a desire to make a secondary amendment or “friendly” amendment.

Rule 10  Rules of Order
The procedures of the House of Delegates shall be governed by the latest edition of Robert’s Rules of Order, provided they are consistent with the APhA Bylaws and the House of Delegates Rules of Procedure.

Rule 11  Amendments to House of Delegates Rules
Every proposed amendment of these rules shall be submitted in writing and will require a two-thirds vote for passage. A motion to suspend the rules shall require an affirmative vote of two-thirds of the total number of delegates present and voting.

Rule 12  Grammar/Punctuation Corrections
The House shall allow the APhA Speaker and staff to the APhA House to make grammar and punctuation corrections to adopted House policy immediately after the conclusion of the House session. To ensure that these corrections do not inadvertently change the meaning of the adopted policy statement, the current sitting APhA House Rules Review Committee will review and approve the corrected statements.

Rule 13  New Business
Items of New Business are due to the Speaker of the House no later than 30 days before the start of the first House of Delegates session.

An urgent item can be considered, without a suspension of the House rules, if presented to the Speaker, with necessary background information, at least 24 hours prior to the beginning of the first session of the House. Urgent items are defined as matters that, due to the nature of their content, must be considered by the House outside of the normal policy processes. The House leadership (Speaker, Speaker-elect [when present], and Secretary) will evaluate submitted urgent items based on the timely and impactful nature of the presented item and determine if the urgent item is to be approved as new business. The House shall then be informed during the first House session of any approved urgent items to be considered by the House. Approved urgent items shall be included with other New Business Items and discussed during the New Business Open Hearing. Appropriate action will then be recommended by the New Business Review Committee in the same manner as other New Business Items and acted upon during the second House session. Urgent items denied consideration by House Officers may still be addressed by the House with a suspension of House rules at the House Session where New Business will be acted upon.

Delegates wishing to amend existing APhA policy on topics not covered within the Policy Committee or Policy Review Committee agenda may submit proposed policy statements through the New Business Review Process. Restatements of existing policy are discouraged.

The New Business Review Committee’s report to the House of Delegates shall include one of the following recommended actions for each New Business Item considered:
   (a) Adoption of the New Business Item
   (b) Rejection of the New Business Item
   (c) Referral of the New Business Item
   (d) Adoption of the New Business Item as amended by the committee
   (e) No action
Rule 13  New Business (continued)
The New Business Review Committee’s recommendations will be addressed by the House of Delegates in the following order:

1. New Items submitted by the Policy Review Committee
2. General New Business Items
3. Urgent New Business Items

If the New Business Review Committee recommends no action on a New Business Item, the Speaker of the House shall place the New Business Item before the House of Delegates for consideration and action. Each whole-numbered statement within the New Business Item shall be considered separately. Consideration of the New Business Item in its entirety requires suspension of House rules.

Rule 14  Policy Review Committee
The House shall receive and consider the recommendations of the House Policy Review Committee to archive, rescind, retain, or amend existing policy at each Annual Meeting of the Association. A singular motion to archive, rescind, retain, or amend, all such existing policy, with limited debate, shall be in order. Items identified by the Policy Review Committee as needing amendment shall be reviewed by the Committee and Speaker of the House to determine that the amendment does not change the intent of the original policy and included in a separate section of the Policy Review Committee report provided to Delegates at the Annual Meeting. Any substantive amendments or those that change the intent of the original policy should be submitted by the Policy Review Committee to the New Business Review Committee for consideration. The Policy Review Committee shall meet annually and review any policy that has (1) not been reviewed or revised in the past 10 years; (2) policy related to statements adopted in the most recent House session; and (3) if applicable, contemporary issues identified by the Speaker.

Rule 15  Policy Reference Committee
The House of Delegates Policy Reference Committee shall consist of the chair of the Policy Committee, two members of the Policy Committee, and three or four new members appointed by the Speaker of the House of Delegates. The Policy Reference Committee will hear comments during the first session of the House of Delegates and the Open Hearing of the Policy Committee at the APhA Annual Meeting and issue the Final Report of the House of Delegates.
<table>
<thead>
<tr>
<th>To Do This:</th>
<th>You Say This:</th>
<th>Must you interrupt speaker?</th>
<th>Must you be seconded?</th>
<th>Debatable?</th>
<th>Amendable?</th>
<th>Vote Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduce business (primary motion)</td>
<td>“I move that…”</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Majority</td>
</tr>
<tr>
<td>Amend a motion</td>
<td>“I move that this motion be amended by…”</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Majority</td>
</tr>
<tr>
<td>End debate</td>
<td>“I move the previous question.”</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Two-thirds</td>
</tr>
<tr>
<td>Request information</td>
<td>“Point of information.”</td>
<td>Yes</td>
<td>No (urgent)</td>
<td>No</td>
<td>No</td>
<td>No vote</td>
</tr>
<tr>
<td>Verify a voice vote</td>
<td>“I call for division of the House.”</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No vote</td>
</tr>
<tr>
<td>Complain about noise, room temperature, smoking</td>
<td>“Question of privilege.”</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Chair decides</td>
</tr>
<tr>
<td>Object to procedure or to a personal affront</td>
<td>“Point of order.”</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Chair decides</td>
</tr>
<tr>
<td>Lay aside an issue temporarily because of emergency</td>
<td>“I move to lay on the table…”</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Majority</td>
</tr>
<tr>
<td>Take up a matter previously tabled</td>
<td>“I move to take from the table…”</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Majority</td>
</tr>
<tr>
<td>Consider something out of scheduled order</td>
<td>“I move to suspend the rules to consider…”</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Two-thirds</td>
</tr>
<tr>
<td>Vote on a ruling by the Chair</td>
<td>“I appeal the decision.”</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Majority</td>
</tr>
<tr>
<td>Postpone consideration of something</td>
<td>“I move we postpone this matter until…”</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Majority</td>
</tr>
<tr>
<td>Reconsider something already disposed of</td>
<td>“I move to reconsider the vote on issue X…”</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Majority</td>
</tr>
<tr>
<td>Have something studied further</td>
<td>“I move to refer this to…”</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Majority</td>
</tr>
</tbody>
</table>
House of Delegates
Policy Topic Ideas

We need your assistance in planning for the 2020-21 policy development process. Let us know what policy topics should be addressed by the 2021 House of Delegates.

Your recommendation will be considered by the Academies Joint Policy Standing Committee and the Board of Trustees for potential assignment to the 2020-21 APhA Policy Committee.

Delegate Name: ____________________________________________

Delegation: ________________________________________________

Proposed Policy Topic:

1. What problem(s) would this proposed policy topic address?

2. What factors have contributed to the problems(s)?

3. Why is this proposed policy topic necessary for the profession?

4. What specific issues should this proposed policy topic address? What specific areas should the Board of Trustees and Policy Committee consider in crafting language related to this topic?

5. Who are the target audiences for the proposed policy topic? (e.g., the public, pharmacists, other health professionals, regulatory bodies)

6. Other comments.

Please return this form to APhA staff before you leave this House session or provide recommendations online at http://fs3.formsite.com/apha/form220/index.html.
2020 House of Delegates
Report of the House Rules Review Committee

Committee Members

Valerie Prince, Chair
Heather Free
Kimberly Sasser Croley
Larry Wagenknecht
May Woo

Ex Officio Members
Joey Mattingly, Speaker of the House
2019-2020
APhA House Rules Review Committee Report

The 2019-2020 APhA House Rules Review Committee (HRRC) consists of the following APhA members and long-time Delegates:

Valerie Prince, Chair
Springville, AL

Heather Free
Hilliard, OH

Kimberly Sasser Croley
Corbin, KY

Larry Wagenknecht
Haslett, MI

May J. Woo
Houston, TX

Overall Charge and Duties
The House Rules Review Committee is appointed each year at the beginning of the First Session of the APhA House of Delegates to review and establish rules and procedures for the conduct of business at each House session (Adopted 1995). The APhA Speaker may assign year-specific charges to the Committee as warranted.

2019-2020 Specific Charges / Work Plan
This year, the following charges were assigned to the HRRC:

The HRRC met via conference call on May 10, 2019, June 18, 2019, August 13, 2019, and February 6, 2020 and made the following recommendations.

1. Observation of the 2019 APhA House of Delegates
Upon completing its review of the proceedings of the 2019 APhA House of Delegates, the Committee took the following action:

By CONSENT, the House Rules Review Committee observed no violations of the House Rules during the proceedings of the 2019 APhA House of Delegates. The Committee observed, reviewed, and discussed challenges and opportunities to maximize the efficiency of House operations. Changes to the APhA House of Delegates Rules are suggested for consideration by Delegates (see Sections 3 and 5).

2. Review of Policy Adopted by the 2019 APhA House of Delegates
The HRRC reviewed, from a grammatical and copy-editing perspective, the policy language approved by the 2019 House of Delegates. Upon completing its review, the HRRC took the following action:

By CONSENT, the House Rules Review Committee approved the 2019 Report of the APhA House of Delegates as prepared by APhA staff.
3. Recommendations to the APhA House of Delegates

The HRRC reviewed comments received from Delegates, members, leaders and staff via surveys, live discussions and other mechanisms, regarding the activities of the House of Delegates.

- Unfilled Delegate Seats
  - The HRRC reviewed the procedures for tracking unfilled delegate seats and does not recommend any immediate changes to this process for 2020.
  - The HRRC did note that additional notes within the current tracking documents will need to be included to track delegate spots related to House Rule 3 where the Speaker of the House appoints an individual to an open Affiliated State Organization position.
  - The HRRC agreed that the determination of unfilled delegate seats would solely be based on participation in the Annual Meeting House sessions.

- Electronic Voting
  - The HRRC recommends that the electronic keypads continue to be used as the primary method of voting for votes requiring a 2/3 majority during House proceedings. It is also recommended that the Speaker should have the latitude to allow a voice vote in accordance with Robert’s Rules of Order and there should not be a mandate to always use electronic keypad voting.

- Delegate Education
  - The HRRC reviewed feedback on the House webinar sessions and associated Delegate education materials. The HRRC recommends continuation of the webinar schedule used in preparation for the 2019 House session. Additionally, it is recommended that the schedule for House of Delegate webinars be released as soon as it is available to ensure delegates add these dates to their calendars in advance of the event.

- Committee of the Whole
  - The HRRC reviewed the schedule used in the 2019 House session that excluded the Committee of the Whole session and recommends continuing without a Committee of the Whole session in the 2020 House sessions.

- House of Delegate Materials
  - The HRRC recommends that all Delegate materials continue to be provided electronically unless otherwise requested by a Delegate. A limited number of Delegate materials will be available onsite.

- New Business Items
  - The HRRC recommends continuation of the existing process described in the House Rules of Procedure for submission and review of all New Business Items during the 2020 House sessions.
  - The HRRC recommends additional training webinars or education be provided to ensure delegates understand the purpose of New Business Items and provide necessary background information to educate delegates on the subject matter to be debated.

- Board of Trustee Speeches
  - The HRRC recommends that APhA staff consider other venues during the APhA Annual Meeting and Exposition for speeches from Board of Trustee candidates. The HRRC agreed to keep time allotted for these speeches in the 2020 House of Delegates agenda.
• The HRRC encourages APhA staff to provide additional opportunities to hear Board of Trustee candidate information including improved use of the meet the candidate’s area, video formats, and organized caucus information.

• The HRRC encourages APhA staff to continue allotting time during the Opening General Session for the Presidential Candidate Speeches.

• Process for Amendment Development During Debate
  o The HRRC reviewed the existing process for developing and submitting an amendment to policy being debated in the House. The HRRC recommends that APhA staff review different options for an electronic format for submitting amendments.
  o The HRRC recommends that the 2020 House sessions continue to use the paper amendment forms while (if possible) testing electronic submission methods as a pilot project.

• Length of House Sessions
  o The HRRC reviewed the overall length and associated scheduling conflicts of the two-House sessions during the APhA Annual Meeting and Exposition. The HRRC recommends maintaining the existing timeframes and encourages staff to increase the Friday House session by 30 minutes to allow for additional discussion time on Policy Committee or New Business Item statements.

• Block Voting
  o The HRRC reviewed the process, through suspension of House Rules, used to combine multiple items for a single vote and recommends continued usage in order to streamline the work of the House, when applicable.

• Delegate Caucus Events
  o The HRRC discussed the engagement of delegates in caucus events and encouraged APhA staff to streamline the process and assist in facilitating broader engagement in caucus events.

• Virtual House of Delegates Session (VHOD)
  o The HRRC discussed the importance of the Annual Meeting face-to-face House sessions. By developing additional rules, guidelines, and processes for a Virtual House of Delegates Session, the HRRC does not intend to limit the important discussions that occur during the Annual Meeting House sessions.
  o The HRRC completed a review of the newly updated House Rules of Procedures and APhA Bylaws before considering modifications to the process.
  o A VHOD should be used to streamline the activities of the Annual Meeting House sessions and provide additional opportunities for delegates to debate issues in a timely manner.
  o The HRRC considered a different level of participation to achieve quorum compared to the Annual Meeting House sessions, but refrained from adjusting these existing rules so as to maintain the quality of decisions made by the overall House of Delegates. Should a VHOD be conducted and a quorum is not achieved, then the discussion that takes place can be used as background information for the Annual Meeting House sessions where any actions would then be considered.

• Policy Review Process
  o The HRRC reviewed the existing Policy Review Process and noted the reduced workload for the Policy Review Committee compared to prior years. The HRRC recommends maintaining the current process.

The HRRC reviewed and evaluated the 2020 APhA House of Delegates Schedule and other newly revised Delegate materials. Upon completing its review, the HRRC took the following action:

By CONSENT, the House Rules Review Committee approved the recommendations for the 2020 APhA House of Delegates schedule and associated Delegate materials. [Attachment A]

5. Review of the APhA House of Delegates Rules of Procedure

After thorough consideration, and in conjunction with the feedback received from Delegates, members, and staff, the HRRC unanimously recommends the following revisions to the APhA House of Delegates Rules of Procedure. Note: proposed deletions are struck through and proposed additions are underlined.

Rule 2 Unfilled Delegate Seats

Unfilled delegate seats at the Annual Meeting House of Delegates of any delegation as defined by APhA Bylaws Article VI, Section 2, Subsection G, shall become inactive if unfilled during both Annual Meeting House sessions for 3 consecutive years. This historical information shall be reported annually to the House Rules Review Committee and the APhA Board of Trustees, in addition to being made available to the representative of any delegation being impacted. Delegates shall be notified 60 days prior to the inactivation of delegate seats and may petition the Secretary of the House for reappointment of any inactive seats.

Rule 4 Delegates and Voting

At the first session of a meeting of the House of Delegates, the Secretary shall report the number of accredited authorized delegates who shall then compose the House of Delegates. Each delegate shall be entitled to one (1) vote. No delegate shall act as proxy of another delegate nor as delegate for more than one (1) association or organization. A member registered as an alternate may, upon proper clearance by the Credentials Committee, be transferred from alternate to delegate at any time during the continuance of business meetings.

Rule 5 Delegate Identification

Each delegate is required to wear a delegate ribbon attached to the convention name badge while seated in a session of the Annual Meeting House of Delegates. Delegates shall affirm their identity when participating in delegate sessions where votes will occur.

Rule 6 Consideration of Committee Reports

The House shall receive and consider the recommendations of each Association Policy Committee on each whole-number section of a Policy Committee report during the first session of the APhA House of Delegates at each Association Annual Meeting. The Committee chair will recommend adoption of policy statements and preside over the debate. Action on the report will be governed by Robert’s Rules of Order (current edition). Other House Committee reports (New Business Review Committee and Policy Review Committee) can be considered during a Virtual House of Delegates session.
Debate in the first session of the Annual Meeting House will be time limited. If the Speaker, the Committee chair, or any delegates feel additional debate on the policy statement is warranted, the item may be carried over to an open hearing at which the Policy Reference Committee will preside. The remaining items requiring action will be brought back to the final session of the Annual Meeting House of Delegates for action. The Policy Reference Committee may recommend adoption, referral, rejection, or amendments to the original Policy Committee report. Action requires a majority vote.

**Rule 9 Amendments to Resolutions**

All amendments to Policy Committee recommendations or New Business Resolutions shall be submitted in writing to the Secretary on a form provided to Delegates. There are no secondary amendments or “friendly” amendments. The Speaker will rule any Delegates out of order who express a desire to make a secondary amendment or “friendly” amendment. No amendments will be considered during a Virtual House of Delegates session.

**Rule 13 New Business**

Items of New Business are due to the Speaker of the House no later than 30 days before the start of the first House of Delegates session with the exception of items to be considered at a Virtual House of Delegates (VHOD) session.

An urgent item can be considered, without a suspension of the House rules, if presented to the Speaker, with necessary background information, at least 24 hours prior to the beginning of the first session of the House. Urgent items are defined as matters that, due to the nature of their content, must be considered by the House outside of the normal policy processes. The House leadership (Speaker, Speaker-elect [when present], and Secretary) will evaluate submitted urgent items based on the timely and impactful nature of the presented item and determine if the urgent item is to be approved as new business. The House shall then be informed during the first House session of any approved urgent items to be considered by the House. Approved urgent items shall be included with other New Business Items and discussed during the New Business Open Hearing. Appropriate action will then be recommended by the New Business Review Committee in the same manner as other New Business Items and acted upon during the second House session. Urgent items denied consideration by House Officers may still be addressed by the House with a suspension of House rules at the House Session where New Business will be acted upon.

New Business Items can be considered at a special session of the APhA Virtual House of Delegates at the discretion of the Speaker in accordance with APhA Bylaws.

Debate in the VHOD sessions will be time limited. At the Speaker’s discretion proposed New Business items may be referred to the Annual Meeting House of Delegates.

Delegates wishing to amend existing APhA policy on topics not covered within the Policy Committee or Policy Review Committee agenda may submit proposed policy statements through the New Business Review Process. Restatements of existing policy are discouraged.

The New Business Review Committee’s report to the Annual Meeting House of Delegates shall include one of the following recommended actions for each New Business Item considered:
(a) Adoption of the New Business Item
(b) Rejection of the New Business Item
(c) Referral of the New Business Item
(d) Adoption of the New Business Item as amended by the committee
(e) No action

The New Business Review Committee’s recommendations will be addressed by the House of Delegates in the following order:

1. New Items submitted by the Policy Review Committee
2. General New Business Items
3. Urgent New Business Items

If the New Business Review Committee recommends no action on a New Business Item, the Speaker of the House shall place the New Business Item before the House of Delegates for consideration and action.

Each whole-numbered statement within the New Business Item shall be considered separately. Consideration of the New Business Item in its entirety requires suspension of House rules.

The VHOD process for consideration of NBI shall not include a New Business Review Committee. Acceptable motions to address VHOD NBI are as follows:
(a) Adoption of the New Business Item
(b) Rejection of the New Business Item
(c) Referral of the New Business Item to the Speaker of the House

Rule 14 Policy Review Committee
The House shall receive and consider the recommendations of the House Policy Review Committee to archive, rescind, retain, or amend existing policy at each Annual Meeting of the Association. A singular motion to archive, rescind, retain, or amend, all such existing policy, with limited debate, shall be in order. Items identified by the Policy Review Committee as needing amendment shall be reviewed by the Committee and Speaker of the House to determine that the amendment does not change the intent of the original policy and included in a separate section of the Policy Review Committee report provided to Delegates at the Annual Meeting. Any substantive amendments or those that change the intent of the original policy should be submitted by the Policy Review Committee to the New Business Review Committee for consideration. The Policy Review Committee shall meet annually and review any policy that has (1) not been reviewed or revised in the past 10 years; (2) policy related to statements adopted in the most recent House session; and (3) if applicable, contemporary issues identified by the Speaker.

If the Policy Review Committee Report is considered in a Virtual House of Delegates session the debate will be time limited. At the Speaker’s discretion recommendations of the Policy Review Committee may be referred to the Annual Meeting House of Delegates session for further deliberation.

Rule 15 Policy Reference Committee
The House of Delegates Policy Reference Committee shall consist of the chair of the Policy Committee, two members of the Policy Committee, and three or four new members appointed by the Speaker of the House of Delegates. The Policy Reference Committee will hear comments
during the first session of the Annual Meeting House of Delegates and the Open Hearing of the Policy Committee at the APhA Annual Meeting and issue the Final Report of the House of Delegates.

**Rule 16 Virtual House of Delegates (VHOD) Special Session Process**
The Speaker of the House shall have 45 days to respond to a delegate request to call a special session of the House for the purpose of considering a New Business Item. The time and mechanism for conducting the virtual house is at the discretion of the Speaker. Delegates must be provided a 10-day notification prior to convening the session.
2020 House of Delegates

Report of the Policy Review Committee

Policies last reviewed ten years ago in 2009
Policies related to newly adopted policy from the 2019 APhA House of Delegates

Committee Members

Betsy Elswick, Chair
Nicholas Dorich
Marsha Gilbreath
Nicole Guist
Alicia Guthrie
Matthew Lacroix
Tamara McCants
Larry Selkow
Krystalyn Weaver

Ex Officio

Joey Mattingly, Speaker of the House

This report is disseminated for consideration by the APhA House of Delegates and does not represent the position of the Association. Only those statements adopted by the House are considered official Association policy.
POLICY STATEMENTS TO BE RETAINED

1. The Committee recommends RETAINING the following policy statement as written.

**2004, 1990 – Freedom to Choose**

1. APhA supports the patient's freedom to choose
2. a provider of health care services and a provider's right to be offered participation in governmental or other third-party programs under equal terms and conditions.
3. APhA opposes government or other third-party programs that impose financial disincentives or penalties that inhibit the patient's freedom to choose a provider or health care services.
4. APhA supports that patients who must rely upon governmentally-financed or administered programs are entitled to the same high quality of pharmaceutical services as are provided to the population as a whole.


2. The Committee recommends RETAINING the following policy statement as written.

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

1. 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, postgraduate 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)

3. The Committee recommends RETAINING the following policy statement as written

**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.

4. The Committee recommends RETAINING the following policy statement as written.

2018 – Pharmacists Electronic Referral Tracking
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, including other pharmacists, irrespective of the health care system, model, or network in which the patient participates.
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.
(JAPhA 58(4):356 July/August 2018)

5. The Committee recommends RETAINING the following policy statement as written.

2019, 2018 – Gluten Content and Labeling in Medications
1. APhA supports labeling of all prescription and nonprescription products, as well as dietary supplement products, to indicate 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.
5. 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, and prescription and nonprescription products.
(JAPhA 58(4):356 July/August 2018)

6. The Committee recommends RETAINING the following policy statement as written.

1. APhA supports the role of the pharmacist to select appropriate drug product packaging.
2. 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.

7. The Committee recommends RETAINING the following policy statement as written.

The employment relationship between pharmacists and their employers must start with the principle that pharmacists have a professional, inherent right to practice in a manner which will engender self-
respect in pursuit of their professional and economic objectives. It is the policy of APhA to further the following basic employment standards:

1. Employers are obligated to respect the professional status, privileges, and responsibilities of employed pharmacists.
2. Employers are obligated to provide working conditions that enhance the ability of employed pharmacists to utilize their full professional capacity in providing patient care service to the public.
3. Employers are obligated to provide employed pharmacists opportunities to increase their professional knowledge and experience.
4. Employers are obligated to fairly compensate employed pharmacists commensurate with their duties and performances. Such compensation should include benefits generally available to other professionals including, but not limited to, vacation, sick leave, insurance plans, and retirement programs.
5. Employed pharmacists are obligated to use their best efforts to further the services offered to the public by their employers.
6. Employed pharmacists are obligated to unhesitatingly bring to the attention of their employers all matters which will assist the employers in maintaining professional standards and successful practices.
7. Employed pharmacists are obligated, when negotiating compensation, to consider not only prevailing economic conditions in their community, but also their economic position relative to other health care professionals.
8. Employed pharmacists are obligated to recognize that their responsibility includes not depriving the public of their patient care services by striking in support of their economic demands or those of others.
9. Both employers and employed pharmacists are obligated to reach and maintain definite understandings with regards to their respective economic rights and duties by resolving employment issues fairly, promptly, and in good faith.

It is the policy of APhA to support these basic employment standards by:

1. Encouraging and assisting state pharmacists associations and national specialty associations to establish broadly representative bodies to study the subject of professional and economic relations and to establish locally responsive guidelines to assist employers and employed pharmacists in developing satisfactory employment relationships.
2. Encouraging and assisting state pharmacists associations and national specialty associations to use their good offices, whenever invited, to resolve specific issues which may arise.
3. Assisting state pharmacists associations and national specialty associations to use their good offices, whenever invited, to resolve specific issues which may arise.
4. Assisting state pharmacists associations and national specialty associations to develop procedures for mediation or arbitration of disputes which may arise between employers and employed pharmacists so that pharmacists can call on their profession for such assistance when required.
5. Increasing its activities directed towards educating the profession about the mutual employment responsibilities of employers and employed pharmacists.
6. Developing benefits programs wherever possible to assist employers in providing employed pharmacists with economic security.
7. Continuously reminding pharmacists that the future development and status of pharmacy as a health profession rests in their willingness and ability to maintain control of their profession.

8. The Committee recommends RETAINING the following policy statement as written.

2004, 1977 – Pharmacy Practice: Professional Judgment
1. APhA supports a pharmacist’s right, regardless of place or style of practice, to exercise individual professional judgment and complete authority for those individual professional responsibilities assumed.
2. APhA supports decision-making processes that ensure the opportunity for input by all pharmacists affected by the decisions.


9. The Committee recommends RETAINING the following policy statement as written.

2004, 1994 – Sexual Harassment in the Workplace
1. APhA supports the principle that all work environments and educational settings be free of sexual harassment.
2. APhA recommends all pharmacy practice environments and educational settings have a written policy on sexual harassment prevention and grievance procedures.
3. APhA recommends that every owner/employer in facilities where pharmacists work institute a sexual harassment awareness education and training program for all employees.
4. APhA supports the wide distribution of the model guidelines on “Sexual Harassment Prevention and Grievance Procedures – Appendix D. APhA Policy and Procedures Manual”.

(Reviewed 2001) (Reviewed 2010) (Reviewed 2015)

Comments: The Policy Review Committee recommends RETAINING these policy statements but had detailed discussion regarding statement 4 and believes that based on recent events, the “Sexual Harassment Prevention and Grievance Procedures” document may need to be reviewed and updated. The Committee wishes to retain this policy statement and add the underlined language noting where the “Sexual Harassment Prevention and Grievance Procedures” document is stored and referenced in the APhA Policy and Procedures Manual.

10. The Committee recommends RETAINING the following policy statement as written.

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.


11. The Committee recommends RETAINING the following policy statement as written.

2012, 1999 – Collective Bargaining/Unionization
1. APhA supports pharmacists’ participation in organizations that promote the discretion or professional prerogatives exercised by pharmacists in their practice, including the provision of patient care.
2. APhA supports the rights of pharmacists to negotiate with their respective employers for working conditions that will foster compliance with the standards of patient care as established by the profession.

12. The Committee recommends RETAINING the following policy statement as written.

2018 – Pharmacist Workplace Environment and Patient Safety
1. 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.

(JAPhA 58(4):355 July/August 2018)

13. The Committee recommends RETAINING the following policy statement as written.

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.


14. The Committee recommends RETAINING the following policy statement as written.

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.

15. The Committee recommends RETAINING the following policy statement as written.

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.


16. The Committee recommends RETAINING the following policy statement as written.

2019, 1997 – Collaborative Practice Agreements
1. APhA supports the establishment of collaborative practice agreements between pharmacists and other health care professionals designed to optimize patient care outcomes.
2. APhA supports the establishment of collaborative practice agreements between one or multiple pharmacists and one or multiple prescribers or entities.
3. APhA supports state laws that do not require a referral or a prior provider-patient relationship as a prerequisite to access services provided under a collaborative practice agreement.
4. APhA opposes state laws that limit collaborative practice agreements to specific patients.
5. APhA supports state laws that allow for pharmacists’ 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 health care professionals or entities.
7. 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.


Comments: The Policy Review Committee recommends RETAINING these policy statements overall. The Committee specifically reviewed the similarities between statements #1 and #2 and believed that removal of the repetitive language would change the original intent of statement 1 and noted that each of the statements stand alone.

17. The Committee recommends RETAINING the following policy statement as written.

2017 – Patient Access to Pharmacist-Prescribed Medications
1. 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)

18. The Committee recommends RETAINING the following policy statement as written.

**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)

19. The Committee recommends RETAINING the following policy statement as written.


1. 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.

20. The Committee recommends RETAINING the following policy statement as written.

1. APhA opposes mandatory Human Immunodeficiency Virus (HIV) testing of pharmacists, student pharmacists, and pharmacy personnel.
2. APhA supports voluntary and confidential Human Immunodeficiency Virus (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 Human Immunodeficiency Virus (HIV) positive health care professionals and students.


**Comments:** The Policy Review Committee recommends RETAINING these policy statements but has noted grammatical changes in this report for transparency to the House. Per APhA House rules, APhA staff can make grammatical edits to policy statements so the inclusion of these is just a note to capture the discussion of the committee. The Committee recommended spelling out Human Immunodeficiency Virus (HIV) in statements 1, 2, and 3 and removing the comma after “personnel” in statement 2.

21. The Committee recommends RETAINING the following policy statement as written.

**1996 – Human Immunodeficiency Virus (HIV) Testing in Pregnant Women**
APhA encourages pharmacists to provide pharmaceutical care to women, including education about the availability and benefits of Human Immunodeficiency Virus (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.


**Comments:** The Policy Review Committee recommends RETAINING this policy statement but has noted grammatical changes in this report for transparency to the House. Per APhA House rules, APhA staff can make grammatical edits to policy statements so the inclusion of these is just a note to capture the discussion of the committee. The Committee recommended spelling out Human Immunodeficiency Virus (HIV) when it is mentioned the first time in the statement and changing the comma after “children” to a period.

22. The Committee recommends RETAINING the following policy statement as written.

**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.

23. The Committee recommends RETAINING the following policy statement as written.

**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.

24. The Committee recommends RETAINING the following policy statement as written.

1. 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.

25. The Committee recommends RETAINING the following policy statement as written.

**1987 – Encouraging Availability and Use of Vaccines**
1. 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.

26. The Committee recommends RETAINING the following policy statement as written.

**2019, 2016 – Substance Use Disorder**
1. 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 comprehensive substance use disorder education, prevention, treatment, and recovery programs.
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)

27. The Committee recommends RETAINING the following policy statement as written.

2016 – Opioid Overdose Prevention
1. 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)

28. The Committee recommends RETAINING the following policy statement as written.

2014 – Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents
1. 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.

29. The Committee recommends RETAINING the following policy statement as written.

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)
30. The Committee recommends RETAINING the following policy statement as written.

2005, 1998 – Administration of Medications
1. 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.


31. The Committee recommends RETAINING the following policy statement as written.

2016 – Point-of-Care Testing
1. 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.


32. The Committee recommends RETAINING the following policy statement as written.

2013 – Pharmacists Providing Primary Care Services
APhA advocates for the recognition and utilization of pharmacists as providers to address gaps in primary care.

33. The Committee recommends RETAINING the following policy statement as written.

2005, 1972 – Prevention and Control of Sexual Transmitted Infections
1. 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.


34. The Committee recommends RETAINING the following policy statement as written.

2009 – Disparities in Healthcare
APhA supports elimination of disparities in health care delivery.


35. The Committee recommends RETAINING the following policy statement as written.

2006 – Cultural Health Beliefs and Medication Use
1. 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.


36. The Committee recommends RETAINING the following policy statement as written.

2005 – Patient Safety
1. 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.

POLICY STATEMENTS TO BE ARCHIVED

37. The Committee recommends ARCHIVING the following policy statement as written.

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.

**Comments:** The Policy Review Committee recommends ARCHIVING this policy statement as the
newly amended 2019, 2006, 2003 Unit-of-Use Packaging policy language encompasses the intent of this
2012 policy and the Committee believes the new 2019 language is stronger overall.

38. The Committee recommend ARCHIVING the following policy statement as written.

Immunodeficiency Virus (HIV) and Other Infections
1. 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 needle/syringe exchange programs when part of a comprehensive approach in the
prevention of the spread of HIV and other blood-borne infections.

**Comments:** The Policy Review Committee recommends ARCHIVING these policy statements as
Committee believes the newly adopted policy 2019 Patient-Centered Care of People Who Inject
Nonmedically Sanctioned Psychotropic or Psychoactive Substances encompasses the intent of these
statements and is more up to date.

39. The Committee recommends ARCHIVING the following policy statement as written.

1982 – Innovative Approaches to Combating Pharmacy Crime
1. 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).

**Comments:** The Policy Review Committee recommends ARCHIVING these policy statements as
statement 1 is now covered in the newly adopted policy 2019 Patient-Centered Care of People Who Inject
Nonmedically Sanctioned Psychotropic or Psychoactive Substances. The Committee is not
opposed to additional programming related to the topic area, but believes the items called or in these two
policy statements have been developed and implemented through existing programs like the Generation
Rx programming and other existing policy supports the continuation of this programming.
2020 House of Delegates
Report of the Policy Committee

❖ Protecting Pharmaceuticals as a Strategic Asset
❖ Accountability of Pharmacists
❖ Specialty Pharmacy and Specialized Pharmacy Services

Committee Members
Melissa Duke, Chair
Heather Free
Christopher Kotschevar
Monica Orsborn
Brent Reed
Garth Reynolds
Reshmi Singh
Terri Smith Moore
Farah Towfic

Ex Officio
Joey Mattingly, Speaker of the House

This report is disseminated for consideration by the APhA House of Delegates but does not represent the position of the Association. Only those statements adopted by the House are official Association policy.
Protecting Pharmaceuticals as a Strategic Asset

The Committee recommends that the Association adopt the following statements:

1. APhA asserts that the quality and safety of pharmaceutical and other medical products and the global pharmaceutical and medical product supply chain are essential to the United States national security and public health.
   [Refer to Summary of Discussion Items 9,10,11,12]

2. APhA advocates for pharmacist engagement in the development and implementation of national and global strategies to ensure the availability, quality, and safety of pharmaceutical and other medical products.
   [Refer to Summary of Discussion Items 13 and 14]

3. APhA calls for the development, implementation, and oversight of enhanced and transparent processes, standards, and information that ensure quality and safety of all pharmaceutical ingredients and manufacturing processes.
   [Refer to Summary of Discussion Items 15,16,17,18,19]

4. APhA calls on the federal government to penalize entities who create barriers that threaten the availability, quality, and safety of United States pharmaceutical and other medical product supplies.
   [Refer to Summary of Discussion Items 14 and 20]

5. APhA calls for the development of redundancy and risk mitigation strategies in the manufacturing process to ensure reliable and consistent availability of safe and high-quality pharmaceutical and other medical products.
   [Refer to Summary of Discussion Items 14,21,22,23]

6. APhA advocates for regulatory and market incentives that bolster the availability, quality, and safety of pharmaceutical and other medical products.
   [Refer to Summary of Discussion Items 14 and 24]

7. APhA calls for greater transparency, accuracy, and timeliness of information and notification to health care professionals regarding drug shortages, product quality and manufacturing issues, supply disruption, and recalls.
   [Refer to Summary of Discussion Items 25 and 26]

8. APhA encourages pharmacy providers, health systems, and payers to develop coordinated response plans, including the use of therapeutic alternatives, to mitigate the impact of drug shortages and supply disruptions.
   [Refer to Summary of Discussion Items 27 and 28]

9. APhA supports federal legislation that engages pharmacists, other health professionals, and manufacturers in developing a United States-specific essential medicines list and provides funding mechanisms to ensure consistent availability of these products.
   [Refer to Summary of Discussion Items 29,30,31]

10. APhA recommends the use of pharmacists in the delivery of public messages, through media and other communication channels, regarding pharmaceutical supply and quality issues.
    [Refer to Summary of Discussion Items 32 and 33]
Summary of Discussion

1. The Committee modified the title of this policy topic to “Protecting Pharmaceuticals as a Strategic Asset” due to initial confusion around the phrase of “National Strategic Asset.” The Committee acknowledged that “National Strategic Asset” is not specifically identified by the Federal Government and instead of calling for a new term, the committee included the more general term of “strategic asset.” “Strategic Asset” is used more frequently in business management and retains the intent of the original charge from the APhA Board of Trustees.

2. The Committee referenced APhA existing policy 2012 Drug Supply Shortages and Patient Care, specifically statements 5 and 7, when discussing this topic and felt these were still current and did not need to be restated in new policy statements.

3. The Committee referenced APhA existing policy 2004 Protecting the Integrity of the Medication Supply during its discussions and did not believe these statements needed to be restated.

4. The committee used the Food and Drug Administration (FDA) definition for drug, which is defined as any of the following: a substance recognized by an official pharmacopoeia or formulary, a substance intended to use in the diagnosis, cure, mitigation, treatment, or prevention of disease, a substance (other than food) intended to affect the structure or any function of the body, a substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device, or biological products that meet the criteria of this definition.

5. The Committee defined “drug product” by using the Food and Drug Administration (FDA) definition of, “the finished dosage form that contains a drug substance, generally, but not necessarily, in association with other active or inactive ingredients.”

6. The committee reviewed the Merriam Webster’s dictionary definition of “medication”, defined as a “drug used to diagnose, cure, treat, or prevent disease.”

7. The committee reviewed the Merriam Webster’s dictionary definition of “pharmaceutical”, defined for use as a noun to mean a compound manufactured for use as a medicinal drug. The Committee decided to use “pharmaceuticals” to encompass all elements of the medication, including the active pharmaceutical ingredient (API), excipients, etc.

8. The Committee referenced current and future public-private partnership initiatives to mitigate drug shortage issues (CivicaRx or other new manufacturing companies).

9. The committee discussed that a policy statement with an assertion of the importance of pharmaceutical products to national security and public health would empower stakeholders to elevate the level of support needed to product pharmaceutical products as a resource of critical importance.

10. The Committee added the term “pharmaceutical products” to the statement as they felt that the term “global pharmaceutical supply chain” was not encompassing of the actual drugs themselves and both are recognized as being essential components of the statement.

11. The Committee discussed including the term “welfare” as it relates to the public but felt this was encompassed within the terminology of “public health”.

12. The committee discussed whether or not to include the term “integrity” as a descriptor, but this was resolved by inclusion of the term “quality,” which encompasses integrity. Additionally, the Committee considered adding the terms stability in other statements, but
also believed “quality” encompassed the overall intent and provided clarity to the statements.

13. The Committee intentionally added the term “global”, because strategies need to apply to processes that also exist outside of the United States.

14. The committee referenced the World Health Organization’s (WHO) definition of “medical products”, which includes medicines, vaccines or in vitro diagnostics and it may also include medical devices at an appropriate time in the future. The Committee felt it was important to include this terminology to also include items like digital therapeutics and future products. Source: https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

15. The Committee discussed if the word “development” was necessary as there are already processes in place, but the word “enhanced” is believed to signify that the committee would like the processes to be reviewed and improved upon to increase safety.

16. The Committee discussed the differences and similarities between the terms “quality” and “integrity” and determined to use “quality” in this statement. The Committee agreed that integrity was a component of quality and wanted to ensure clarity and consistency among the statements by using the term “quality” throughout.

17. The Committee discussed calling for labeling where all pharmaceutical ingredients in a drug product were included. The Committee agreed that this would be ideal but would be limiting. Instead, the Committee developed the statement to call for things (processes, standards, and information) that could include this type of information while also being broader.

18. The Committee discussed the existence of drug quality standards, which are implemented during research trials and the drug development process and did not believe a separate statement was necessary on drug quality standards at this time.

19. The Committee reviewed recent stories around ARB medications with high levels of N-Nitrosodimethylamine (NDMA) in the final drug product. The Committee developed statement 3 around the issues noted in these stories that led the occurrence of NDMA in these products. It was noted that contemporary testing processes might have identified the issue sooner.

20. The Committee wanted to clarify that the term “barriers” encompasses barriers to access for inspections, barriers when allowing the drug supply to be released to the US, deceptive practices, and the counterfeiting of products.

21. The Committee discussed whether the term “pharmaceuticals” would suffice in this statement or if it needed “high quality” as an adjective. The Committee agreed that it is important to call out “high-quality” because a product might be safe, but these strategies should be aiming to protect the quality in situations where manufacturers might compromise the quality for safety.

22. The Committee debated using the term “risk management” in place of “risk mitigation”. “Risk mitigation” was specifically chosen to emphasize the need for work to be done before a situation occurs that then needs to have a separate risk management strategy. The Committee recognized that “mitigation” is referring to an action of reducing severity, seriousness, or painfulness of something.

23. The Committee acknowledged that an implementable plan needed to be in place that could be activated when needed, versus having operations in place.
24. The Committee acknowledged the need for regulatory and market incentives, including funding, to drive the overall initiative to ensure product availability and enhance safety of pharmaceuticals and other medical products.

25. The Committee developed statement 7 with the intent to call for more communication from entities to ensure continuity of care. The Committee originally considered the verb “encourages” but opted for “calls for” to strengthen the verbiage of the statement.

26. The Committee referenced existing APhA policy **2012 Drug Supply Shortages and Patient Care**, specifically statement 1, as it was a concern that this statement was possibly redundant. The Committee decided redundancy with the 2012 policy was not a concern, and this new statement is instead implying that timelier provider access to this information will avoid disruption in the continuity of care.

27. The Committee agreed that the term “coordinated response plans” encompassed the terms “policies and procedures”.

28. The Committee felt that early provider notification allows for timely and comprehensive addressing of drug shortages and supply disruptions.

29. The Committee reviewed the World Health Organization’s (WHO) Essential Medicines list but identified that it may not be the most applicable for the needs of the United States.

30. The Committee intends for pharmacists to play an active role in the development of the essential medicines list.

31. The Committee discussed the purpose of the United States National Stockpile as managed by Department of Health and Humans Services (HHS) and how a potential essential medicines list would be used differently to meet the needs of a community.

32. The Committee intentionally separated this idea from other communication related statements because historically, the media has obtained information before providers, which causes confusion and a delay in the patient care process. The Committee agreed that this statement needed to stand on its own.

33. The Committee also recognized the medication use and distribution expertise of the pharmacist and felt that pharmacists should be the team members who the media utilizes in the delivery of messages regarding supply and quality issues.
Protecting Pharmaceuticals as a Strategic Asset (not yet copyedited)
Background Information Prepared for the 2019–2020 APhA Policy Committee

Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2019–2020 Policy Committee to recommend policy to the APhA House of Delegates related to protecting pharmaceuticals as a strategic asset. The Board’s guidance on this topic included, but was not limited to, the role of the federal government, manufacturers, providers, and the public related to maintain a safe and high quality medication supply.

Background

Critical Infrastructure/Key Resources (CI/KR)
"Critical Infrastructure" is defined by federal law as "systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters." The U.S. Department of Homeland Security has identified 18 critical infrastructure sectors, as diverse as agriculture and food, emergency services, and cyber networks.

Critical infrastructure provides enormous benefits, services, and opportunities on which we rely, and the U.S. Department of Homeland Security is very mindful of the risks to this infrastructure posed by terrorists, pandemic diseases and natural disasters. We know that these threats can have serious effects, such as cutting populations off from clean water, power, transportation, or emergency supplies. 1

National Stockpile information

• The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) process helps plan which resources the stockpile will need to protect the nation’s health. 2
  o The PHEMCE annually assesses and updates a PHEMCE Strategy Plan (SIP) to ensure optimal allocation of resources to address high-priority threats.
  o The PHEMCE is led by HHS Office of ASPR and includes the CDC, FDA, and NIH, as well as DoD, VA, DHS, and USDA.
• Products in the stockpile require an Emergency Use Authorization.
• The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation’s public health protections against CBRN threats by facilitating the availability and use of MCMs needed during public health emergencies. 3

HHS Development of Medical Countermeasures

• Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through
advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile.  

- BARDA develops and procures needed MCMs, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, whether natural or intentional in origin. To-date, BARDA has supported 42 FDA approvals for products addressing CBRN, PI, and EID threats.

- The BARDA Strategic Plan 2011-2016 emphasizes five goals BARDA will use to accomplish its mission:
  
  o Goal 1: An advanced development pipeline replete with medical countermeasures and platforms to address unmet public health needs, emphasizing innovation, flexibility, multi-purpose and broad spectrum application, and long-term sustainability.
  o Goal 2: A capability base to provide enabling core services to medical countermeasure innovators.
  o Goal 3: Agile, robust and sustainable U.S. manufacturing infrastructure capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats.
  o Goal 4: Responsive and nimble programs and capabilities to address novel and emerging threats.
  o Goal 5: A ready capability to develop, manufacture and facilitate distribution of medical countermeasures during public health emergencies.

**Strategic Asset Definitions**

Generally, strategic assets can be defined as, “Assets that are needed by an entity in order for it to maintain its ability to achieve future outcomes. Without such assets the future well-being of the company could be in jeopardy.” There is no current Federal definition for a “Strategic Asset” or “National Strategic Asset.”

The term “Strategic Asset” has recently been mentioned by the federal government in a project titled *Leverage Data as a Strategic Asset*. Additionally, the Center for Development of Security Excellence, a nationally accredited, award-winning directorate within the Defense Counterintelligence and Security Agency (DCSA) differentiates between the terms business asset and national security asset.

**Additional Guidance and Drug Shortage References**

The following five resources provide additional background from FDA and ASHP on related activities related to drug shortages:

- FDA Strategic Plan for Preventing and Mitigating Drug Shortages 2013, [https://www.fda.gov/media/86907/download](https://www.fda.gov/media/86907/download)
API and Excipient Standards
The FDA requires by law that Active Pharmaceutical Ingredients (APIs) are manufactured under current good manufacturing practices (CGMPs). The following items are available online as questions and answers regarding CGMPs and a few specific items are included as general background information when considering the source of some drug quality issues.

- **Q15.** Who is responsible for analytically testing APIs to ensure they comply with their specifications and with USP requirements, if any?9

  - API manufacturers perform analytical testing on APIs to confirm that they meet all applicable specifications established for release. Finished drug product manufacturers ensure that APIs used in their products meet all their established specifications and—for compendial APIs—meet USP requirements. Additional information is provided below. **API Manufacturer Responsibilities** Section 501(a)(2)(B) of the FD&C Act requires all drugs (including APIs) to be manufactured in compliance with CGMP. FDA therefore expects API manufacturers to follow the recommendations in ICH guidance for industry *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients*. API labeling supplied by the API manufacturer includes a certificate of analysis (COA). Section 11.4 of ICH Q7 recommends that the API manufacturer’s COA should include, as applicable, the API’s name, grade, batch/lot number, date of release, and a list of “each test performed in accordance with compendial or customer requirements, including the acceptance limits, and the numerical results obtained . . . .” For example, for a compendial-grade API, the COA should identify the compendial tests that were performed (as well as customer-specified tests, if any) and the test results. If a compendial-grade API differs from a USP standard of strength, quality, or purity, that difference should be clearly declared on the label.

**Finished Drug Product Manufacturer Responsibilities** In the CGMP regulations for finished pharmaceuticals, 21 CFR 211.80 states that “[T]here shall be written procedures describing in sufficient detail the . . . testing . . . of [finished drug product] components . . . .” Additionally, 21 CFR 211.84(d)(2) states that “[E]ach component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier’s analyses through appropriate validation of the supplier’s test results at appropriate intervals.” Therefore, if the finished drug product manufacturer accepts the test results from an API supplier’s COA rather than performing the tests itself (other than for identity, which the manufacturer is required to perform), the manufacturer must validate the API supplier’s reliability. This validation procedure is established by the finished drug product manufacturer and should be consistent with the principles of CGMP and risk management. The finished drug product manufacturer should also ensure that compendial-grade APIs comply with compendial specifications, either by testing the APIs or by validating API suppliers’ reliability, as described above. References:

  - FD&C Act Chapter V: Drugs and Devices
  - 21 CFR 211.80: General requirements
  - 21 CFR 211.84: Testing and approval or rejection of components, drug product containers and closures
  - FDA Guidance for Industry, 2001, ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

- **Q14.** Must each batch of a United States Pharmacopeia (USP)-grade API be tested using the analytical procedures specified in the USP monograph?9
No; however, in the event of a dispute, the compendial method is considered conclusive (see USP reference, below). Section 201(g) of the FD&C Act includes “articles intended for use as a component” of a finished drug product, including APIs (or drug substances), under its definition of a drug, and section 501(b) requires a drug recognized in USP to meet the standards of strength, quality, and purity in the official monograph or to be clearly labeled to designate how it differs from USP standards. Although each batch of a compendial article must conform to the monograph specifications/acceptance criteria, the analytical procedures used to show conformance may differ from official USP methods if the alternative methods are fully validated, suitable for use, and give equivalent or better results than the official USP method. All APIs must also be manufactured in compliance with CGMP as stated in section 501(a)(2)(B) of the FD&C Act.

References:
- FD&C Act Chapter V: Drugs and Devices

In the summer of 2018, some generic version of angiotensin II receptor blocker (ARB) medications contained impurities including N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA), which are probable human carcinogens. The FDA issued a response to these safety issues and described strategies for mitigating future occurrences of this nature.\(^\text{10}\)

Additionally, the following two resources provide information related to standards for excipient ingredients. FDA and the International Pharmaceutical Excipients Council (IPEC) share best practices and guidance for excipient products.

The European Union as an Additional Case Study

Approximately 80% of all active substances in the medicines used in Europe come from outside the European Union (EU).\(^\text{11}\) The European Medicines Agency (EMA) cooperates with a number of countries and organizations outside the European Union (EU) based on specific types of agreement, which enable the signatories to share confidential information or facilitate market access and achieve greater international harmonization while protecting consumer safety.\(^\text{11}\) The EU works with several programs to develop medical countermeasures. In a paper developed by the Centre for Global health Policy at the University of Sussex in the United Kingdom, the following procedures and methods have taken place to develop countermeasures for various situations.

“In Europe such initiatives to develop new medical countermeasures are still largely conducted at the level of national governments – with considerable disparities in terms of the political will and capabilities of countries to undertake such programmes. In the United Kingdom, for example, the Defence Science & Technology Laboratory (DSTL) – located within the Ministry of Defense – similarly initiated a medical countermeasures programme to develop a range of new pharmaceutical products for protecting the UK population. What is more, when it comes to the mass procurement (rather than the development) of medical countermeasures for stockpiling purposes, greater degrees of co-operation are also beginning to emerge at the European level. A recent agreement reached on health security in the European Union, for example, established the legal basis for the voluntary joint procurement of medical countermeasures, especially of vaccines.\(^\text{12}\)”
• “In Europe, for example, the European Commission has spent much of the past decade developing its own health security framework – focusing on prevention, preparedness, and responses to threats. A new agreement on strengthening EU health security reached in 2013 also: provides for the possibility that the Commission recognizes a situation of public health emergency for the purposes of conditional marketing authorizations for medicinal products and for derogations of the terms of a marketing authorization for a human influenza vaccine. This would allow accelerated marketing of medicinal products or vaccines in an emergency situation."

• “Such procedures would enable – again under exceptional emergency conditions only – medical countermeasures to be deployed even without marketing approval or, in the case of Europe, via expedited approval procedures. Deploying the state’s exceptional power to temporarily suspend existing regulatory frameworks during an emergency thus marks another pivotal axis in the extraordinary medical countermeasures regime that governments have been creating."

Related APhA Policy

2012 Drug Supply Shortages and Patient Care
1. APhA supports the immediate reporting by manufacturers to the U.S. Food and Drug Administration (FDA) of disruptions that may impact the market supply of medically necessary drug products to prevent, mitigate, or resolve drug shortage issues and supports the authority for FDA to impose penalties for failing to report.
2. APhA supports revising current laws and regulations that restrict the FDA’s ability to provide timely communication to pharmacists, other health care providers, health systems, and professional associations regarding potential or real drug shortages.
3. APhA encourages the FDA, the Drug Enforcement Administration (DEA), and other stakeholders to collaborate in order to minimize barriers (e.g., aggregate production quotas, annual assessment of needs, unapproved drug initiatives) that contribute to or exacerbate drug shortages.
4. APhA should actively support legislation to hasten the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products.
5. APhA encourages pharmacists and other health care providers to assist in maintaining continuity of care during drug shortage situations by: (a) creating a practice site drug shortage plan as well as policies and procedures, (b) using reputable drug shortage management and information resources in decision making, (c) communicating with patients and coordinating with other health care providers, (d) avoiding excessive ordering and stockpiling of drugs, (e) acquiring drugs from reputable distributors, and (f) heightening their awareness of the potential for counterfeit or adulterated drugs entering the drug distribution system.
6. APhA encourages accrediting and regulatory agencies and the pharmaceutical science and manufacturing communities to evaluate policies/procedures related to the establishment and use of drug expiration dates and any impact those policies/procedures may have on drug shortages.
7. APhA encourages the active investigation and appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.
(JAPhA NS52(4) 457 July/August 2012)(Reviewed 2017)

2004 Protecting the Integrity of the Medication Supply
1. APhA encourages pharmacists to enhance their role in protecting the integrity of the medication supply, including careful consideration of the source and distribution pathways of the medications they dispense.
2. APhA recommends that all individuals and entities of the pharmaceutical supply system, including manufacturers, wholesalers, pharmacies, pharmacists, and others, adopt appropriate technology, tracking mechanisms, business practices, and other initiatives to protect the integrity of the drug supply.
3. APhA supports public education about the risk of using medications whose production, distribution, or sale does not comply with U.S. federal and state laws and regulations.
4. APhA urges pharmacists and other health care professionals to report suspected counterfeit products to the Food and Drug Administration.


2004,1970 Licensure/Registration of Drug Manufacturers
APhA supports the requirements that all drug manufacturers must obtain a federal license or registration, conditioned upon an inspection of the manufacturer's facilities, before manufacturing is begun.


1. APhA supports:
   a) the use of contemporary communications technologies to enhance communication of recall information to all relevant parties,
   b) developing and promoting strategies to identify and communicate with patients who may have received recalled products, when appropriate,
   c) identifying compensation mechanisms for resources expended in responding to recalls, and
   d) maintaining the FDA recall program, which ensures that appropriate promptness of action can be taken based on the depth and severity of the recall.


References
The Committee recommends that the Association adopt the following statements:

1. APhA affirms pharmacists’ professional accountability in all practice settings.
   [Refer to Summary of Discussion Items 2,3,4]

2. APhA advocates that pharmacists be granted and accept authority, autonomy, and accountability for patient-centric actions to improve health and medication outcomes, in coordination with other health professionals, as appropriate.
   [Refer to Summary of Discussion Items 5,6,7,8]

3. APhA reaffirms 2017 Pharmacists’ Role Within Value-based Payment Models and supports continued expansion of interprofessional patient care models that leverage pharmacists as accountable members of the healthcare team.
   [Refer to Summary of Discussion Items 9 and 10]

4. APhA advocates for sustainable payment and attribution models to support pharmacists as accountable patient care providers.
   [Refer to Summary of Discussion Items 11 and 12]

5. APhA supports continued expansion of resources and health information infrastructures that empower pharmacists as accountable healthcare providers.
   [Refer to Summary of Discussion Item 13]

6. APhA supports the enhancement of comprehensive and affordable professional liability insurance coverage that aligns with evolving pharmacist accountability and responsibility.
   [Refer to Summary of Discussion Item 14]
Summary of Discussion

1. The Committee discussed existing APhA policy statements at length and felt that there was enough urgency and timeliness related to these topics that warranted the reaffirmation of existing policy statements. Additionally, the committee felt it was important to have a complete set of policy statements organized around the specific topic of accountability of pharmacists.

2. The Committee considered adding the term “responsibility” to the topic title and within Statement 1 but decided against including this term as the intent of the policy statements is focused on the individual pharmacist as opposed to the shared responsibility of a team. The Committee discussed how the healthcare team has a shared responsibility to provide care and each individual team member is accountable for various aspects of that care. The Committee discussed that the term accountability more specifically addressed the charge to the committee to focus on the individual pharmacist.

3. The Committee included the term “professional” to infer that a pharmacist is accountable for actions taken in alignment with their pharmacy practice act. They acknowledged that a pharmacist’s accountability will depend on their practice setting and roles and responsibilities, but all pharmacists are accountable for the actions they take to impact patient outcomes.

4. The Committee viewed and intends for this statement to reiterate APhA’s stance on the role of the pharmacist in any practice setting and support existing APhA policy that acknowledges the pharmacist’s role on the patient care teams.

5. The Committee discussed using the term “collaboration” as opposed to “coordination,” but agreed that collaboration insinuates that the pharmacist must have discussion with other members of the healthcare team prior to making a decision about patient care within the pharmacists’ scope of practice. Coordination is when team members share information needed for patient care in a way that coordinates care and empowers each individual member of the healthcare team.

6. The Committee discussed whether the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacist’s Patient Care Process should be included in this statement and reasoned that inclusion of the Pharmacist’s Patient Care Process could exclude decisions unrelated to direct patient care.

7. The Committee recognizes that pharmacists use the patient care process to guide and formalize their practice.

8. The Committee felt that it was important to include both autonomy and authority in this statement. Authority refers to the pharmacist’s ability to execute their decision and autonomy refers to the pharmacist’s ability to make the decision on their own. In addition to the actions for which a pharmacist is presently accountable, more authority and autonomy will expand the opportunity for more accountability.

9. The committee believed that existing APhA policy 2017 Pharmacists’ Role Within Value-based Payment Models covered multiple points relevant to pharmacist accountability (attribution, compensation, and coordinated care) and reaffirming the language in new policy was the most streamlined process to emphasize its importance in the context of accountability.

10. The committee considered additional language not covered in the 2017 Pharmacists’ Role Within Value-based Payment Models policy statement and agreed upon the
importance to call for continued expansion of care models. The terminology of leverage was specifically selected to emphasize the pharmacist’s role.

11. The Committee specifically included “sustainable” to recognize that various types of payment and incentives are emerging to support health care practitioners in health care practices, including pharmacists. The approaches used to financially justify a pharmacist need to be sufficient and scalable. Likewise, attribution models need to be developed so that pharmacists’ contributions to meeting quality metrics and cost targets can be better recognized and valued.

12. The Committee further referenced existing APhA policy 2017 Pharmacists’ Role Within Value-based Payment Models when considering language around the attribution of pharmacists’ services within value-based models.

13. The Committee discussed that “resources” in statement 5 would include, but are not limited to, education and training for pharmacists and student pharmacists.

14. The Committee acknowledged the importance of professional liability insurance and wants to ensure that future insurance options advance in parallel with the advancing level of accountability and responsibility of pharmacists.
**Accountability of Pharmacists**
*(Beyond Controlled Substances)*

*Background Paper Prepared for the 2019–2020 APhA Policy Committee*

Meg Freiter, PharmD
2019–2020 Executive Resident
American Pharmacists Association Foundation

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**Issue**

The American Pharmacists Association (APhA) Board of Trustees has directed the 2019–2020 Policy Committee to recommend policy to the APhA House of Delegates related to the corresponding responsibility of a pharmacist in patient care. The Board’s guidance on this topic included, but was not limited to, the role and accountability of pharmacists on the health care team, alignment with the Patient Care Process, and the aspirational goal of where pharmacists should be positioned in a value-based payment model.

**Summary of Key Concepts**

- The Joint Commission of Pharmacists Practitioners (JCPP) vision statement reads, “Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.”
- Seventy-eight percent of pharmacists across pharmacy settings look forward to playing a greater role in patient care, and the majority expect to spend more time on patient-focused activities in the next five years.
- Recent graduates are entering the job market with the knowledge, skills, abilities, and attitudes to function as the drug expert in collaborative health care models.
- The pharmacist is accountable for taking the steps outlined in the Patient Care Process while collaborating with others, communicating effectively, and documenting his or her work.
- Although other nonphysician practitioners have gained considerable authority to participate in this prescribing process, the pharmacist remains limited to offering recommendations and counseling rather than acting as a decision maker.
- Reimbursement opportunities for pharmacists abound in payment models that incentivize optimal medication use rather than drug costs alone.
- Scope-of-practice expansion and a shift toward value-based payment models have the potential to increase liability; however, there are ways that pharmacists can minimize risk.

**Background**

**Defining Accountability**

*Accountability* means answering to actions taken. The difference between responsibility and accountability is that responsibility can be shared, whereas accountability reflects individual ownership of the steps taken toward an outcome. As the health care system shifts from volume to value-based reimbursement, health care professionals have an increasing responsibility to optimize patient outcomes in team-based care. However, there is a corresponding need to further define pharmacists’ accountability to the patients they serve and the outcomes they foster.
The JCPP adopted the following vision statement in 2017: “Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.” JCPP serves as a forum on matters of common interest and concern to national organizations of pharmacy practitioners.

In alignment with this vision is the APhA core value of accountability, which states, “We hold ourselves to the highest standards of performance toward reasonable and achievable goals. We accept responsibility for the outcome of our work, as well as the process that leads to it.” The Pharmacists’ Patient Care Process was developed by JCPP in 2014, and it outlines the steps a pharmacist is accountable for when caring for a patient. The goal of this process is to achieve high-quality, cost-effective, and accessible care for patients through team-based care. The Patient Care Process defines what a pharmacist is accountable for and his or her responsibility to both the patient and the health care team.

Current Landscape
Pharmacists are increasingly engaging in expanded roles with a focus on patient care rather than dispensing, but barriers continue to limit the pharmacist’s impact on the public’s health. A study conducted by AmerisourceBergen in 2018 found that 78 percent of pharmacists across pharmacy settings look forward to playing a greater role in patient care and that the majority expect to spend more time on patient-focused activities in the next five years. The study surveyed pharmacists across four settings: chain, independent, specialty, and hospital pharmacy. Across pharmacy settings, as new technologies and medical advancements transform the health care environment, what excites pharmacists most is playing a greater role in patient care and, more broadly, in health care.

The pace varies at which pharmacy settings are shifting from traditional dispensing roles to decision-making health care providers. Chain pharmacists continue to spend the majority of their time filling prescriptions, more than any other practice site. On average, pharmacists report that they are able to spend only 10% of their time counseling and they feel that they will spend more time in the future with activities such as counseling, medication therapy management, preventive care screenings, immunization administration, and data reporting. Pharmacists in the independent pharmacy setting feel the most empowered to make decisions about their patients. Nearly 60% of independent pharmacists are considered the final decision maker, compared with the hospital (33%), community (25%), and specialty (20%) settings.

Education Transformation
Recent graduates are entering the job market with the knowledge, skills, abilities, and attitudes to function as the drug expert in collaborative health care models. Since the 1990s, colleges of pharmacy have transitioned to a four-year doctor of pharmacy degree. Residency and fellowship programs continue to abound, with 4,777 individuals matched to more than 2,300 programs in 2018. The number of residency positions available has nearly doubled over the past five years. New practitioners have more formal training than ever before, but reimbursement lags the surplus of pharmacists well versed in advanced pharmacy practices and population-oriented services.
Evidence shows that more time spent gaining practical pharmacy experience improves confidence. However, a body of research and exploratory studies in Canada underscore the trend toward decision-making avoidance related to professional responsibility toward outcomes.\(^6\)\(^7\) Identifying as educators, rather than as decision makers accountable for patient outcomes, could limit the adoption of advanced pharmacy practices. Preliminary evidence from small exploratory studies indicates that pharmacists identify with strengths such as creating harmony and have a tendency toward decisional avoidance.\(^8\) Studies that explore whether advanced training improves a pharmacist’s decision-making abilities and accountability for patient outcomes are lacking.

**Other Nonphysician Practitioners**
Largely considered the most underused member of the health care team, pharmacists lag behind other nonphysician practitioners gaining decision-making authority and traction in their efforts to expand scope of practice. Nurse practitioners (NPs) and physician assistants (PAs) have become increasingly accountable for patient outcomes and are able to provide expanded access to health care.

NPs may prescribe medications in every state and may practice to the fullest extent of their license in 23 states, but practice may be reduced or restricted in other states. Full practice provides for NPs to evaluate patients, diagnose, order and interpret diagnostic tests, and initiate and manage treatments—including prescribing medications and controlled substances—under the exclusive licensure authority of the state board of nursing. Reduced practice requires the NP to operate under a regulated collaborative practice agreement, and restricted practice requires career-long supervision, delegation, or team management by another health provider.\(^9\)

The PAs’ supervision requirements, prescriptive authority, and scope of practice are determined by the state medical board or law, or at the practice level. PAs have prescriptive authority, and PAs in 43 states are authorized to prescribe Schedule II–V medications. In 47 states, PAs are supervised by physicians, and the PA’s scope of practice is determined by the supervising physician at the site. Collaborative practice agreements or alternate arrangements define the PA’s scope of practice in other states. With a majority of decision-making capabilities determined on the basis of the practice site, PAs are experiencing more autonomy through their relationships with physicians.\(^10\)

**Patient Care Process**
Since the creation of the Patient Care Process in 2014, this consistent model for patient care has been widely incorporated into pharmacy practice and education. Pharmacists are uniquely positioned to streamline care in a system susceptible to frequent medication changes made by multiple, often disconnected, prescribers. The pharmacist is largely considered the most accessible and trusted health care provider—according to research conducted by the National Association of Chain Drug Stores, nearly 90% of Americans live within 5 miles of a community pharmacy.\(^11\) Furthermore, pharmacists are positioned to detect whether actual medication use and patient behavior conflict with prescriber intent.

Frequent patient encounters at the pharmacy favor the initial step of the Patient Care Process, which is to “establish a patient-pharmacist relationship that supports engagement and effective communication with patients, families, and caregivers throughout the process.”\(^2\) On average,
patients will visit their pharmacy 35 times per year, with only 4 visits to their primary care physician during that time. Additionally, patients may see, on average, 9 outpatient health care providers, including specialists; physical therapists; and home health care, behavioral health care, and nutrition professionals.\(^{12}\)

The Pharmacists’ Patient Care Process was designed to support consistent care delivery across all pharmacy settings. The pharmacist is accountable for taking the steps outlined in the Patient Care Process while collaborating with others, communicating effectively, and documenting his or her work.

The Patient Care Process has been included below for your reference.\(^2\)

1. **Collect:** The pharmacist assures the collection of necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient. Information may be gathered and verified from multiple sources including existing patient records, the patient, and other health care professionals. This process includes collecting:
   a. A current medication list and medication use history for prescription and nonprescription medications, herbal products, and other dietary supplements
   b. Relevant health data that may include medical history, health and wellness information, biometric test results, and physical assessment findings
   c. Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors that affect access to medications and other aspects of care

2. **Assess:** The pharmacist assesses the information collected and analyzes the clinical effects of the patient’s therapy in the context of the patient’s overall health goals in order to identify and prioritize problems and achieve optimal care. This process includes assessing:
   a. Each medication for appropriateness, effectiveness, safety, and patient adherence
   b. Health and functional status, risk factors, health data, cultural factors, health literacy, and access to medications or other aspects of care
   c. Immunization status and the need for preventive care and other health care services, where appropriate

3. **Plan:** The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective. This process includes establishing a care plan that:
   a. Addresses medication-related problems and optimizes medication therapy
   b. Sets goals of therapy for achieving clinical outcomes in the context of the patient’s overall health care goals and access to care
   c. Engages the patient through education, empowerment, and self-management
   d. Supports care continuity, including follow-up and transitions of care as appropriate

4. **Implement:** The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver. During the process of implementing the care plan, the pharmacist:
   a. Addresses medication- and health-related problems and engages in preventive care strategies, including vaccine administration
   b. Initiates, modifies, discontinues, or administers medication therapy as authorized
   c. Provides education and self-management training to the patient or caregiver
   d. Contributes to coordination of care, including the referral or transition of the patient to another health care professional
   e. Schedules follow-up care as needed to achieve goals of therapy

5. **Follow-up:** Monitor and Evaluate: The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the
patient or caregiver as needed. This process includes the continuous monitoring and evaluation of:

a. Medication appropriateness, effectiveness, and safety and patient adherence through available health data, biometric test results, and patient feedback
b. Clinical endpoints that contribute to the patient’s overall health
c. Outcomes of care, including progress toward or the achievement of goals of therapy

The steps of the Pharmacists’ Patient Care Process provide a framework that adapts to any care delivery setting. Depending on the setting, the pharmacist’s approach to the Collect and Implement steps will differ the most. For example, some pharmacists are able to access more patient information than others. Similarly, differences in scope of practice alter the pharmacist’s capacity to implement a patient-centered care plan when addressing medication and health-related problems.

The pharmacist collects subjective and objective information from a variety of available sources, including the patient’s pharmacy profile, prescription drug monitoring programs, immunization information system, the patient or his or her caregiver, and sometimes through an electronic medical record. Because collecting information is the first step in the Pharmacists’ Patient Care Process, the information collected results in a downstream effect on medication use and patient outcomes.

As we move toward a value-based system, pharmacists continue to make access to patient information a priority through interprofessional collaboration. Pharmacists are unique in their ability to collect patient adherence and drug pricing information. In the community setting, the pharmacist is able to collect prescribing information across multiple providers, which helps detect duplications and interactions. Complete, accurate, and accessible patient information influences many of the actions pharmacists are accountable for in their approach to patient care.

**Pharmacist Scope of Practice**

Evidence is mounting that expanded pharmacist scope of practice increases patient access to health care, improves patient outcomes, and reduces costs. Every state enables pharmacist prescriptive authority under collaborative practice agreements (CPAs), standing orders, or statewide protocols, but a continuum exists as a result of variable models and approaches to prescriptive authority. While many scope-of-practice activities are consistent across state lines, prescriptive authority varies significantly from state to state, as does a pharmacist’s ability to order/interpret labs and administer medications and tests. As pharmacists advocate for greater ability to implement patient-centered care plans, a broad understanding of prescriptive authority is imperative to identify the best models for pharmacists’ state and practice settings.

The American College of Clinical Pharmacy defines prescribing as a process that includes selecting, initiating, monitoring, continuing, discontinuing, modifying, and/or administering drug therapy. Pharmacists participate in some aspects of prescribing, such as extending an emergency refill, monitoring drug use and adherence, and administering some drug therapies. The Drug Enforcement Administration rests a corresponding responsibility with the pharmacist to ensure that a prescription for a controlled substance is issued for a legitimate medical purpose, uniquely involving the pharmacist in the initiation of a controlled substance to combat potential diversion.
Although other nonphysician practitioners have gained considerable authority to participate in the prescribing process, the pharmacist remains limited to offering recommendations and counseling rather than acting as a decision maker. The importance of pharmacist-driven interventions was captured by a recent study that found that patient retention was increased significantly when a patient with HIV received a pharmacist-clinic action plan and had three or more encounters with the pharmacist. A pharmacist-clinic action plan involved shared patient information and empowered pharmacists to act as a decision maker when medication changes were necessary. Neither adherence counseling nor counseling related to medication use (e.g., instructions to take with food) alone was significantly associated with patient retention.16

Two overarching categories describe the current landscape of pharmacist prescriptive authority: collaborative prescribing and autonomous prescribing. In comparison, collaborative prescribing is more restrictive and results from a voluntary relationship between a prescriber and a pharmacist, in which the prescriber delegates his or her authority to prescribe to the pharmacist. All 50 states and the District of Columbia have in place CPAs, which are the most common model of collaborative prescribing. In 2016, 36 states allowed pharmacists to initiate medications in the outpatient setting under a CPA, whereas CPAs in other states only allowed for therapy modifications or required initiation to take place at an inpatient setting.13 Furthermore, CPAs may differ by whether they are patient-specific or population-specific. A patient-specific CPA restricts the services provided to the specific patients identified therein, whereas a population-specific CPA identifies categories of patients who may be eligible for services.

Autonomous prescribing encompasses statewide protocols and unrestricted category-specific prescribing. A statewide protocol is set by an authorized government body, such as the board of pharmacy or the department of health. Currently, statewide protocols and standing orders are applied to the following categories: naloxone (25), immunizations (18), tobacco cessation (12), contraceptives (10), general authority (4), tuberculosis testing (2), fluoride (2), travel medicine (2), and epinephrine (2).14 Under an unrestricted category-specific prescribing model, pharmacists may prescribe a medication without the supervision of a collaborating physician for a legitimate medical purpose within the scope of the pharmacist’s usual course of professional practice. Autonomous prescribing generally allows pharmacists to address such conditions that do not require differential diagnosing. Expanding the pharmacist’s scope of practice through autonomous prescribing has historically been a means to address important public health issues.

The Pharmacist and Value-Based Payment
Growing health care costs across the country have led to a vested interest in value-based care and a steady shift away from volume-based payment models. Reimbursement opportunities for pharmacists abound in payment models that incentivize optimal medication use rather than drug costs alone. Several such payment models exist, including episodic bundled payments, patient-centered medical homes, and, most predominantly, accountable care organizations (ACOs). These models share similar characteristics, such as risk-based payment, care coordination, and outcomes measurement.17 As the most accessible health care providers, pharmacists are poised to play an essential role in payment reform, in which the impact of pharmacist-driven medication optimization is in line with the goals of reducing costs and improving the quality of patient care.
The ACO reimbursement model relies on quality metrics that describe overall population health management across care settings. According to APhA, this model “requires identification and management of risk for all populations, coordination of care, optimization and synchronization of best practices, enhanced data intelligence and consumer engagement.”18 Quality measures that reflect medication use are increasingly driving pharmacist engagement in these new models of care delivery and reimbursement. Pharmacists are improving the delivery of medication-related services through medication therapy management and transitions of care. The role of the pharmacist is expanding to address access issues through innovations such as telehealth, and the pharmacists’ overall accessibility and competence are increasingly being leveraged to address pertinent public health issues such as the opioid crisis and immunization rates.19 Opportunities continue to emerge for pharmacists able to identify and address gaps in care, to develop and manage best practices, and to help meet medication-related quality metrics.18

Amid the trend toward quality, pharmacists feel there are barriers to good care. The survey conducted by AmerisourceBergen reports that pharmacists feel that lack of staff/bandwidth and concerns about the amount of time spent communicating with health care providers and dispensing medications limit good care. To overcome these barriers, those surveyed felt that data sharing and developing relationships with providers are key. Building relationships with physicians and other health care providers is an important strategy to implement patient care services. Past successes point to face-to-face contact early in the relationship to build trust, and pharmacies are beginning to hire staff to assist with relationship building. According Bacci et. al., “Chain management support can increase pharmacists’ capacity to build these relationships by providing resources such as additional staffing to enable a pharmacist to leave the pharmacy and engaging clinical pharmacist managers to provide on-the-job training on outreach strategies.”20

**Liability**

As scope of practice expands and value-based payment takes hold, pharmacists must be prepared to be held accountable. Without accountability, pharmacists will struggle to receive reimbursement for the outcome of their services; however, there is also an increased liability attributed to the health care team’s newfound responsibilities. New payments models are distributing risk to the level of the practitioner to affect behavior rather than receiving a capitated payment at the institution level.

These collective changes may increase the potential for liability, so taking the time to become familiar with the new laws and regulations is an important preventive step. The 2018 Healthcare Providers Service Organization (HPSO) Pharmacist Liability Claim Report identifies and addresses professional liability exposures. It states that “There is essentially no defense for working outside the state-established scope of practice. Being less than cognizant of regulations and standards related to pharmacist practice represents a substantial risk.”21 Many state pharmacy associations are developing resources that help guide pharmacists through these changes in practice and are preparing pharmacists for expanded opportunities. An emphasis on preparedness through education will help protect pharmacists from scope-of-practice claims that average a paid indemnity of greater than two times the overall paid indemnity in the 2018 HPSO report.
Another way to combat liability related to scope of practice is to advocate for and create scope-of-practice regulations that best suit each state and its patient population. In a paper by Adams and Weaver, they note that “Pharmacists following a statewide protocol may be less exposed to liability concerns than if they are following a CPA in which they negotiate the parameters.” There are risks and benefits inherent in any service and, often in any medication, but pharmacists are well trained to assess patients and manage medication use. In New Mexico, for example, pharmacists have been prescribing smoking-cessation medications for 12 years, and “we are not aware of any civil or administrative cases alleging harm from pharmacist-prescribed cessation medications.” Exposure to liability may increase as a result of expanded scope of practice and new payment models, but there is little evidence to suggest this risk would outweigh the benefit of enhanced pharmacist-provided services.

**Conclusion**

The pharmacists’ role is expanding, and there is a growing need for accountability to improved patient outcomes and cost reductions as a result of pharmacist-provided care. Pharmacists are experiencing more decision-making authority depending on their practice setting, and a shift is anticipated from traditional dispensing roles to opportunities for interprofessional collaboration and medication therapy management. Education and residency training should equip pharmacists with the confidence to be accountable for the actions taken throughout the patient care process, and the profession must continue to advocate for the expanded ability to collect patient information and implement patient care plans that support expanded access to care, improved care delivery, and optimized medication use. As value-based payment takes hold, pharmacists should be considered the medication experts and the most qualified health care professionals to ensure optimized medication use. While the health care team will become increasingly responsible for patient care outcomes, pharmacists must ensure that they are accountable for the improvements to care that result from the time and actions they contribute to the health care team.

**References**

Related APhA Policy

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

1. 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)

2011 Pharmacist’s Role in Health Care Reform

1. 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.

2. 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).

3. 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.
4. 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. 
5. 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.  
(JAPhA NS51(4) 482;July/August 2011) (Reviewed 2016) 

2009 Pharmacist’s Role in Patient Safety
1. It is APhA’s position that patient safety initiatives must include pharmacists in leadership roles. 
2. APhA encourages dissemination of best practices derived from nationally aggregated reporting data systems to pharmacists for the purpose of improving the medication use process and making informed decisions that directly impact patient safety and quality. 
3. APhA encourages the profession of pharmacy to continually review and evaluate ways to enhance training, curricula, continuing education and accountability of pharmacists to improve patient safety. 
4. APhA encourages risk management and post-marketing surveillance programs to be standardized and include infrastructures and compensation necessary to allow pharmacists to support these patient safety programs. 
5. APhA supports the creation of voluntary, standardized and interoperable reporting systems for patient safety events to minimize barriers to pharmacist participation and to enable aggregation of data and improve quality of medication use systems. The system should be free, voluntary, non-punitive, easily accessible, and user friendly for all providers within the health care system. 
6. APhA supports the elimination of hand-written prescriptions or medication orders. 

2002 Professional Practice Regulation
1. APhA encourages the revision of pharmacy laws to assign the responsibility and accountability to the pharmacy license holder for the operations of the pharmacy, including but not limited to quality improvement, staffing, inventory, and financial activities. Further, APhA supports the responsibility and accountability of the pharmacist for dispensing of the pharmaceutical product and for the provision of pharmaceutical care services. 
2. APhA encourages the pharmacy license holder to provide adequate resources and support for pharmacists to meet their professional responsibilities, and for pharmacists to utilize the resources and support appropriately and efficiently. APhA encourages state boards of pharmacy to hold pharmacy license holders accountable for failure to provide such adequate resources and support. 

1991 Mission of Pharmacy
APhA affirms that the mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes. 
2019–20 APhA Policy Committee Report

Specialty Pharmacy and Specialized Pharmacy Services

The Committee recommends that the Association adopt the following statements:

1. APhA recognizes that certain complex medications require more specialized care and resources; and APhA asserts that delineation of medications as specialty versus non-specialty, and associated payer and manufacturer practices, introduces risk of continuity of care disruption, patient access issues, and financial inequities.
   [Refer to Summary of Discussion Items 4,5,6]

2. APhA supports pharmacists and pharmacies that choose to specialize or incorporate specialty pharmacy services into their practice and provide enhanced patient care and other services to optimize patient outcomes.
   [Refer to Summary of Discussion Item 7 and 8]

3. APhA opposes payer policies and practices that limit patient choice of qualified pharmacy providers, disrupt continuity of care, or compromise patient safety through the creation of specialty drug lists, and restrictive specialty pharmacy networks.
   [Refer to Summary of Discussion Items 7,8,9,10,11,12,13,14,15]

4. APhA opposes manufacturer distribution and related business practices that restrict patient and pharmacy access to medications, medical products, and patient care services.
   [Refer to Summary of Discussion Items 16,17,18,19]

5. APhA advocates for the adoption of pharmacy profession-developed, harmonized practice standards for specialized pharmacy practices, and specialty pharmacy services and products.
   [Refer to Summary of Discussion Items 5,6,20,21,22,23,24,25,26,27,28,29]

6. APhA encourages increased availability and use of clinical practice, data integration, patient financial assistance, and other resources to support the provision of specialized pharmacy practices and specialty pharmacy services.
   [Refer to Summary of Discussion Items 8,11,30,31]

7. APhA supports the availability of education and training for pharmacists and student pharmacists related to specialized pharmacy practices and specialty pharmacy services.
   [Refer to Summary of Discussion Items 32,33,34]
Summary of Discussion

1. The committee discussed existing APhA policy statements at length and felt that there was enough urgency and timeliness related to these topics that warranted the reaffirmation of pieces of existing policy statements within these proposed statements. Additionally, the committee felt it was important to have a complete set of policy statements organized around the specific topic of specialty pharmacy and specialized pharmacy services.

2. The Committee reviewed existing information that provides a clarification for Medicare Part D plans and noted that, “Centers for Medicare and Medicaid Services (CMS) Part D plans may not restrict access to certain Part D drugs to “specialty” pharmacies within their Part D network in such a manner that contravenes the convenient access protections of §1860D-4(b)(1)(C) of the Social Security Act and 42 CFR §423.120(a). Specifically, Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Therefore, Part D plans may not restrict access based solely on the placement of a Part D drug in a “specialty/high cost” tier because this tier placement alone is not indicative of any special requirements associated with such drug.” CMS goes on to clarify reasonable requirements must be put in place for network pharmacies by Part D plans and “requiring pharmacies to accept different reimbursement rates for certain “specialty” drugs is inconsistent with standard industry practice.” Source: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf.

3. We also recognize that specialization in pharmacy occurs and naturally blends in this specialty pharmacy space. As of October 2019, over 10% of pharmaceutical drug spend is tied to ‘specialty pharmacy medicines.’ There is only growth anticipated in this space, creating a sense of great urgency for APhA’s House of Delegates to create policies that support continuity of care and ultimately improve patient safety as well as patient access to critical, lifesaving medicines.

4. The Committee discussed that the term “financial inequities” could also apply to pharmacies, patients, or other entities outside of the pharmacy profession.

5. The Committee noted that pharmacists providing specialized pharmacy services are encountering barriers from payers when working with medications that are identified as a specialty pharmacy product because the pharmacist is not practicing at a “specialty pharmacy.” The Committee believes standards should be developed to use existing definitions of “specialty pharmacy” to distinguish the difference between services, location of service provision, and products.

6. The Committee acknowledged limitations among the multiple existing definitions for specialty pharmacy and therefore did not call for the development of another definition, but instead practice standards that work from existing definitions and practices.

7. The Committee reviewed existing APhA policy 1978 Post-Marketing Requirements (Restricted Distribution) and 2004, 1966 Distribution Programs: Circumvention of the Pharmacist and believes Statements 2 and 3 are more specific to current practices and policies that are limiting patient access.
8. The Committee discussed evolving pharmacy practice environments and wanted to reaffirm APhA’s support for pharmacists and pharmacies advancing into specialized practices. The Committee reviewed existing APhA policy **2006 Continuity of Care**, which “supports patient access to pharmacists with specialized skills and expertise.”

9. The Committee specifically used the terminology “policies and practices” to have broad and inclusive language that would apply to any business, payer, system, company or other entity that may have control over patient choice.

10. The Committee reviewed existing APhA policy **2004, 1990 Freedom to Choose** and believes a reemphasis of patient choice is important to mention in this proposed policy statement in addition to this existing policy.

11. The Committee discussed the importance of maintaining the continuity of care to continue any existing relationship with a patient. The Committee also reviewed existing APhA policy **1995 Continuum of Patient Care** and referenced the importance to patient safety.

12. The Committee included “qualified” before “pharmacy providers” to note that additional criteria may need to be achieved to provide services, but the committee noted that the criteria need to be reasonable to achieve and could be determined within practice standards.

13. The Committee noted that some pharmacies are still encountering barriers to provide specialty pharmacy services, even after achieving accreditation through recognized programs.

14. The Committee reviewed existing APhA policy **2019 Consolidation within Healthcare** and believed these policies do not need to be restated but are relevant to the intent behind statement 3.

15. The Committee considered specifically referencing “payers and health systems” within this statement, as they acknowledged the practices highlighted in this policy are occurring in these two settings. The Committee considered health-system networks and the Centers for Medicare and Medicaid as a payer.

16. The committee referenced the World Health Organization’s (WHO) definition of “medical products”, which includes medicine, vaccine or in vitro diagnostic and it may also include medical devices at an appropriate time in the future. The Committee felt it was important to include this terminology to also include items like digital therapeutics and future products. Source: [https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1](https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1)

17. The Committee reviewed and recognized the following World Health Organization definition for “distribution practices”: “That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.”

18. The Committee agreed that the terminology of “business practices” would also include those business practices or tactics that health-systems or other entities may use but wanted to specifically include manufacturer in the statement.

19. The Committee reviewed and considered reaffirming existing APhA policy **1994 Product Licensing Agreements and Restricted Distribution**, but believes the proposed statement is broader and addresses more current issues that what are specifically mentioned in the
1994 policy. The Committee recommends modifications be considered by the Policy Review Committee as appropriate based on the final adopted policy.

20. The Committee originally discussed including descriptions on the standards, such as cost, limited distribution, and coverage, but shifted away from being prescriptive in the description of the standards and instead intends that these items would be identified and discussed through the process to develop and harmonize standards.

21. The Committee considered modifiers to practice standards such as evidence based, or consensus based. The Committee did not want to limit any standards to only be evidence based to allow for consideration of new or potential standards that may lack direct evidence. Consensus based was replaced with “pharmacy profession developed” as the intent is for the pharmacy profession to drive the process instead of just having a consensus of stakeholders that may not involve pharmacy profession representatives.

22. The Committee discussed existing practice standards and noted that some of these standards were developed by non-pharmacy groups or did not have representation from pharmacy organizations during the standard development process. The Committee specifically chose the word “harmonized” to incorporate these existing standards into a single standard that the profession of pharmacy can collectively support. The Committee also noted and discussed that some standards are not only developed by but are imposed on pharmacy practice by other entities such as payers, manufacturers, or other external accreditation agencies.

23. The committee agreed that the word “adoption” in statement 4 includes the use and establishment of the practice standards.

24. The Committee discussed calling for consensus on a “definition”, but instead used the terminology of “practice standard” as this will use the multiple definitions that have already been developed and apply the definitions to an actionable set of standards.

25. The terminology “pharmacy practice” was intentionally used to ensure that the profession of pharmacy is driving the development of these standard and engaged in review and implementation of the standards.

26. The Committee reviewed existing specialty pharmacy accreditation programs by the Center for Pharmacy Practice Accreditation (CPPA) and URAC.

27. The Committee discussed the topic of pharmacist certification in specialty practices and reviewed the current Certified Specialty Pharmacist certification offered by the National Association of Specialty Pharmacy. The Committee decided to not propose a potential statement in this area as they believed a pharmacist should pursue certification in the area in which they specialize.

28. The Committee reviewed APhA policy 2012, 1989 Recognition of Pharmacy Practice Specialties when considering a statement on pharmacist certification and still believes the process set forth by the Board of Pharmacy Specialties should still be the preferred method for consideration of future certification opportunities.

29. The Committee reviewed multiple examples of specialized pharmacy services and agreed that any specialized pharmacy service is focused in a specific practice area. This would include specific disease-state related services provided by a pharmacist in any type of pharmacy practice setting. For example, the Committee discussed HIV pharmacy services, diabetes management services, and hypertension management services as initial examples.
30. The Committee discussed the importance of a pharmacists to have access to resources and does not intend for APhA to create new resources, but to more so promote the access and use of existing resources in the marketplace.

31. The Committee’s intent with this statement is to ensure continuity of care across all providers of services.

32. The Committee debated not including a statement on education and training as they believed there is clinical care information included in the PharmD curriculum. However, the Committee identified specialty pharmacy and service components such as pharmacy operations, medication supply management, patient assistance programs, and administrative functions that are not currently well covered in the PharmD curriculum.

33. The committee agreed that education and training does not need to be focused in the didactic portion of the PharmD curriculum but could be a component in experiential learning.

34. The committee did not believe education and training should be mandated or required for all PharmD students, but rather this information should be available for any students interested in this practice area.
Specialty Pharmacy Services and Limited Drug Distribution

_E. Michael Murphy, PharmD_
Pharmacy Advancement Fellow
The Ohio State University College of Pharmacy

**Issue**

The American Pharmacists Association (APhA) Board of Trustees has directed the 2019–2020 Policy Committee to recommend policy to the APhA House of Delegates related to the scope and services provided by specialty pharmacy and the topic of limited drug distribution. Issues that the Board directed the Committee to address in this policy topic include, but are not limited to, defining scope and services provided by specialty pharmacy, addressing the educational requirements of personnel working in specialty pharmacy, ensuring appropriate team-based collaboration and patient safety and access to medications and education provided through specialty pharmacies, and establishing criteria for limited drug distribution within specialty pharmacy.

**Summary of Key Concepts**

- The concept of specialty medications and specialty pharmacy has been defined by multiple organizations and stakeholders; however, a consensus is lacking on a standardized definition of those terms.
- The challenges of defining specialty pharmacy are in part the result of multiple distribution models that specialty pharmacies can incorporate into the dispensing of medications, as well as the fact that specialty pharmacy is not federally regulated beyond that of normal pharmacy practice.
- The traditional pharmacy business model is more efficient at serving a high number of patients with lower-cost medications as opposed to higher-cost medications that require a significant amount of time and specialized skills to dispense.
- Although initially seen as a niche market, specialty medications and expenditures on them were on the rise by 2006. As year-to-year spending on nonspecialty medications grew between 2% and 6%, specialty medications spending had grown to more than 10% and was consuming 19% of overall drug expenditures.
- In 2018, prescriptions for specialty medications accounted for 2.2% of all prescriptions written and a 49.5% share of overall drug expenditures in the United States.
- The specialty pharmacist may play a role in monitoring medication adherence to communicate to the manufacturer in addition to traditional pharmacist-provided services, such as, but not limited to, patient education, medication management services, and coordination of therapy adjustments with interprofessional care team members.
- Unfortunately, there is no national standard for education, training, or certification for pharmacists or support staff who work within specialty pharmacy.
- Manufacturers and/or payers may justify the use of limited drug distribution networks because of the ability to control inventory, data collection, consistent handling on medications, utilization tracking, and case management support.
- Although justifiable benefits of using limited distribution networks for specialty pharmaceuticals exist, there are also potential complications to patients, such as, but not limited to, decreasing patient access to medications, polypharmacy, hindering generic and biosimilar drug development, and increasing drug costs.
• Specialty pharmacies provide many services, which can be broken into four categories: access-to-care services, clinical outcome services, drug affordability services, and operational services.

**Background**

**Definition**

The concept of specialty medications and specialty pharmacy has been defined by multiple organizations and stakeholders; however, a consensus is lacking on a standardized definition of those terms. The stakeholders range from professional member organizations to large chain drugstores and accrediting bodies that recognize pharmacies with the specialty pharmacy designation. Themes across these definitions include, but are not limited to, providing access to higher-cost medications, treating/controlling complex and/or rare disease states, and handling medications that require special storage and/or administration. A compilation of these definitions is included in Table 1.

<table>
<thead>
<tr>
<th>Academy of Managed Care Pharmacy (AMCP)</th>
<th>Specialty Pharmacy – “The preferred distribution by payers for prescription benefit specialty drugs because of its lowest net cost, patient education and adherence support.”</th>
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<tbody>
<tr>
<td>American Society of Health-System Pharmacists (ASHP)</td>
<td>Specialty Pharmacy – “Specialty pharmacy practice encompasses the provision of specialty pharmaceuticals, which typically require unique fulfillment and patient care support services.”</td>
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<tr>
<td>The Center for Pharmacy Practice Accreditation (CPPA)</td>
<td>Specialty Pharmacy Practice – “practice that, (1) manages the medication access and handling requirements of specialty pharmaceuticals, including dispensing and distribution, and (2) provides clinical management services for patients with rare and/or chronic disease who receive specialty medications designed to achieve the desired patient therapeutic and economic outcomes.”</td>
</tr>
<tr>
<td>CVS</td>
<td>Specialty Medication(s) – “often treat complex and chronic conditions. They tend to be more expensive and can require special storage like refrigeration or special administration, like an injection. And most require additional support.”</td>
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| National Association of Specialty Pharmacy (NASP) | Specialty Pharmacy – “A specialty pharmacy is a state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders.” | Specialty Medication – “Specialty drugs are more complex than most prescription medications and are used to treat patients with serious and often life threatening conditions including cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, hemophilia and other bleeding disorders. These medications may be taken orally but often must be injected.
or infused and may have special administration, storage and delivery requirements.”

| National Comprehensive Cancer Network (NCCN) | Goals of Specialty Pharmacy | “the optimization of pharmaceutical care outcomes through ensuring appropriate medication use, maximizing medication adherence, and optimizing economic outcomes through avoiding unwanted drug expenditure.” |
| Walgreens | Specialty Medication | “used to treat chronic, complex or rare conditions like cancer, rheumatoid arthritis, hepatitis C and others.” |

As recognized by NCCN, it is challenging to define specialty pharmacy because the range of business models that can fall within this designation is quite variable. This varied range is due in part to the multiple distribution models that specialty pharmacies can incorporate into the dispensing of medications, and because specialty pharmacy is not federally regulated beyond that of normal pharmacy practice. As a result of this lack of federal regulation, there is no nationwide standardized certification, which allows for the potential of specialty pharmacy practice to vary from pharmacy to pharmacy. Currently, there are four agencies for specialty pharmacy accreditation: Accreditation Commission for Health Care (ACHC), CPPA, the Joint Commission, and the Utilization Review Accreditation Commission (URAC). Although there is no national standard for accreditation, two-thirds of payers prefer URAC accreditation.

One of the distribution techniques that can contribute to the challenge of defining specialty pharmacy is when drug manufacturers or payers limit the distribution of a medication through an individual specialty pharmacy or a selected network of specialty pharmacies. This practice is commonly known as limited drug distribution.

A Historical Look at the Specialty Pharmacy Landscape

Specialty pharmacies began in the 1970s and were focused on the preparation and delivery of injectable medications. In the 1990s, expensive medications began entering the market to treat rare and complex disease states. Although these medications may be lifesaving to those afflicted with one of these disease states, patient access to these vital drugs was put in jeopardy by “paperwork and treatment costs” associated with the dispensing of these medications. Additionally, the traditional pharmacy business model was more efficient at serving a high number of patients with lower cost medications as opposed to higher cost medications that required a significant amount of time and specialized skills to dispense.

Recognizing a gap in the marketplace, Stadtlander Pharmacy in Pittsburgh, Pennsylvania, began focusing on disease states that required higher cost prescription medications, such as HIV, transplant, and multiple sclerosis. Other pharmacies would later follow Stadtlander’s lead into this niche marketplace. Because of the growth of specialty medications, by the time Stadtlander was purchased by CVS in 2000, revenues were greater than $100 million. Although revenues had grown significantly, this deal at the time was seen as a risk, with the New York Times, for example, describing Stadtlander Pharmacy as a “struggling specialty pharmacy business.” This description may be attributed to the fact that in the 1990s and early 2000s, specialty pharmaceuticals were seen largely as a niche market and were not expected to contribute to a significant percentage of overall drug expenditures. However, by 2006, as year-to-year spending on non-specialty medications was growing between 2% and 6%, specialty medications spending had grown to more than 10% and was consuming 19% of overall drug expenditures.

Pharmacists who worked in specialty pharmacies were able to increase patient access to these vital medications through assisting in patient paperwork and coordinating benefits to ensure patients were not subjected to large costs. In an effort to further increase access, specialty pharmacies began offering the ability to deliver medications. Although specialty pharmacy initially was a niche market filled mostly with independent pharmacies, the significant growth in revenues caught the attention of large chain
drugstores and pharmacy benefit managers (PBM) resulting in mergers and acquisitions. This progression has shaped the current specialty pharmacy marketplace by making it a marketplace primarily of large organizations, although some small and independent specialty pharmacies remain in this field.

**Current Specialty Pharmacy Landscape**

The use of specialty medications has continued to increase in the United States, resulting in their use growing twice as quickly as non-specialty medications between 2017 and 2018. Prescriptions for specialty medications now account for 2.2% of all prescriptions written in the United States. However, the cost of these medications accounts for a large, growing part of overall drug expenditures. From 2009 to 2018, specialty medication share of overall drug expenditures rose from 26.2% to 49.5%. Net total spending on medications is expected to continue to rise over the next 5 years, projected from $344 billion in 2018 to $405 billion to $435 billion in 2023. If the specialty medications’ share of overall drug expenditures continues to rise, it can be assumed that specialty medications will contribute significantly to this $61 billion to $91 billion estimated growth.

In this market that is consuming a growing amount of net total spending on medications, the pharmacist is a key figure in providing patient care services and facilitating the cost-effective dispensing of specialty pharmaceuticals to patients. As a result of tracking prescription data within the limited drug distribution network, the pharmacist may play a role in monitoring medication adherence to communicate to the manufacturer in addition to traditional pharmacist-provided services, such as, but not limited to, patient education, medication management services, and coordination of therapy adjustments with interprofessional care team members. Although the pharmacist and personnel who work within specialty pharmacies have been recognized as experts in the medications that they oversee, national organizations have recommended education and training to ensure patients are receiving the most optimal level of care.

Unfortunately, there is no national standard for education, training, or certification for pharmacists or support staff who work within specialty pharmacy. NCCN has provided recommendations that specialty pharmacy support staff should receive standardized training so that their triage of patient problems can be based on the most frequent patient populations they serve. Additionally, training is recommended on specialty products and on the focus of patient care beyond product-specific issues. NASP offers continuing education and certification of specialty pharmacists in an effort to ensure that pharmacists working in this field are receiving appropriate education to best serve their patients. Additionally, pharmacists can pursue the Certified Specialty Pharmacist (CSP) credential from the Specialty Pharmacy Certification Board. The CSP credential is not a requirement to practice in specialty pharmacy, although one specialty pharmacist has written that it “was an investment well made.” Many other training programs exist, including the Fundamentals of Managed Care Pharmacy Certificate Program from AMCP. Although it is beneficial that a vast amount of educational programming is available, the lack of a nationwide standardized training program for specialty pharmacists and support staff can result in patient care experience varying from pharmacy to pharmacy. This result may contribute to a lack of consensus around the services patients can expect to receive if they visit multiple specialty pharmacies.

Today, services provided by specialty pharmacies can come from a diverse group. NCCN recognizes that a specialty pharmacy may be an independent organization, a part of a PBM, or a community pharmacy; it may be a provider of home infusion services; and it may be integrated with health insurance plans. This variety is understandable from the historical perspective of specialty pharmacy, which includes a significant number of mergers and acquisitions.

An important topic that has been discussed frequently around specialty pharmacies is the limited drug distribution network, which is a distribution technique. Details from the standpoint of the manufacturer and payer, and potential implications for patient care, will be discussed in the following section.
**Limited Drug Distribution Networks**

A distribution technique frequently used by manufacturers and payers for specialty medications through specialty pharmacies is the limited drug distribution network. Three common types of distribution models are used to dispense specialty pharmaceuticals to patients, as detailed in Table 2.\(^{11}\)

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<th><strong>Table 2:</strong> Specialty Pharmaceutical Limited Drug Distribution Models(^{11})</th>
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<tr>
<td><strong>Open Channel</strong></td>
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<td><strong>Controlled Distribution System</strong></td>
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<td><strong>Hybrid</strong></td>
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These distribution models can range from being more open to very restrictive about where specialty pharmaceuticals may be dispensed from. Justifications for the use of these distribution models include inventory control, data collection, consistent handling of medications, utilization tracking, and case management support.\(^{11}\)

Because of the extreme cost of specialty pharmaceuticals, one can recognize the appeal of a consistent set of trained professionals overseeing the inventory and handling of medications that often require special storage conditions.\(^{11}\) Additionally, data can be a powerful tool to manufacturers and payers for a variety of purposes, such as forecasting. Through limited drug distribution networks, these stakeholders can receive standardized data on specialty pharmaceutical use from a restricted group of pharmacies. These specialty pharmacies can also serve in a case management support role if patients face challenges with insurance or copayment costs.\(^{11}\) The cost associated with adding a specialty pharmacy location can be an additional explanation by manufacturers and payers to justify the use of limited distribution networks. It has been estimated that it can cost a manufacturer more than $90,000 to add a single location to dispense its specialty pharmaceutical.\(^{19}\)

Although justifiable benefits exist for specialty pharmaceuticals, there are also potential complications from the use of this distribution technique. Limiting where specialty pharmaceuticals can be dispensed from can decrease patient access to care.\(^{20,21}\) Several national professional pharmacy organizations have supported laws, often referred to as “any willing pharmacy” legislation, that would allow patients the ability to choose the pharmacy that they feel fits their needs best as opposed to limiting patients’ ability to fill at a specific pharmacy.\(^{22,23}\) Limited distribution networks can result in patients filling prescriptions at multiple pharmacies. The practice of filling medications at multiple community pharmacies can decrease patient adherence and increase risk of drug–drug interactions.\(^{6,24}\) One specialty pharmacist described the inability of patients to fill all of their specialty pharmaceuticals at one location as leading “to challenges in establishing clear roles and responsibilities” within that specialty pharmacy.\(^{20}\)

In addition to concern that limited drug distribution networks can compromise patient care, there have been reports that the use of this distribution technique can hinder generic and biosimilar drugs from entering the market and are resulting in rising drug prices in the United States.\(^{21}\) Within limited distribution networks, manufacturers can contractually prohibit the sale of their medication to generic or biosimilar companies. These companies may be able to purchase these medications eventually through litigation; however, limited distribution networks can result in a significant barrier for these companies.
to produce generic or biosimilar products. It has been widely published that generic medications can decrease patient and payer costs, exemplified by the use of generic medications having reportedly saved the U.S. health care system more than 2 trillion dollars in the past 10 years.\textsuperscript{25} Through these findings, one could be led to believe that barriers put in place to the production of generic and/or biosimilar specialty pharmaceuticals could be contributing to an increase in costs to the U.S. health care system.

There are significant complexities around the distribution techniques used to maintain market share of specialty pharmaceuticals dispensed at specialty pharmacies. However, at those pharmacies, just like at all pharmacies, there are health care practitioners providing important services to their patients.

**Specialty Pharmacy Services**

As defined by the Pharmaceutical Care Management Association, “Specialty pharmacy services are designed for a small, but growing population of patients with relatively complex and chronic diseases that require expensive and challenging drug regimens.”\textsuperscript{26} These services are provided to individuals with complex conditions that include, but are not limited to, hemophilia, HIV/AIDS, organ transplant, hepatitis C, and many more.\textsuperscript{26} Services provided to these patients can be placed into four categories: access-to-care services, clinical outcome services, drug affordability services, and operational services.

Category 1: Access-to-care specialty pharmacy services are focused on provider and patient engagement and/or guidance services. Examples of these services include access for health care providers to receive consultations on questions and best practices for conditions that specialty pharmaceuticals treat. In addition to services that are focused on the health care profession, there are access-to-care services that are more patient centric.\textsuperscript{26} The ability for patients to consult with physicians and/or other health care professionals, and the provision of care management services that provide disease- and drug-specific oversight to ensure patient safety are examples of services provided by specialty pharmacy that are more focused on the patient.\textsuperscript{26}

Category 2: Clinical outcome specialty pharmacy services are designed to enhance the therapeutic outcomes of conditions that are being treated with specialty pharmaceuticals. Those services can be completed through the tracking of clinical outcomes measures in an effort to associate the efficacy of specialty pharmaceuticals with patients reaching therapeutic outcomes.\textsuperscript{26,27} Additionally, patient adherence programs can be used to ensure proper compliance with medication regimens. Such services can be particularly important in decreasing overall health care expenditures; it has been shown that increases in adherence to medications are associated with decreases in hospitalizations and emergency department visits.\textsuperscript{28,29} Finally, Risk Evaluation and Mitigation Strategy (REMS) is frequently used as a clinical outcomes service by specialty pharmacies to ensure appropriate prescribing of medications and to minimize potential danger to patients of high-risk medications.\textsuperscript{26,27}

Category 3: Drug affordability services were some of the first identifiable services provided by specialty pharmacies. These services were previously described in this paper through viewing the historical and current perspectives of this field. Drug affordability services can be vitally important to patients being treated with specialty pharmaceuticals, because patients can frequently find it complicated to navigate their insurance system to result in specialty pharmaceuticals being covered. Additionally, specialty pharmacies can provide patient assistance in ensuring that qualified patients are enrolled in patient assistance programs, and through plan optimization to maximize therapeutic outcomes while weighing economic cost associated when reviewing insurance formularies.\textsuperscript{26,27}

Category 4: The final category of services provided by specialty pharmacies is operational services. Operational services can be further categorized into non-patient care operational services and patient care operational services. Non-patient care operational services include the supply chain management expertise that the pharmacist provides to ensure specialty pharmaceuticals maintain their strict handling
instructions. Patient care operational services include the pharmacist’s collaboration with physicians and other members of the health care team in regard to chronic disease state management, care coordination, and more, and providing delivery services to patients to increase customer service and, potentially, adherence rates.

An example of the impact of specialty pharmacy services can be seen in a 2013 study published in the *Journal of Managed Care Pharmacy*. The study evaluated the clinical and economic outcomes associated with a mandatory transplant specialty pharmacy program for post-renal transplant patients as compared with patients receiving traditional pharmacy services. This study identified that patients in the specialty pharmacy group had a 13% decrease in overall health care costs and a 30% decrease in medication costs as associated with the traditional group. Additionally, adherence rates were higher in the specialty pharmacy group, as well as rates of medication possession ratio, both of which were used as markers for therapeutic outcomes. This study identifies the therapeutic and economic value associated with specialty pharmacy services.

Pharmacists in the specialty pharmacy field provide a significant number of specialized services to their patients. These services can be categorized as described earlier and help to exemplify the true value of the pharmacist in this ever-growing marketplace.

**Conclusion**

Since the beginning of specialty pharmaceuticals in the 1970s, their boom in the 1990s and through the present, their use has continued to grow, resulting in their share of net total spending on medications reaching nearly 50% in 2018. Numerous stakeholders and professional organizations have defined specialty pharmacy and specialty pharmaceuticals; however, a consensus on the definition has not been agreed upon within the industry. Contributing to this lack of a consensus definition is the absence of federal oversight and a standard accreditation procedure for specialty pharmacies. Similarly, a vast number of educational, training, and certification programs are available for specialty pharmacists and support staff; however, there are no nationwide standards or requirements. Specialty pharmacists have the ability to assist patients in navigating a complex health care system in order for patients to receive these expensive and often lifesaving medications. Specialty pharmacy services also oversee clinical outcomes, access to care, and operational services. However, requirements by manufacturers and/or payers to practice within limited drug distribution networks, while potentially beneficial to manufacturers, may contribute to negative patient outcomes and increase drug costs. As the cost of medications is expected to continue to rise, specialty pharmacy has cemented itself as an important piece of the profession. As a result, a consensus definition of specialty pharmacy and specialty pharmaceuticals, standardized educational requirements for specialty pharmacists and support staff, and guidelines around the use of distribution techniques, such as limited distribution networks, would be beneficial for this growing field of the profession of pharmacy.

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Relevant APhA Policies

1994  **Product Licensing Agreements and Restricted Distribution**
APhA opposes any manufacturer-provider relationship which involves product licensing agreements and/or restricted distribution arrangements which infringe on pharmacists' rights to provide pharmaceuticals and pharmaceutical care to their patients.

1978  **Post-Marketing Requirements (Restricted Distribution)**
APhA opposes any legislation that would grant FDA authority to restrict the channels of drug distribution for any prescription drug as a condition for approval for marketing the drug under approved labeling.

1964  **Specialty Organizations in Pharmacy (2004.archived)**
APhA should continue its policy of meeting with any and all specialty organizations in pharmacy to seek mutual understanding and to develop programs to achieve the objectives and policies of APhA.

2004, 1966  **Distribution Programs: Circumvention of the Pharmacist**
APhA opposes distribution programs and policies by manufacturers, governmental agencies, and voluntary health groups which circumvent the pharmacist and promote the dispensing of prescription, legend drugs by non-pharmacists. These programs and policies should, in the public interest, be eliminated.

2004, 1968  **Manufacturers’ Pricing Policies**
APhA supports pharmaceutical industry adoption of a “transparent pricing” system which would eliminate hidden discounts, free goods, and other subtle economic devices.
1985  **Pharmaceutical Pricing**
APhA supports a system of equal opportunity with the same terms, conditions, and prices available for all pharmacies.

1985  **Reduction of Federal Laws and Regulations (Paperwork Burden)**
APhA supports the reduction and simplification of laws, regulations, and record-keeping requirements which affect pharmacy practice and are not beneficial in protecting the public welfare.
Committee Members

Jeffrey J. Neigh, Chair
Ally Dering-Anderson
Lauren E. Boden
Heather Hellwig
Brian Hose
Norman Tomaka
Jonathan Parker Vincent

Ex Officio
Joey Mattingly, Speaker of the House
NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: ____________________________

(Name)

1/21/2020 APhA Academy of Pharmacy Practice and Management (APhA-APPM)

(Date) (Organization)

Subject: E-Prescribing Standardization

Motion: To amend existing policy to include the following new statement #5 on 2010 E-prescribing Standardization:

5. APhA supports laws and regulations that require e-prescribing of controlled substances to eliminate many types of fraudulent prescriptions.

Background:

E-prescribing is widely accepted by the healthcare industry as a tool that reduces medication errors by improving the accuracy and understandability of prescriptions, and simplifying the prescription process for doctors and patients.1,2 In the decade since APhA adopted its statement on e-prescribing, the technology has largely become the preferred method for writing prescriptions nationwide. Much of what APhA supports has been implemented by organizations like NCPDP and the nation’s largest insurer, Medicare, which took several regulatory steps and implemented financial incentives to encourage its adoption nationwide.3

Meanwhile, in recent years opioid abuse has emerged as a major public health crisis.3 The Drug Enforcement Administration (DEA) identified early on that prescription fraud is a major factor in increasing the supply of illicit opioids.4 The DEA’s Pharmacist’s Guide to Prescription Fraud released in 2000 identified five major avenues for forged prescriptions. All five methods are essentially eliminated with the use of e-prescribing. In 2010 the DEA made the connection and issued regulations allowing the use of the technology for controlled substance prescribing.

Initially, states were slow to adopt e-prescribing for controlled substances. From 2010 to 2018, only 4 states had mandated its use.5 However, as standards and technology have improved, additional benefits such as 2-factor identification and cross-referencing with prescription drug monitoring programs have increased the
ability to reduce fraudulent and inappropriate controlled substance prescribing. With added benefits and confidence, several other states have reassessed their initial reluctance. As of August 2019, a total of 27 states have passed laws that require controlled substances be e-prescribed, with planned implementation dates ranging from 2020 – 2023. Interestingly though, approximately half of these states allow for program waivers and include no penalties for non-compliance.

The recent progress is very encouraging, but it is worth noting that as of August 2019, only one additional state has legislation pending consideration. More work is needed to maintain the momentum, and ensure all states require controlled substance e-prescribing. The APhA-APPM encourages APhA members to modernize their stance on e-prescribing by adding their explicit support of a requirement for controlled substances.


Current APhA Policy & Bylaws:

2010 E-prescribing Standardization
1. APhA supports the standardization of user interfaces to improve quality and reduce errors unique to e-prescribing.
2. APhA supports reporting mechanisms and research efforts to evaluate the effectiveness, safety, and quality of e-prescribing systems, computerized prescriber order entry (CPOE) systems, and the e-prescriptions that they produce, in order to improve health information technology systems and, ultimately, patient care.
3. APhA supports the development of financial incentives for pharmacists and prescribers to provide high quality e-prescribing activities.
4. APhA supports the inclusion of pharmacists in quality improvement and meaningful use activities related to the use of e-prescribing and other health information technology that would positively impact patient health outcomes.


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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: ___________________ Sarah Ray __________________________
(Name)

1/21/2020   APhA Academy of Pharmacy Practice and Management (APhA-APPM)
(Date)   (Organization)

Subject: Community-based Pharmacists as Providers of Care

Motion: To adopt the following new policy statements:

1. APhA advocates for the identification of medical conditions that may be safely and effectively treated by community-based pharmacists.
2. APhA encourages the training and education of pharmacists and student pharmacists regarding identification, treatment, monitoring, documentation, follow-up and referral for medical conditions that may be safely and effectively treated by community-based pharmacists.
3. APhA strongly advocates for laws and regulations that allow pharmacists to identify and manage medical conditions that may be safely and effectively treated by community-based pharmacists.
4. APhA strongly advocates for appropriate remuneration for the assessment and treatment of medical conditions that may be safely and effectively treated by community-based pharmacists from government and private payors to ensure sustainability and access for patients.
5. APhA supports research to examine the outcomes of services that focus on medical conditions that may be safely and effectively treated by community-based pharmacists.

Background:

Patients are only able to receive care if they have access to care. There are many barriers inhibiting patients from receiving the care they need. Primary care provider shortages and geographical limitations, limited appointment availability and office hours, and transportation barriers are just a few of the examples of how patient access to quality healthcare can be challenging. Patients need to be able to access convenient care when and where they need it.

In 2010, physicians in the United States estimated that about 10% of their appointments could have been self-managed by the patient and between 2006 and 2009, 10.1% of emergency department (ED) visits were triaged...
as “non-urgent”. One study found that 32% of non-urgent ED visits were due to lack of accessibility to their primary care provider. There is a need to restructure healthcare expenditures for sustainability of the healthcare system, increase patient access to care, and improve patient outcomes. Historically, community-based pharmacists have served patients primarily in dispensing roles, ensuring the safe and accurate distribution of medication. As the practice of pharmacy and training of pharmacists continues to evolve, pharmacists are now being utilized more for their clinical expertise and gradually being recognized as important members of the healthcare team. Community-Based pharmacists have proven their worth in improving outcomes through chronic care management, improving medication adherence and optimizing medications for patients, working in a variety of settings in the community. Specific examples of these settings include chain and independent pharmacies, hospital-based outpatient clinics and pharmacies, physician offices, free clinics, federally qualified health centers, nursing homes, telehealth, houses of worship, barber shops, and community health events.

Community-based pharmacists are the focus of these policy statements, because they are often the first point of contact with patients seeking medical advice or over-the-counter medications and are in an ideal position to assess and prescribe prescription-only drug therapy for certain conditions, potentially decreasing physician office and emergency room visits. Additionally, many community-based pharmacists can provide care to patients outside of physician office traditional business hours due to extended hours during evenings, weekends and holidays, increasing patient access to care. Whether a patient has a positive influenza test or a chronic cough, assessment and initiation of treatment at the pharmacy by a pharmacist reduces time to therapy versus the current standard of practice of patients being referred to another prescriber for a prescription and then returning to a pharmacy to have the prescription filled. Community-Based pharmacists are well suited to fill the gap in patient access to health care and manage certain conditions due to their extensive training, drug information expertise and accessibility to patients to provide care when and where patients need it.

Although there are some examples (Idaho, Washington) of pharmacists prescribing medications through CPAs or government legislation/regulation, pharmacists’ authority to safely and effectively treat medical conditions varies state by state, and there is no accepted definition of medical conditions that are appropriate for a community-based pharmacist to treat. It is imperative that APhA leads the way in the identification of medical conditions that can be safely and effectively treated by community-based pharmacists.


**Current APhA Policy & Bylaws:**

**2017 Patient Access to Pharmacist-Prescribed Medications**

1. 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.

*(JPhA 57(4): 441 July/August 2017)*

**2016 Point-of-Care Testing**

1. 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)*

**2011 Pharmacist’s Role in Health Care Reform**

1. 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.

2. 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).

3. 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.

4. 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.

5. APhA actively promotes the outcomes-based studies, pilot programs, demonstration projects, and other activities that document and reconfirms pharmacists’ impact on patient health and well-being, process of care delivery, and overall health care costs.

(JAPhA NS51(4) 482; July/August 2011)(Reviewed 2016)

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.

(JAPhA NS51(4) 482; July/August 2011)(Reviewed 2016)

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.

(JAPhA NS51(4) 482; July/August 2011)(Reviewed 2016)

2017, 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 toward establishing a consistent and accurate perception of the contemporary role and practice of pharmacists by the general public, patients, and all persons and institutions engaged in health care policy, administration, payment, and delivery.

3. APhA supports continued collaboration with stakeholders to facilitate adoption of standardized practice acts, appropriate related laws, and regulations that re-ect 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 continued 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.

(JAPhA NS52(4) 457 July/August 2012)(Reviewed 2016) (JAPhA 57(4): 441 July/August 2017)

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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: ___________________ William “Chris” Charles ____________________
(Name)

1/21/2020 APhA Academy of Pharmacy Practice and Management (APhA-APPM)
(Date) (Organization)

Subject: Integrated Nationwide Prescription Drug Monitoring Program

Motion: To amend and to add a new statement to existing policy statement on Integrated Nationwide
Prescription Drug Monitoring Program (2015):

AMEND Current Statement #1:

1. APhA supports advocates for nationwide integration and uniformity of prescription drug monitoring
 programs (PDMP) that incorporate federal, state, and territory databases for the purpose of providing
 health care professionals with accurate and real-time information to assist in clinical decision
 making when providing patient care services related to controlled substances.

ADD a new statement #8:

8. APhA opposes laws and regulations that may place an onerous burden on pharmacies by mandating
 system query prior to dispensing a controlled substance.

Background:

We would like to amend statement #1 of the Integrated Nationwide Prescription Drug Monitoring Program
2015 (henceforth referred to as the 2015 Policy) to more accurately reflect the current challenges with
PDMP’s utility in helping pharmacists address the opioid crisis. In order to maximize its utility the state
based PDMPs need to be integrated and uniform nationwide rather than regionally.

We are leaving statements #2 through 7 of the 2015 Policy as originally written as they are still pertinent
and needed.
We are adding statement #8 to the 2015 Policy to address a concerning trend in state legislation mandating pharmacists check the PDMP before dispensing controlled substances. We understand the benefit of reviewing the PDMP prior to dispensing a controlled substance; however, mandates are disruptive to the dispensing process. Mandating review of the PDMP would require an additional task in an already complicated process. Due to declining prescription drug reimbursements, pharmacies have been forced to reduce staffing levels in order to stay in business. Adding an additional step to every controlled substance prescription a pharmacy dispenses would significantly increase workload potentially leading to an increase in dispensing errors.

Currently, pharmacists are trained to recognize ‘red flags’ and react accordingly, including checking the PDMP, verifying the prescription by calling the prescriber, and notifying law enforcement officials if needed. Typical practice includes checking the PDMP for new patients, new prescriptions, and any ‘red flags’; once a consistent, reliable pharmacist-patient relationship is established, checking the PDMP generally occurs on a periodic basis rather than with every prescription. Mandating pharmacies check the PDMP with every prescription limits our ability to offer a high-quality service to our patients in a timely fashion. We believe the pharmacist has the right to decide when it is necessary to check the PDMP.

The American Medical Association does not have an official position regarding mandatory system query; however, they do have one that states they will work to ensure it “does not place an onerous burden” on physician practices1.


Current APhA Policy & Bylaws:

2015 Integrated Nationwide Prescription Drug Monitoring Program

1. APhA supports nationwide integration of prescription drug monitoring programs (PDMP) that incorporate federal, state, and territory databases for the purpose of providing health care professionals with accurate and real-time information to assist in clinical decision making when providing patient care services related to controlled substances.

2. APhA supports pharmacist involvement in the development of uniform standards for an integrated nationwide prescription drug monitoring program (PDMP) that includes the definition of authorized registered users, documentation, reporting requirements, system response time, security of information, minimum reporting data sets, and standard transaction format.

3. APhA supports mandatory prescription drug monitoring program (PDMP) enrollment by all health care providers, mandatory reporting by all those who dispense controlled substances, and appropriate system query by registrants during the patient care process related to controlled substances.

4. APhA advocates for the development of seamless workflow integration systems that would enable consistent use of a nationwide prescription drug monitoring program (PDMP) by registrants to facilitate prospective drug review as part of the patient care process related to controlled substances.

5. APhA advocates for continuous, sustainable federal funding sources for practitioners and system operators to utilize and maintain a standardized integrated and real-time nationwide prescription drug monitoring program (PDMP).
6. APhA supports the use of interprofessional advisory boards, that include pharmacists, to coordinate collaborative efforts for (a) compiling, analyzing, and using prescription drug monitoring program (PDMP) data trends related to controlled substance misuse, abuse, and/or fraud; (b) providing focused provider education and patient referral to treatment programs; and (c) supporting research activities on the impact of PDMPs.

7. APhA supports education and training for registrants about a nationwide prescription drug monitoring program (PDMP) to ensure proper data integrity, use, and confidentiality.

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Sarah Ray

(Name)

1/21/2020

(Date)

APhA Academy of Pharmacy Practice and Management APhA-APPM

(Organization)

Subject: Coordination of the Pharmacy and Medical Benefit

Motion: To adopt the following new policy statement:

APhA supports coordination of patients’ comprehensive pharmacy and medical benefits that allows for provision of and compensation for pharmacists’ patient care services; aligns incentives to optimize patient outcomes; streamlines administrative processes; reduces overall healthcare costs and preserves patients’ right to choose providers for the pharmacy and medical benefits.

Background:

The 2018-2019 Policy Committee, in deliberating the topic of Consolidation in Healthcare in October 2018, felt the issue of integration and coordination of the pharmacy and medical benefit was a topic that was beyond the scope of the issues the Committee was charged with. The Committee determined that existing policy does not address this issue, and thus it represents a policy “gap” in an important area. The Committee felt this issue was contemporary and needed to be addressed if pharmacists are to be optimally integrated within value-based models, yet just beyond the scope of the charge of the committee on the topic of mergers and acquisitions in healthcare.

The APhA Board of Trustees reviewed this topic and added it to the 2019 Joint Policy Standing Committee’s suggested topics for further policy development. While the 2019 Joint Policy Standing committee was extremely supportive of the need for policy, it was not selected as a final topic assigned to the 2019-2020 Policy Committee. APhA-APPM found this topic important and is introducing the NBI.

The proposed policy aims to support efforts to alleviate the increasing cost of healthcare for patients due to a fragmented health system. Studies have shown that aligning pharmacy and medical benefits can allow integrated health systems a chance to optimize patient care based on patients’ unique circumstances, subsequently reducing healthcare-related costs⁴. This policy would endorse the advent of, and compensation
for, pharmacists’ patient care services in order to increase patients’ access to healthcare while reducing cost and allowing them the freedom to select the appropriate providers and pharmacies that best fit their needs.

A recent study by Cigna showed that cohesive pharmacy and medical benefits created a 12% increase in the number of members participating in health coaching and case management programs. This study serves as an example of how comprehensive medical and pharmacy benefits can align organizations’ incentives to optimize patient outcomes while increasing patients’ access to care. The committee advocates for policy specifically aimed at the topic of integration and coordination of the pharmacy and medical benefit to ensure pharmacists’ positions within value-based models.


**Current APhA Policy & Bylaws:**

**2017 Pharmacists' Role Within Value-based Payment Models**

1. APhA supports value-based payment models that include pharmacists as essential health care team members and that promote coordinated care, improved health outcomes, and lower total costs of health care.

2. APhA encourages the development and implementation of meaningful, consistent process-based and outcomes-based quality measures that allow attribution of pharmacist impact within value-based payment models.

3. APhA advocates for mechanisms that recognize and compensate pharmacists for their contributions toward meeting goals of quality and total costs of care in value-based payment models, separate and distinct from the full product and dispensing cost reimbursement.

4. APhA advocates that pharmacists must have real-time access to and exchange of electronic health record data within value-based payment models in order to achieve optimal health and medication-related outcomes.

5. APhA supports education, training, and resources that help pharmacists transform and integrate their practices with value-based payment models and programs.

(JAPhA 57(4): 441 July/August 2017)
2019 Consolidation within Health Care

1. APhA advocates that health care mergers and acquisitions must preserve the pharmacist–patient relationship.

2. APhA supports optimizing the role of pharmacists in the provision of team-based care following health care mergers and acquisitions in order to: • Enhance patient experience and safety, • Improve population health, • Reduce health care costs, and • Improve the work life of health care providers.

3. APhA asserts that the scope of review by federal agencies must have a focus on the impact of health care mergers and acquisitions on patient access and the provision of care to ensure optimal patient outcomes. Therefore, APhA calls for: • Reform of the pre–health care mergers and acquisitions process; • Implementation of an ongoing post–health care mergers and acquisitions evaluation process to preserve patient choice and access to established patient–pharmacist relationships; and • Continuous transparent dialogue among stakeholders throughout the process.

4. APhA calls for the Federal Trade Commission (FTC) to develop a task force to monitor health care mergers and acquisitions activity.

(JAPhA 59(4):e16 July/August 2019)

2016, 1994 Pharmacy Services Benefits in Health Care Reform

APhA supports reform of the U.S. health care system and believes that any reform at the state or national level must provide for the following

1. Universal coverage for pharmacy service benefits that include both medications and pharmacists' services;

2. Specific provisions for the access to and payment for pharmacists' patient care services.

3. A single set of pricing rules, eliminating class-of-trade distinctions, for medications, medication delivery systems, and other equipment so that no payer, patient, or provider is disadvantaged by cost shifting;

4. The right for every American to choose his/her own provider of medications and pharmacists' services and for all pharmacists to participate in the health plans of their choice under equally applied terms and conditions;

5. Quality assurance mechanisms to improve and substantiate the effectiveness of medications and health services;

6. Information and administrative systems designed to enhance patient care, eliminate needless bureaucracy, and provide patients and providers price and quality information needed to make informed patient-care decisions;

7. Relief from antitrust laws and regulations to enable pharmacists to establish systems that balance provider needs relative to corporate and governmental interests;

8. Reform in the professional liability system, including caps on non-economic damages, attorneys' fees, and other measures;

9. Representation on the controlling board of each plan by an active health care practitioner from each discipline within the scope of the plan; and

10. Recognition of the pharmacist's role in delivering primary health care services.

2011 Pharmacist's Role in Health Care Reform

1. 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.
2. 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).
3. 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.
4. 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.
5. 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.

(JAPhA NS51(4) 482; July/August 2011) (Reviewed 2016)

2013 Ensuring Access to Pharmacists' Services

1. Pharmacists are health care providers who must be recognized and compensated by payers for their professional services.
2. APhA actively supports the adoption of standardized processes for the provision, documentation, and claims submission of pharmacists' services.
3. APhA supports pharmacists' ability to bill payers and be compensated for their services consistent with the processes of other health care providers.
4. APhA supports recognition by payers that compensable pharmacist services range from generalized to focused activities intended to improve health outcomes based on individual patient needs.
5. APhA advocates for the development and implementation of a standardized process for verification of pharmacists' credentials as a means to foster compensation for pharmacist services and reduce administrative redundancy.
6. APhA advocates for pharmacists' access and contribution to clinical and claims data to support treatment, payment, and health care operations.
7. APhA actively supports the integration of pharmacists' service level and outcome data with other health care provider and claims data.

(JAPhA 53(4): 365 July/August 2013) (Reviewed 2018)

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).


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NEW BUSINESS

(To be submitted and introduced by Delegates only)

 Introduced by: Daniel Hussar

(Name)

2/14/2020

(Date)

Pennsylvania Pharmacists Association

(Submitted as an individual delegate)

Subject: Unity and Strength of the National Pharmacy Practitioner Organizations

Motion: APhA should initiate discussions/negotiations with other national pharmacy practitioner organizations (to include but not be limited to ASHP, NCPA, ASCP, ACCP and ACA) for the purpose of considering mergers, acquisitions, and/or the establishment of a collaborative/federated organizational structure to represent and promote the interests of pharmacy practitioners and the profession of pharmacy.

Background: The challenges facing pharmacy practitioners and the profession of pharmacy are unprecedented and threatening. The profession of pharmacy does not presently have an organizational structure with sufficient unity and strength to most effectively represent the profession in responding to these challenges. In some situations, the programs and actions of the national pharmacy organizations are more competitive than collaborative, with the result that advocacy for the profession is compromised.

A merged and unified national organizational structure to represent pharmacy should be established as a goal, but may not be attainable in the near future. The important and urgent need to quickly address certain of the challenges facing the profession requires attention to strategies that may be less than optimal but may be easier for the national pharmacy organizations to consider on a timely basis. One such concept is that of a collaborative/federated structure that will include the current national pharmacy practitioner organizations. Because the American Pharmacists Association is the largest national pharmacy organization with the most diversified membership and widely-recognized name, the name of the proposed organizational structure should be the American Pharmacists Association. Other current national pharmacy practitioner organizations that would be participants in the proposed structure would retain their current names, autonomy, policies, budgets, leadership, employees, programs, buildings/real estate, and anything else they value as individual organizations. An action-oriented, policy-making body would be developed for the new structure, with representation of the
individual organizations based on their membership and resources. This would facilitate approval and implementation of policies and actions on behalf of the profession of pharmacy, rather than representing views of a coalition of individual and separate pharmacy organizations.

The proposed strategy is cumbersome and inefficient, but may offer the most realistic and timely hope for a more unified and stronger organizational structure to which the profession of pharmacy can commit its efforts. With time, changes in leadership, and creative ideas, the initial structure may become more consolidated and unified in a manner that would result in efficiencies (e.g., buildings/offices, computer/communication systems, consolidation of duplicative programs/services) that would provide greatly increased resources that can be devoted to the profession’s highest priorities.

Current APhA Policy & Bylaws: N/A

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Lorri Walmsley (AZ), Jennifer Adams (ID), Chelsea Baker (IN), Julie Akers (WA)

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

Item No: 6
Date received: 2/19/2020
Time received: 4:59 PM

Subject: Pharmacy Technicians Role in Immunization Administration

Motion:
• Adopt the proposed APhA Pharmacy Practice policy – Pharmacy Technicians Role in Immunization Administration to read as follows:

Pharmacy Technicians Role in Immunization Administration

1. APhA urges state boards of pharmacy and state legislative bodies to authorize immunization administration by qualified pharmacy technicians as a technical function that may be delegated by immunizing pharmacists.
2. APhA supports the development of standardized training in immunization administration and continuing education opportunities for immunizing pharmacy technicians.
3. APhA supports pharmacists individual discretion in delegating immunization administration to qualified pharmacy technicians with the requisite education, training, and experience.
4. APhA supports voluntary participation by pharmacy technicians in the training and provision of immunization administration.
5. APhA supports the role of pharmacists as the healthcare professional providing clinical patient assessment, decision making, and patient counseling for all immunizations administered by a pharmacy technician.

Background:
Background Disclaimer:
The italicized information detailed within the background of this policy proposal is a direct incorporation of previously published peer reviewed literature. This background information is not meant to serve as a plagiarized copy of previous
Public Health Benefits

Pharmacy-based immunizations have been one of the most significant public health achievements of the profession in recent years. The Centers for Disease Control and Prevention (CDC) has lauded the profession’s efforts to increase vaccination rates in the United States. Various studies have demonstrated that pharmacists increase vaccination rates against influenza, pneumonia, and herpes zoster. Patients have demonstrated high acceptance of pharmacy-based immunizations, with 97% of vaccinated patients’ surveyed reporting satisfaction with their experience in the pharmacy. One third of all influenza vaccines given during the 2013-2014 flu season were provided in a community pharmacy. In addition, studies have demonstrated that pharmacy-based immunizations are more cost-effective than those provided in other settings, including physician offices. [1]

When it comes to barriers to receiving immunizations, less talked about or mentioned are the statutes and regulations surrounding them or who may be authorized to provide them. Given that pharmacies are one of the most accessible health destinations for the general public, they have served as a gateway to increase vaccination rates and improve access to care. According to data reported by the American Pharmacist Association (APhA) and National Alliance of State Pharmacy Associations (NASPA), pharmacists are authorized legally to administer vaccines in all 50 states and D.C. Pending a couple of states that have worked on recent law changes (New Jersey, New York), student pharmacists (interns) will soon be able to administer vaccines in all states as well. [2]

As pharmacist roles continue to evolve over time, so will those of pharmacy technicians. Pharmacists’ professional delegation has become a key shift towards ensuring workload allocations and safe practices can remain intact. Working together with pharmacists and student pharmacists, pharmacy technicians play a critical role in impacting public health. Technicians represent a key opportunity to add a team member to help attribute to the public health initiative of increasing access to vaccinations. More recently, a technical, but seemingly innovative, role for pharmacy technicians, administration of vaccines, has emerged. With recent outbreaks of vaccine preventable diseases, and patient safety at the forefront of missions of boards of pharmacy, the public may benefit from adding another pharmacy team member to help increase access to vaccinations. [3]

Early State Adopters

In 2016–17, Idaho adopted rule language that directly permitted pharmacy technicians to administer immunizations. [3]

With this, they became the first state within the U.S. to do so and also became the first state to actively involve pharmacy technicians in a training program and administration at local pharmacies. Since then, four additional states have made changes within their scope of practice permissions to include pharmacy technician administration of vaccinations, including Rhode Island, Utah, Washington, and Illinois with others pending. [4-7]

Federal Pharmacy Success

From the federal level, the Commissioned Corps of the U.S. Public Health Service announced that credentialed pharmacists have the chance to provide federal pharmacy technicians an opportunity to obtain training to administer vaccines. In White River, Arizona within the Indian Hospital, pharmacy technicians have administered vaccines to patients of all ages (including children) with oversight from a federal pharmacist. With change on the horizon and precedent set, investigation and categorization of laws in other states were identified as gap areas within published literature. [2]

Our federal pharmacy leaders have previously reported to the House of Delegates body, of their utilization of pharmacy technicians in many innovative ways, often happening decades before states permitted the authority. Authorizing immunization administration by qualified pharmacy technicians as a technical function that may be delegated by immunizing pharmacists, serves as yet another excellent example.

Education and Training:

APhA current policy and bylaws on “Pharmacy Technician Education, Training, and Development” was addressed and adopted by the House of Delegates in 2017. The 2017 policy details our associations professional expectations for pharmacy technician education and training, and subsequently dovetails nicely with the inclusion of this proposed policy.
McKeirnan et al. and Washington State University (WSU) developed a training program that is specific for pharmacy technicians. The program was designed to be less time intensive or in-depth (2-hour self-study, 4 hour live) compared to the pharmacist/student program (~20 hours) with a clear separation of the technical versus clinical aspects of vaccine administration.  

A study on the first program [WSU program] to train pharmacy technicians on proper vaccine administration technique described how, following the completion of a home study and live training program, technicians self-reported an increased confidence with vaccine administration skills. These technicians went on to successfully administer 953 immunizations without issue. The program has since expanded, along with at least two other training programs, and to date more than 300 Idaho technicians have completed vaccine administration training. An estimated 25,000 vaccines having been administered by Idaho technicians and no adverse events or errors reported to the state’s Board of Pharmacy.  

In general, public policy should be established based on the public interest. The experience in Idaho lends credence to the strong safety profile that has accompanied pharmacy-technician-administered vaccines. This track record is of little surprise, as technicians have a similar educational background to other health professions (namely, medical assistants) that have administered vaccines for years under the delegation and supervision of physicians. Further, states continue to explore opportunities to transition to a more permissive “standard of care” approach to regulation that lends itself to all members of the pharmacy team practicing to the full extent of their clinical ability. Thus, additional states should remove their regulatory restrictions and allow properly trained technicians to administer vaccines in the years ahead.  

More recently, the opinions of pharmacists who supervised immunizing pharmacy technicians (trained through the WSU program) were surveyed regarding initial trust of immunizing technicians, perceived quality of the training program, need for additional on-the-job training, frequency of technician utilization, and recommendations for other pharmacists who are considering implementation of an immunizing technician. The study concluded:

Community pharmacists who supervise pharmacy technicians trained to administer immunizations were receptive to this new advanced technician role. Pharmacists’ opinions revealed that working with newly trained immunizing pharmacy technicians has not only positively affected the morale of their team, but can help to increase the number of vaccinations given by the pharmacy. Understanding pharmacist perceptions about technicians as immunizers may lead to regulation changes and adoption of this advanced technician role.  

Originally developed by Washington State University (WSU) and recently revised through a partnership between WSU and the American Pharmacists Association (APhA), the APhA/WSU Pharmacy-Based Immunization Administration by Pharmacy Technicians training program explores the expanding role of the pharmacy technician by providing additional skills training to administer immunizations. This two-part program emphasizes a health care team collaboration between pharmacists and technicians which seeks to improve population health by increasing immunization rates in states that allow technicians to immunize. Composed of an online self-study component combined with a live seminar that teaches hands-on immunization techniques, this program will provide a total of six hours of continuing education for technicians and pharmacists.

Pharmacist Workplace Environment and Patient Safety
To address this important issue, the APhA House passionately discussed and adopted a policy on “Pharmacist Workplace Environment and Patient Safety” in 2018. Further in July 2019, a collaboration was formed between the American Association of Colleges of Pharmacy (AACP), the Accreditation Council for Pharmacist Education (ACPE), the American Pharmacists Association (APhA), the National Association of Boards of Pharmacy (NABP), and the National Alliance of State Pharmacy Associations (NASPA) and the Enhancing Well-Being and Resilience Among the Pharmacist Workforce: A National Consensus Conference was conducted. A total of 50 recommendations were developed and approved by consensus to provide immediate, viable, and sustainable solutions to create improvements in critical areas related to well-being and resilience for pharmacy professionals at the societal level, at the organizational level, and the individual level. The intent of these recommendations is broad, with opportunities for action by any individual or organization within the pharmacy profession to effect change within their spheres of influence.

Recommendations Related to the Improvement of Pharmacist Work Conditions and Patient Safety (2 of 12):
- State boards of pharmacy should evaluate legislative and regulatory requirements to streamline and remove unnecessary burden on pharmacists and their ability to safely provide patient care.
• Employers and pharmacist managers should advocate for expanded roles for pharmacy technicians and support technician career advancement to enhance the pharmacist’s ability to provide patient care. [10]

This proposed policy on pharmacy technicians role in immunization administration, serves as yet another actionable item that perfectly aligns with APhA’s efforts to improve workplace conditions within the pharmacy, and provide for flexibility in patient care services.

“Can” and “Should” Pharmacy Technicians Administer Immunizations

“Can pharmacy technicians be trained to administer immunizations?” In that respect, administering a vaccine encompasses tasks that technicians already perform (e.g., selecting proper needle gauge and length, loading syringe, and safely disposing of needles and syringes) and tasks that would generally be considered new (e.g., identifying the proper site of injection and using the proper route of administration). We believe a technician can master these new tasks as other licensed and unlicensed health professionals with similar career experience and training have mastered them. [1]

In discussing technician immunization administration with multiple stakeholders, we have not encountered anyone to date who has openly argued that an appropriately trained technician would not be technically able to safely and effectively administer vaccines at the discretion of their supervising pharmacist. Instead, arguments to date have centered around “Should pharmacy technicians be able to administer immunizations?” We have heard several points to this effect which are reviewed in Table 1. [1]

<table>
<thead>
<tr>
<th>Point</th>
<th>Counterpoint</th>
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<tbody>
<tr>
<td>Pharmacy associations have worked hard to attain pharmacist immunization authority and it is too early to “give this up.”</td>
<td>In the described model, pharmacists would remain in charge of the immunization process. Specifically pharmacists would assess the patient, prescribe the right vaccination, and monitor for adverse events. Thus the pharmacist is not “giving up” immunizations just as pharmacists have not “given up” dispensing by better leveraging technicians in the medication use process. Instead, the pharmacist’s time is better directed at the activities that require professional judgment in the immunization process. Technicians are already critically involved with immunizations; this would just add the technical, non-clinical task of vaccine administration to the roles that a pharmacist could delegate to a technician.</td>
</tr>
<tr>
<td>Pharmacists in some states are still working to increase the types of vaccines they may provide, and the patient populations they may provide them to. In other states, pharmacists are currently working to allow student pharmacists to administer vaccines. In addition, some interest groups are still increasing their acceptance of pharmacy based immunizations, and delegation to pharmacy technicians could undermine growing support.</td>
<td>We believe that the value of pharmacy-based immunizations has been well documented over the past two decades and is broadly accepted in terms of safety, effectiveness, and cost-effectiveness. This is perhaps most clearly demonstrated by the fact that one in five vaccinated Americans has voluntarily sought a vaccine in a pharmacy when they could have chosen any other venue for care and the fact that one third of all influenza vaccines were provided in pharmacies during the 2013-2014 flu season. Thus, we believe we are beyond the point at which we need to gain additional support for pharmacist immunizations as consumers have clearly embraced pharmacy-based immunizations.</td>
</tr>
<tr>
<td>Immunizations are one of the few areas where pharmacists are able to demonstrate the expanded role of pharmacist. Technician delegation may forfeit this positive image.</td>
<td>While we believe pharmacy-based immunizations are a significant public health achievement, we do not believe it represents the edge of the clinical profession. Indeed, pharmacists have recently made significant strides with services such as point-of-care testing, prescriptive authority for select conditions, chronic disease state management, and Medication Therapy Management, among other advanced care services. Immunizations have critically and importantly served as a gateway to patient acceptance of these advanced care services and have bolstered pharmacist confidence for the provision thereof, but we believe the time is ripe to move the needle (pun intended).</td>
</tr>
<tr>
<td>Pharmacist: “I would not trust my technician to administer vaccines” or “My technicians do not have any interest in administering vaccines”</td>
<td>It would be up to each supervising pharmacist to decide whether or not to delegate vaccine administration to an appropriately trained technician once the pharmacist has prescribed it. If a pharmacist is not comfortable with a technician performing this task he or she may simply choose not to delegate it, but it does not seem reasonable to hold back every other pharmacist and technician just because some pharmacists are uncomfortable with their own support staff. Such regulation to the “lowest common denominator” is rarely in the best interest of patient care.</td>
</tr>
<tr>
<td>Technician: “I do not like shots and would... “</td>
<td>Similarly, some technicians would embrace this activity, others would not be...</td>
</tr>
</tbody>
</table>

The point of this discussion is that pharmacy associations have worked hard to attain pharmacist immunization authority and it is too early to “give this up.” In the described model, pharmacists would remain in charge of the immunization process. Specifically pharmacists would assess the patient, prescribe the right vaccination, and monitor for adverse events. Thus the pharmacist is not “giving up” immunizations just as pharmacists have not “given up” dispensing by better leveraging technicians in the medication use process. Instead, the pharmacist’s time is better directed at the activities that require professional judgment in the immunization process. Technicians are already critically involved with immunizations; this would just add the technical, non-clinical task of vaccine administration to the roles that a pharmacist could delegate to a technician. We believe that the value of pharmacy-based immunizations has been well documented over the past two decades and is broadly accepted in terms of safety, effectiveness, and cost-effectiveness. This is perhaps most clearly demonstrated by the fact that one in five vaccinated Americans has voluntarily sought a vaccine in a pharmacy when they could have chosen any other venue for care and the fact that one third of all influenza vaccines were provided in pharmacies during the 2013-2014 flu season. Thus, we believe we are beyond the point at which we need to gain additional support for pharmacist immunizations as consumers have clearly embraced pharmacy-based immunizations.
not want to give one either." excited about the prospects of vaccine administration, just as some pharmacists refused to become immunizers. Just because some technicians would not want to administer vaccines is not a reasonable reason to not allow any technician to do so.

The salary for pharmacy technicians is such that additional training and risk of liability may be difficult to take on. A broad discussion of appropriate salaries for pharmacy technicians is beyond the scope of the single issue of immunizations and represents more of a business discussion than a regulatory discussion. However, it may be reasonable to assume that salary is in part influenced by value to the employer from a business operations standpoint and by supply and demand. Therefore, if there is a smaller subset of pharmacy technicians adequately trained to administer immunizations, and if the ability for pharmacy technicians to provide immunizations brings additional value to the employer, it would be reasonable to expect market forces to drive up salaries for such appropriately trained pharmacy technicians. [1]

Other Healthcare Practitioners Delegation Authority
A comparator study would be the 2015 study by Stewart and colleagues which examined the state laws and standing orders for immunization services. Within this study, authors did not examine pharmacy technicians specifically, but looked more broadly at non-physician health professionals. Interestingly, it was found that medical assistants had delegated authority to administer vaccines in fourteen (14) states, own authority in one (1) state and laws were silent within thirty-six (36) states and D.C. State laws also varied, but a general trend noted was that physicians are able to delegate the task of vaccine administration to medical assistants in many states. [2]

Payment for Immunization Services:
APhA current policy and bylaws on “Pharmacists’ Role in Immunizations” was amended and adopted by the House of Delegates in 1996. The policy notes, APhA supports the compensation of pharmacists for the administration of immunizations and the reimbursement for vaccine distribution. Further, APhA current policy and bylaws on “Ensuring Access to Pharmacists’ Services” was addressed and adopted by the House of Delegates in 2013. The 2013 policy details our associations expectations of pharmacists being health care providers who must be recognized and compensated by payers for their professional services. The proposed policy provides support to the role of pharmacists as the healthcare professional providing clinical patient assessment, decision making, and patient counseling for all immunizations administered by a pharmacy technician.

Pharmacy Technicians Are People Too:
Some have offered support for technicians performing expanded duties but temper that support by saying that it would be premature to advance technician roles until pharmacists have provider status or some other pharmacist-centric end point. First, in this chicken-versus-egg scenario, provider status will have to be earned and, thus, follow best practices that include positive re-engineering and workflow design for all pharmacy employees. But perhaps even more important, it is dehumanizing to technicians to only consider expanding technician roles to the extent that it benefits pharmacists. [11]

As with any intervention, new service, workflow redesign, or regulation, the primary concern should be the public interest and safety. If evidence suggests that technicians can perform a function safely and effectively relative to usual care, that alone should compel the function’s allowance in practice. Freeing up pharmacist time for higher-order care is indeed a positive corollary to technician advancement, but it need not be a precondition for it. Considering the humanistic side of pharmacists and support personnel concurrently is what truly creates a win-win for the pharmacy organization, its constituent employees, and its patients. Pharmacy technicians are, indeed, people too, and the research is increasingly clear: unlocking the full potential of pharmacy technicians can lead to significant gains in patient care and public health. [11]

References:


Current APhA Policy & Bylaws:
Pharmacy Technician Education, Training, and Development (2017)
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)

1. 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.

(JAPhA 58(4):355 July/August 2018)

1. 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.


Ensuring Access to Pharmacists’ Services (2013)
1. Pharmacists are health care providers who must be recognized and compensated by payers for their professional services.
2. APhA actively supports the adoption of standardized processes for the provision, documentation, and claims submission of pharmacists’ services.
3. APhA supports pharmacists’ ability to bill payers and be compensated for their services consistent with the processes of other health care providers.
4. APhA supports recognition by payers that compensable pharmacist services range from generalized to focused activities intended to improve health outcomes based on individual patient needs.
5. APhA advocates for the development and implementation of a standardized process for verification of pharmacists’ credentials as a means to foster compensation for pharmacist services and reduce administrative redundancy.
6. APhA advocates for pharmacists’ access and contribution to clinical and claims data to support treatment, payment, and health care operations.
7. APhA actively supports the integration of pharmacists’ service level and outcome data with other health care provider and claims data.


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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Cindy Mende Russell

(Name)

2/18/2020 Illinois Pharmacists Association

(Date) (Organization)

Subject: Transfer of Schedule III-V prescriptions for Purposes of Initial Fill as well as Refill

Motion: APhA should adopt the following policy language:

APhA supports that the DEA update and amend Section IX (Valid Prescription Requirements) of the DEA’s Manual and relevant administration rules concerning that a pharmacy can only transfer for “the purpose of a refill dispensing between pharmacies” to also include for the purposes of an initial fill.

Background:
Some states allow the transfer of schedule 3-5 for an initial fill as well as a refill. There are times when it is necessary to transfer an initial fill of a schedule 3-5 prescription (out of stock, insurance limits, etc) and not being able to do this limits access to the patient, delays therapy, and also can cause multiple prescriptions at multiple pharmacies. The Illinois Pharmacists Association has asked for clarification on this multiple times and has received zero response.

Current Language: Transfer of Schedules III-V Prescription Information

A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies, on a one time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

Current APhA Policy & Bylaws: none

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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: Matt Lacroix, PharmD, MS, BCPS
(Name)

2/19/2020
(Date)
Rhode Island Delegation
(Organization)

Subject: Increasing Access to and Advocacy for Medications for Opioid Use Disorder (MOUD)

Motions: To adopt the following policy statements listed below.

1. APhA supports the use of evidence-based medication as first-line treatment for opioid use disorder for patients, including healthcare professionals, such as pharmacists, in and out of the workplace, for as long as needed to treat their disease.

2. APhA encourages pharmacies to maintain an inventory of medications of public health importance, particularly medications for opioid use disorder, to ensure access for patients.

3. APhA encourages pharmacists and payers ensure patients have equitable access to and coverage for at least one medication from each class of medications used in the treatment of opioid use disorder, such as making medications available on the payor's lowest cost-sharing tier.
Background:
Opioid use disorder (OUD) is a chronic relapsing-remitting disorder characterized by both biological and psychological components exacerbated by sequences of use and return use due to physical symptoms of withdrawal. These include cravings, nausea, vomiting, body aches, anxiety, diaphoresis, and tachycardia. The most effective treatments for opioid use disorder across all treatment settings to enable recovery are medications such as methadone, buprenorphine, and naltrexone (MOUD). Maintenance MOUD are significantly more effective at reducing opioid overdose and other serious events at 3 and 12 months than treatments that do not include medications, including inpatient rehabilitation, behavioral health, and detoxification. Maintenance therapy results in significantly better treatment retention. Most importantly, long-term use of some medications reduces mortality by at least 50% and are cost-effective. Treatment duration lasts as long as the person needs to take the medication in their recovery, due primarily to the significantly higher risk of overdose when medications are discontinued. MOUD are first-line treatments of OUD according to the American Society for Addiction Medicine (ASAM) the National Academies of Sciences, Engineering, and Medicine, the US Department of Health and Human Services (DHHS), the Canadian Medical Association the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO). The American Pharmacists’ Association should join these organizations in support of MOUD as first line treatment, and work with them to reduce logistical and financial barriers for this frequently marginalized and vulnerable population.

Of the more than 2 million people living with OUD, only 1 of 5 people receive any form of treatment. Healthcare professionals, a group at higher risk of developing OUD, particularly lack access to MOUD in employee assistance plans and in recovery networks. Few, if any, other chronic disease medications are limited as much as MOUD for patients and for healthcare workers, including medication classes with more narrow therapeutic indices and greater risks of adverse effects such as antipsychotics, insulins, benzodiazepines, and opioids. In a 2019 commentary, the authors outlined the discrepancies in OUD care between what is recommended and prioritized in physician recovery programs versus what is the gold standard for our patients, namely, evidence-based medications for opioid use disorder. Although current programs for physicians and likely pharmacists do show good outcomes, the data showing this is derived from small, incomplete, biased sources; programs do not transparently report the comprehensive data needed to determine true outcomes that lack self-selection bias. APhA must support equitable access to and use of first-line treatment for OUD for patients, providers, and pharmacists.

Even when people voluntarily obtain treatment for their OUD, further barriers await them, unique to this common chronic illness. To receive methadone, one of the most studied medications in the world, a patient must travel to a clinic, if they have transportation, sometimes for hours, on a daily basis.
regulations require near-monthly counseling and regular, observed urine samples for toxicology testing to receive methadone. Opioid treatment programs also employ other non-patient-centered restrictions, in addition to limited operating hours only in the mornings. Although several countries, including Canada, Australia, and the United Kingdom embrace pharmacy methadone access, and methadone is permitted to be stocked in community pharmacies, current Drug Enforcement Agency (DEA) regulations prohibit methadone dispensing for OUD from pharmacies.

To obtain buprenorphine, the patients’ provider must have completed training and applied to receive a waiver from the federal government to prescribe it. The waiver is currently only available to physicians, midwives, nurse practitioners, and physician assistants, although APhA joined other pharmacy organizations in a letter to the Centers for Medicare and Medicaid service (CMS) to expand the scope of the pharmacist by adding them to the list of providers able to obtain a waiver. For current providers, this 8-24 hour training is only rarely integrated into any curricula nor post-graduate training, leaving 40% of the counties in the United States without even one waivered provider and little possibility of a sustainable supply. Once a waiver is obtained, providers are limited to how many patients that they can treat – limits that are not proven to reduce diversion, ostensibly the reason that limits were established. In fact, few providers have come close to their patient limit, and many providers are not treating anyone with OUD.

In several areas, when patients bring buprenorphine prescriptions to be filled at their pharmacy, an improvement over the current methadone access model, the pharmacy may not stock their desired formulation, or any formulation of this essential medicine. This has led patients to take serious and often life-threatening risks with the increasingly unsafe and potent supply of illegal opioids just to mitigate or avoid physical symptoms of withdrawal. When patients first appointment was delayed, a significant and large number of patients starting using opioids again.

Pharmacists must make every effort to stock buprenorphine as they would any other medication of public health importance, especially as efforts to expand treatment access and the number of waivered providers increase.

Patients who do obtain buprenorphine and find a pharmacy that stocks their formulation, then often face financial barriers and other delays related to prior authorizations and co-pay limits. All payors should follow the example of public third-party payors and eliminate financial and prior authorization barriers to MOUD access, saving lives, reducing ED and inpatient admissions, and costs in the process.
References


21. Geographic disparities affect access to MOUD.


Current APhA Policy & Bylaws:

2011 Potential Conflicts of Interest in Pharmacy Practice

1. APhA reaffirms that as health care professionals, pharmacists are expected to act in the best interest of patients when making clinical recommendations.
2. APhA supports pharmacists using evidence-based practices to guide decisions that lead to the delivery of optimal patient care.
3. APhA supports pharmacist development, adoption, and use of policies and procedures to manage potential conflicts of interest in practice.
4. APhA should develop core principles that guide pharmacists in developing and using policies and procedures for identifying and managing potential conflicts of interest.

(JAPhA NS51(4) 482;July/August 2011)(Reviewed 2016)

2019 Patient-Centered Care of People Who Inject Non-Medically Sanctioned Psychotropic or Psychotropic Substances

1. APhA encourages state legislatures and boards of pharmacy to revise laws and regulations to support the patient-centered care of people who inject non-medically sanctioned psychotropic or psychoactive substances.
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, postgraduate 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 non-medically sanctioned psychotropic or psychoactive substances.
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 nonmedically sanctioned psychotropic or psychoactive substances 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 non-medically sanctioned psychotropic or psychoactive substances 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.

(JAPhA 59(4):e17;July/August 2019)

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)
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.

(JAPhA NS51(4) 482;July/August 2011)(Reviewed 2012)(Reviewed 2016)

1983  Stocking a Complete Inventory of Pharmaceutical Product

APhA supports the rights and responsibilities of individual pharmacists to determine their inventory and dispensing practices based on patient need, practice economics, practice security, and professional judgment.


2005, 1977  Government-Financed Reimbursement

1. APhA supports only those government-operated or -financed, third-party prescription programs which ensures that participating pharmacists receive individualized, equitable compensation for professional services and reimbursement for products provided under the program.
2. APhA regards equitable compensation under any government-operated or -financed, third party prescription programs as requiring payments equivalent to a participating pharmacist's prevailing charges to the self-paying public for comparable services and products, plus additional, documented, direct and indirect costs which are generated by participation in the program.
3. APhA supports those government-operated or -financed, third-party prescription programs which base compensation for professional services on professional fees and reimbursement for products provided on actual cost, with the provision of a specific exception to this policy in those instances when equity in professional compensation cannot otherwise be attained.


2005, 1981  Third-party Reimbursement Legislation

APhA supports enactment of legislation requiring that third-party program reimbursement to pharmacists be at least equal to the pharmacists prevailing charges to the self-paying public for comparable services and products, plus additional documented direct and indirect costs, which are generated by participating in the program.


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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: Matt Lacroix, PharmD, MS, BCPS
(Name)

2/19/2020 Rhode Island Delegation
(Date) (Organization)

Subject: HIV testing in Pregnant Women

Motion: To amend existing APhA Policy 1996 HIV Testing in Pregnancy to read as follows:

1996 HIV Testing in Pregnant Women

APhA encourages pharmacists to provide pharmaceutical care to women, including education about the availability and benefits of opt-out HIV testing in prenatal and perinatal care, to decrease the risk of HIV transmission to unborn children and between partners. APhA encourages pharmacists to provide education about the availability and benefits of opt-out HIV testing in prenatal and perinatal care, including offering and/or performing testing to the patients and their partners.

Background:
The exact changes to the existing 1996 HIV Testing in Pregnant Women policy are shown below with new language underlined and removed language struck through and bolded:

1996 HIV Testing in Pregnant Women

APhA encourages pharmacists to provide pharmaceutical care to women, including education about the availability and benefits of opt-out HIV testing in pregnancy prenatal and perinatal care, to decrease the risk of HIV transmission to unborn children and between partners. APhA encourages pharmacists to provide education about the availability and benefits of opt-out HIV testing in pregnancy prenatal and perinatal care, including offering and/or performing testing to the patients and their partners.

The Centers for Disease Control and Prevention (CDC) the US Department of Health and Human Services HHS Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission, and the Committee on Obstetric Practice HIV Expert Work Group of the American College of Obstetricians and Gynecologists (ACOG) all support opt-out HIV testing of as a routine part of prenatal care, and as early
as possible in pregnancy.1–3 Existing APhA policy supports pharmacist-performed point-of-care testing and clinical services.

References:


Related APhA Policies:

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.


2005, 1993 HIV Testing
1. 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.


2016 Point-of-Care Testing
1. 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.

(JAPhA 56(4); 369 July/August 2016)(Reviewed 2018)(Reviewed 2019)

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NEW BUSINESS
(To be submitted and introduced by Delegates only)

 Introduced by: Richard Dang
(Name)

February 19, 2020
(Date)
California Pharmacists Association (CPhA)
(Organization)

Subject: Digital Health Integration in Pharmacy

Motion: To adopt the following new policy statements on digital health integration in pharmacy:

1. APhA supports education about digital health technologies and integration in pharmacy practice, in pharmacy school curricula, and for the pharmacy workforce.
2. APhA supports inclusion of pharmacists in the design and development of digital health technologies.
3. APhA supports that digital health technologies be interoperable with and integrated into pharmacy management systems and electronic health records.
4. APhA supports pharmacists applying digital health technologies to optimize patient care outcomes.

Background:
Digital health is an umbrella term that encompasses a wide range of products at the intersection of health and technology for prevention, diagnosis, treatment, and management of health and diseases. Digital health category examples include: mobile health apps, health information technology (HIT), sensor-enabled medication (pills, inhalers, insulin pens), wearables, devices, digital therapeutics (evidence-based therapeutic interventions driven by high quality software programs), telehealth/telemedicine, and precision medicine. Link for more information: https://medium.com/digital-medicine-society-dime/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference-92344420c4d5

As digital health technologies become more common, healthcare providers, including pharmacists, will incorporate digital health into their practices to optimize treatment outcomes. The FDA’s perspective on digital health is that it may reduce inefficiencies, improve access, reduce cost, increase quality, and make medicine more personalized for
patients. Considering FDA’s stance, digital health technologies align perfectly within the pharmacist’s role in improving patient care quality and health/economic outcomes. Link for more information: https://www.fda.gov/medical-devices/digital-health Until recently, there was a lack of formal guidance on what qualifies as digital health products and services from the FDA. Now products are receiving FDA-clearance and there is a pre-certification program being piloted to reimagine how these digital health products are regulated. Link for more information: https://www.fda.gov/medical-devices/digital-health/digital-health-software-pre-certification-pre-cert-program In 2020, the first digital health formulary was released by Express Scripts to improve access to these rapidly expanding treatment modalities.

The California Pharmacists Association (CPhA) adopted the following policy in the 2019 HOD.

Digital Health Integration in Pharmacy

5. The California Pharmacists Association supports education about digital health devices and technologies in pharmacy school curricula and for the pharmacy workforce.
7. The California Pharmacists Association supports that digital health devices and technologies be interoperable with and integrated into pharmacy management systems and electronic health records.

Current APhA Policy & Bylaws:
Policy specific to digital health isn’t included in current APhA policy.

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: ___________________________ Hillary Blackburn

(Name)

1/21/2020 APhA Academy of Pharmacy Practice and Management (APhA-APPM) on behalf of the Care of Underserved Patients Special Interest Group (SIG)

(Organization)

Subject: Providing Affordable and Comprehensive Pharmacy Services to the Underserved

Motion: To adopt the following new policy statements:

1. APhA supports the expansion and increased sources of funding for pharmacies and pharmacy services that serve the needs of underserved populations to provide better health outcomes and lower healthcare costs for underserved populations.

2. APhA supports charitable pharmacies and pharmacy services that ensure the quality, safety, drug storage, and integrity of the drug product and supply chain, in accordance with applicable law.

Background:

This policy will increase awareness of charitable pharmacy programs as an option for patients who are uninsured or underinsured as a method to increase medication adherence in these populations through reduced cost of their medications. By increasing medication adherence, this population would see improved healthcare outcomes leading to less preventable healthcare utilizations and a decrease in uncompensated care costs. Medication nonadherence is a $100-300 billion annual issue to our healthcare system. A contributing factor to nonadherence is the cost of medications, which is commonly ranked among top reasons why patients refuse to use medications. Cost is particularly a burden for the large number of uninsured (~28 million) and underinsured patients across the country who often go without medications that would manage many of their chronic conditions on an outpatient basis.

Charitable pharmacies (standalone, in clinics, and in hospitals) have been growing across the country to support those lacking access to medications. Pharmacists are uniquely positioned to establish comprehensive medication access programs to significantly lower the cost of unnecessary hospital utilizations due to lack of adherence. With access to medicine, underserved populations would gain increased adherence and decreased utilization of the healthcare system; thus, pharmacies can play a critical role in reducing their overall health system’s budget.
by helping patients get access to their medications. This reduces uncompensated costs when uninsured patients are admitted to the ED or hospital due to lack of medication to manage their conditions.

By supporting charitable pharmacies and the pharmacists working in them through awareness campaigns, APhA can help patients in medically underserved communities have better access to healthcare services provided by pharmacists, whom are often found in rural communities. This policy highlights the work of pharmacists providing care for underserved patients which can increase the support for pharmacists achieving provider status through The Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/S. 314).

**Current APhA Policy & Bylaws:**

*None.*
NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: __________ Robin Murphy ________________________________
(Name)

2/18/2020 Delegate of APhA-APPM, but Submitting on behalf of herself
(Organization)

Subject: Non-execution Related Use of Pharmaceuticals in Correctional Facilities

Inmate’s health care is substantially and negatively affected by the refusal of multiple drug manufacturers to supply certain pharmaceuticals to any and all correctional facilities, regardless of the intended use.

Motion: To adopt the following new policy statements:

1. APhA opposes drug manufacturer’s refusal to supply certain drugs to correctional health services units for the purpose of medical treatment of inmates. APhA recognizes that this means of political advocacy prevents humane medical care from being provided to inmates.

2. APhA advocates for inmates to have an opportunity, equal to that of non-inmates, to access medications that correctional providers deem medically necessary for appropriate and humane health care treatment.

3. APhA advocates for correctional providers to have equal opportunity (as non-correctional providers) to access, prescribe, and procure pharmaceuticals deemed necessary for medical treatment of inmates.
4. APhA calls upon drug manufacturers to immediately:

a. stop advancing political agendas at the expense of inmates’ health care.

b. allow inmates an equal opportunity (as non-inmates) to access drugs that correctional providers deem necessary for appropriate and humane medical treatment.

c. supply correctional health care providers and correctional facilities’ health service units with equal access (as non-correctional providers and facilities) to prescribe and procure pharmaceuticals necessary for provision of appropriate and humane health care services.

d. stop refusing to provide correctional facilities’ health service providers and correctional facilities’ health care units with the same access (and ability to prescribe) to medically-necessary pharmaceuticals as it allows non-correctional providers and facilities.

**Background:**

In order to make a political statement with regard to lethal injections, multiple drug manufacturers refuse to provide certain drugs to any correctional facility at all, regardless of whether the intended use of the drugs is for medical/healthcare purpose(s). Multiple manufacturers, including Hospira, Mylan, Akorn, Fresenius Kabi, Westward, Par, Sun, Sandoz, BD, and Sagent, have alerted wholesalers that they will no longer permit certain products “to be sold to U.S. state prisons, penitentiaries, jails or other incarceration facilities”. Wholesalers who want to remain authorized distributors must agree not to distribute these products to any of those listed facility types or “other customers that they deem ‘unqualified’”. The manufacturers’ lists of items restricted from correctional facilities include drugs believed to be useable in executions (whether by existing protocol or substituted for one of the drugs in protocol). Most of these manufacturers have put an outright ban on providing these to any correctional facility or jail, even in states with no death penalty. That outright ban goes well
beyond what is necessary to prevent their product’s use in executions and actually causes patient harm and suffering.

One specific problem encountered is due to lack of availability of IM/IV fentanyl, midazolam, and Propofol, which precludes proper medicating of the inmate prior to certain oral surgeries. Hence, the inmate can either forego the dental procedure or undergo the procedure while awake and in pain. Additionally, the inability to stock IM/IV lorazepam and diazepam in the ER kits limits the ability to properly treat emergent psychiatric conditions or status epilepticus. This poses a danger not only to the affected inmate needing medication, but also to other inmates and staff.

Supplying these drugs to health services for medical treatment of inmates is not at all the same as supplying them for use in executions. In the Oklahoma Department of Corrections (ODOC), health services stands entirely separate from those within the agency who perform executions. First of all, their goals are entirely different. Health service’s goals include “providing appropriate, timely”iii and “humane medical and dental care for offender patients”.iv Further, health services operates independent of those charged with executions. Medical/health service providers maintain their own DEA and state registrations (medical board, nursing board, Oklahoma Bureau of Narcotics, etc.). Medical/health services have separate sites; executions are performed in the execution chamber, not within the medical services unit. Medical personnel used in executions is not the same medical/health services staff (they are contracted from outside the agency). The means of procuring execution drugs is entirely unknown to health services staff. There is no involvement of ODOC health services staff in any step of performing executions, including the procurement of any drug for use in executions.

Hence, in refusing to provide these drugs to health services units, the manufacturers are not preventing executions; they are only preventing inmates from receiving humane medical treatment, as inmates will have to either forego these procedures altogether or undergo them without being properly medicated. Any good intended to come from this ban is entirely thwarted by the patient harm it causes. There are already too many obstacles to patient care to contend with, especially in this particular patient population, so manufacturers need not add unnecessary barriers to the struggle.
**Current APhA Policy & Bylaws:**

1983  **Stocking a Complete Inventory of Pharmaceutical Product**

APhA supports the rights and responsibilities of individual pharmacists to determine their inventory and dispensing practices based on patient need, practice economics, practice security, and professional judgment.


2004, 1990  **Freedom to Choose**

1. APhA supports the patient's freedom to choose a provider of health care services and a provider's right to be offered participation in governmental or other third-party programs under equal terms and conditions.

2. APhA opposes government or other third-party programs that impose financial disincentives or penalties that inhibit the patient's freedom to choose a provider or health care services.

3. APhA supports that patients who must rely upon governmentally-financed or administered programs are entitled to the same high quality of pharmaceutical services as are provided to the population as a whole.


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1 Cardinal Health Memo, March 8, 2016
2 Cardinal Health Memo, March 8, 2016
3 [http://doc.ok.gov/rehabilitative-services](http://doc.ok.gov/rehabilitative-services) accessed 2.13.20